

# welcome NOTE from the president

#### Dear all,

In a rapidly changing innovation scenario, vaccines have emerged as a crucial global health strategy towards the controlling, elimination and eradication of vaccine preventable diseases. They have become increasingly important in a complex international epidemiological context, facing the emergence of pandemic diseases while fighting old diseases, which requires new and effective prevention technologies.

At the same time, the vaccine industry is undergoing important changes in its production paradigm, leading to new technologies and innovative products.

This complex scenario poses new challenges for the global governance of innovation and underlines the key role of collaboration and networking strategies for research, develop-ment and production in the health field.

The Developing Countries Vaccine Manufacturers Network (DCVMN) is a good example of a successful networking strategy based on excellence. Since its foundation, 12 years ago, our member companies have achieved great results in order to turn high quality vaccines affordable and accessible to the developing world. DCVMN connects the main national and international companies producers of vaccines in the world and this confers to our network a strategic and leading role in vaccine innovation and production. This role is favored by its diversity, public and private nature and multi-country origin, which has contributed to its internationally recognized outcomes.

Nevertheless, this networking strategy reaches far beyond these advances. It has allowed the exchange of knowledge and experiences among our member companies, in the way to promote the necessary sinergy among and between the members in research, development, production and assessment of the diverse vaccine strategies, which are rapidly emerging in different countries.

In this XII Annual General Meeting we will certainly search to innovate the way we address the new challenges. We will also discuss how members and others stakeholders can join efforts in order to strengthen DCVMN's role in the global changing scenario. It will allow different perspectives from our diverse organizations, making this event a singular one. I am sure we will all benefit from this great opportunity to share our contributions, our experiences and our prospects for the future.

It is very important to point out the increasing participation of our members in the building of a consistent and sustainable world vaccine production capacity to supply high quality vaccines at affordable price to the children and the poor of the world. Nevertheless, to attain this goal, our member companies have to overcome several challenges in order to increase their share in the international market and to supply high quality and affordable vaccines to the developing world. To achieve this, several organizational and regulatory challenges should be overcome.

From the organizational perspective, it will be necessary to build strong partnerships for vaccine innovation and to stimulate technological transfer to the developing world in strategic areas for vaccine development.

Another crucial issue in the organizational area is WHO pre-qualification. It remains as a big challenge as the regulatory environment has become even more stringent and requires massive investments in modernization, new facilities, as well as, the R&D for new product development and the incorporation of new technologies of production.

Moreover, from the regulatory perspective, other complex ethical, regulatory and intellectual property issues related to vaccine research, development and production should be overcome in order to avoid unnecessary delays in vaccine approval.

All these efforts are also dependent upon the continued and important support we have had from organizations such as the WHO, UNICEF among others.

I am pleased to present this year the second edition of DCVMN Directory with our members' profiles so it can be disseminated worldwide.

I'd like to thank all members, speakers, resource institutions, sponsors, contributors for their willingness, time and strive to be part of DCVMN and to be here at the XII<sup>th</sup> Annual General Meeting, giving us the opportunity to exchange knowledge and experiences.

Finally but not least, I hope you may take the opportunity to visit some of the famous places in Xiamen and China, and of course the facilities of Xiamen Innovax Biotech Co. Ltd.

Dr. Akira omma, President, DCVMN

## STEERING COMMITTEE MEMBERS



Dr. Akira Homma President of DCVMN Bio-Manguinhos (Fiocruz), Brazil



Dr. Steven Gao Xiamen Innovax Biotech Co. Ltd.



Mr. Mahendra Suhardono PT Bio Farma, Indonesia



Dr. G.V.J.A.Harshavardhan Bharat Biotech International Limited, India



Dr. Morena Makhoana The Biovac Institute, South Africa



Dr. Luciana Cerqueira Leite Instituto Butantan, Brazil



Ms. Mahima Datla DCVMN Representative on GAVI Board, Biological E. Limited, India

## List of Member Countries

۲	Argentina
	Brazil
*	Cuba
<u>ii</u>	Egypt
۲	India
	Indonesia
Ψ	Iran
۲	Mexico
*1	People's Republic of China
	Republic of Korea
	Romania
	South Africa
	Thailand
$\star$	Vietnam

DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK





Pioneering research. Healthy tomorrow.

Name of the company :Bharat Biotech International LimitedHead of Institution:Dr. Krishna M. Ella, Chairman & Managing DirectorEstablished:1996Country:India

#### Overview of the company

Bharat Biotech International Limited (BBIL) was incorporated as a company in 1996 at Hyderabad, Andhra Pradesh, India. BBIL was founded by Dr. Krishna M. Ella and Mrs. Suchitra K. Ella, to establish a knowledge base for new vaccine development in the developing world. BBIL has a vision to develop novel vaccines against neglected diseases of the developing world. Dr. V. Krishna Mohan, President, heads the day to day operations.



BBIL is a multi-dimensional biotechnology company specializing in product-oriented research, development and manufacturing of vaccines and bio-therapeutics. BBIL is providing affordable, global health care solutions at world class quality. The company pioneered manufacture of the world's first Cesium chloride- free Hepatitis-B vaccine with HIMAX<sup>®</sup> technology, a novel purification matrix patented globally. BBIL has successfully manufactured preservative -free Hep-B and Hib vaccines. BBIL is the first Indian company to obtain a global patent for a biotech molecule r-LYSOSTAPHIN, to fight Staphylococcal infections. BBIL was certified by KFDA for the manufacture of parenterals. Hepatitis B Vaccine, Monovalent OPV1, Monovalent OPV3 and Bivalent OPV 1&3 of BBIL are WHO Pre-Qualified. BBIL has a strong focus on innovation and intellectual property rights, with a belief in "developing our own IPR and not violating IPR". The focus on neglected diseases is unparalleled at BBIL: vaccines against malaria, chikungunya, Japanese encephalitis, severe rotavirus gastroenteritis, human papiloma, Salmonella typhi are in the pipeline.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
	1	viai/Ampoule	0.57 1.07 5.07 10.0111
Revac-B+	Hepatitis B Vaccine, rDNA (Pichia pastoris), 20 µg of HBsAg/1.0 mL (Adult)	Vial	0.5 mL,1.0 mL, 2.5 mL, 3.0 mL, 5.0 mL,10.0 mL
Revac-B mcf	Hepatitis B Vaccine, rDNA (Pichia pastoris) Thiomersal Free, 20 µg of HBsAg/1.0 mL (Adult)	Vial	0.5 mL,1.0 mL
INDIRAB	Rabies Vaccine Vero Cell-Derived; Pitman-Moore strain of Rabies virus Potency = 2.5 I.U/0.5 mL	Vial	0.5 mL
TYPBAR	Vi Capsular Polysaccharide Typhoid Vaccine Vi Capsular polysaccharide of S. typhi (Ty2 strain) 25 µg/ 0.5 mL	Vial	0.5 mL, 2.5 mL
BIOPOLIO	Trivalent Oral Poliomyelitis Vaccine Live, Attenuated (Sabin) 0.1 mL (2 drops)	Vial	2 mL,1 mL
BIOPOLIO M1	Monovalent Oral Poliomyelitis Vaccine Type 1 Live, Attenuated (Sabin) 0.1 mL	Vial	2 mL,1.0 mL
BIOPOLIO M3	Monovalent Oral Poliomyelitis Vaccine Type 3 Live, Attenuated (Sabin) 0.1 mL	Vial	2 mL, 1.0 mL
BIOPOLIO 1&3	Bivalent Oral Poliomyelitis Vaccine Type 1&3 (Sabin) 0.1 mL	Vial	2.0 mL,1.0 mL
ComVac4-HB (DPT+Hep-B)	Diphtheria, Pertussis (w),Tetanus, Hepatitis-B Vaccine (Quadrivalent Vaccine) 0.5 mL	Vial	0.5 mL, 2.5 mL, 5.0 mL
ComVac5 (DPT+Hep B+Hib)	Diphtheria, Pertussis(w),Tetanus, Hepatitis-B & Haemophilus influenzae Vaccine, (Pentavalent Vaccine) 0.5 mL	Vial	0.5 mL, 2.5 mL. 5.0 mL
ComVac3	Diptheria Tetanus Pertussis Vaccine (DTP Vaccine) 0.5 mL	Vial	0.5 mL, 2.5 mL, 5.0 mL
REGEN-D 150	r- Human Epidermal Growth Factor Gel 150 µg/gm	Tube	7.5g, 15g, 30g, 60g, 150g
REGEN-D 60	r- Human Epidermal Growth Factor Gel 60 μg/gm	Tube	7.5g, 15g, 30g, 60g, 150g
BIO-ENOX 20 mg	Low Molecular Weight Heparin Enoxaparin Sodium Injection. 20mg/0.2 mL (2,000 anti-Xa I.U)	PFS	0.2 mL Pre-Filled Syringes
BIO-ENOX 40 mg	Low Molecular Weight Heparin Enoxaparin Sodium Injection 40mg/0.4 mL (4,000 anti-Xa I.U)	PFS	0.4 mL Pre-Filled Syringes
BIO-ENOX 60 mg	Low Molecular Weight Heparin Enoxaparin Sodium Injection.60mg/0.6 mL (6,000 anti-Xa I.U)	PFS	0.6 mL Pre-Filled Syringes
BIO-ENOX 80 mg	Low Molecular Weight Heparin Enoxaparin Sodium Injection. 80mg/0.8 mL (8,000 anti-Xa I.U).	PFS	0.8 mL Pre-Filled Syringes
HEPASOLV 1000 IU	Heparin Sodium Injection, Sterile	Vial	5mL Vial
HEPASOLV 5000 IU	Heparin Sodium Injection, Sterile	Vial	5mL Vial
HEPASOLV 25000 IU	Heparin Sodium Injection, Sterile	Vial	5mL Vial
BIOGIT / FloraNorm	Saccharomyces boulardii (Granular) 250 mg, oral	Sachet	Sachet
BioHib	Purified capsular polysaccharide of Hib [covalently bound to 20-40 μg Tetanus toxoid (PRP-TT)] 10 μg	PFS	0.5 mL

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Recombinant Human Growth Hormone					
Recombinant Human Serum Albumin					
Recombinant Parathyroid Hormone					
THR-100 [Recombinant Staphylokinase]					
Lysostaphin for S.aureus infections, topical					
Rotavirus Vaccine Candidate 116E					
Malaria Vaccine Candidate -1 (r-PvRII)					
Malaria Vaccine Candidate -2 (PfMSP-19)					
Malaria Vaccine Candidate -3 (PfF2)					
Vi Capsular Polysaccharide Typhoid Conjugate Vaccine					
Japanese b encephalitis Vaccine					

- Development of Novel vaccines for Neglected diseases
- O Development of novel adjuvants
- Development of novel therapeutics

#### Contact Details ·

Name of contact person : Mr. Sai D. Prasad, Vice-President

Address : Bharat Biotech International Limited, Genome Valley, Shameerpet.	Phone : +91 40 2348 0567
City : Hyderabad	Mobile : +91 984 888 7866
State : Andhra Pradesh	Fax : + 91 40 2348 0560
Country: India	email : prasadsd@bharatbiotech.com
Postal code: 500 078	Website: www.bharatbiotech.com



Areas of Interest for Collaboration



Name of the company : Biological E. Limited Head of Institution : Dr. Vijay Kumar Datla, Chairman & Managing Director

Biological E.	Limited
Celebrating Life	Everyday

Head of Institution	: Dr. Vijay I
Established	: 1953
Country	: India

#### Overview of the company

Biological E. Ltd. (Bio E) a globally focused biopharmaceutical company develops, manufactures and markets innovative vaccines and biologics that respond to healthcare needs worldwide. Established in 1953 at Hyderabad, India, Bio E, which is privately owned, is India's first private sector vaccines and biologics company. In the past 54 years, Bio E has achieved a dominant position in the Indian vaccines market. It is a major supplier to the National Immunization Programme (EPI programme) of the Government of India. Over the past 10 years alone Bio E has supplied over 1 billion doses of vaccine towards the immunization needs of India. With the receipt of our first WHO pre-qualification in 2009 Bio E has been supplying to UN



organisations and expanding its market reach globally.

The company has achieved the WHO Prequalification status of its second vaccine, the pentavalent vaccine (Lyo) recently and aiming to become a major supplier of this product to UN organisations and other international markets.

The company's product development efforts are driven by an internationally experienced management team and through former strategic alliances with leading biotechnology / pharmaceutical companies and research institutes around the world such as Evans, Glaxo, Solvay, ICI and Aventis Pasteur. These alliances have allowed Bio E to expand its product range, market reach and inculcate the best international practices in manufacturing and management. Currently we have collaborations with Intercell AG and Netherlands Vaccin Institut (NVI).

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
BETT	Tetanus Toxoid (adsorbed) (TT)	Vial & Ampoule	0.5, 5.0, 10.0 ml
TRIPVAC	Diphtheria, Tetanus and Pertussis vaccine (adsorbed) (DTPw)	Vial & Ampoule	0.5, 5.0 ml
BEVAC	Diphtheria & Tetatnus Toxoid (DT)	Vial & Ampoule	0.5, 5.0, 10.0 ml
BE Td	Diphtheria and Tetanus vaccine (Td) (for adolescents & adults)	Vial & Ampoule	0.5, 5.0 ml
BEVAC	Hepatitis B vaccine (recombinant)	Vial	0.5, 1.0, 2.5, 5.0, 10.0 ml
TRIPVAC HB	Diphtheria, Tetatnus, w-Pertussis, Hepatitis B (recombinant) (DTPw+HepB)	Vial	0.5, 1.0, 2.5, 5.0 ml
ERAPOL	Poliomyelitis Vaccine (Inactivated) (IPV)	Vial	0.5, 5.0 ml
HiBE	Haemophilus type b conjugate vaccine (lyophilized) (Hib)	Vial (combipack)	0.5, 1.0, 2.5, 5.0 ml
ComBE Five	Diphtheria, Tetatnus, Pertussis, Hepatitis B and Haemophilus type B conjugate vaccine (DTPw+Hep B + Hib)	Vial (lyophilized)	0.5, 1.0, 2.5, 5.0 ml
ComBE Five	Diphtheria, Tetatnus, Pertussis, Hepatitis B and Haemophilus type B conjugate vaccine (DTPw+Hep B + Hib)	Vial (liquid)	0.5, 1.0, 2.5, 5.0 ml

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
DTwP-IPV					
Inactivated JE vaccine					Q1 2012
Live Tetravalent Dengue Vaccine					
Live Tetravalent Rotavirus Vaccine					
Meningococcal Conjugate Vaccine					

Areas of Interest for Collaboration

• Vaccines

• Therapeutic Proteins

#### Contact Details ·

Name of contact person : Ms. Kala Naidu

Address : 18/1&3, Azamabad

City : Hyderabad

State : Andhra Pradesh

Country: India

Postal code: 500 020

Phone : +91 40 2760 3742 +91 40 3021 3999

Mobile : +91 98495 57083

Fax : +91 40 2763 0307 +91 40 2761 5309

email: kala.g@biologicale.co.in

Website: www.biologicale.com



G	Instituto de Tecnologia em Imunobiológicos <b>Bio-Manguinhos</b>	Name of the company	: Bio-Manguinhos - Institute of Technology on Immunobiologicals The Oswaldo Cruz Foundation - Ministry of Health
ስምሳ	Ministério da Saúde	Head of Institution	: Artur Roberto Couto, Director
	FIOCRUZ Fundação Oswaldo Cruz	Established	: 1976
		Country	: Brazil

#### Overview of the company

Bio-Manguinhos is a Technical Unit of Oswaldo Cruz Foundation (Fiocruz), Ministry of Health, dedicated to technological development and production of vaccines, biopharmaceuticals and IVD reagents for diagnosis. Formally established in 1976, Bio-Manguinhos plays a strategic role supplying most of the vaccines required by the Brazilian National Immunization Program.

Our production facility is one of the largest and most modern vaccine industrial plant in Latin America. We are investing heavily in technological innovation of immunobiological needed to public health programs and have established several national and



international partnerships, in order to accelerate the incorporation of new production technologies. Two vaccines are pre-qualified by WHO and are exported through the United Nations Agencies: the yellow fever and meningitis meningococcus vaccines. About 71 countries have already received these vaccines.

The production of kits for laboratory diagnosis has increased in the last year, especially for infectious and parasitic diseases, such as AIDS, Hepatitis C Leishmaniasis, Chagas Disease, Leptospirosis, among others. Around 8 million tests are produced each year.

The biopharmaceutical production of Interferon and Erythropoietin is around of 10 million vials per year.

Most rewarding to Bio-Manguinhos has been the contribution to the success of the Brazilian National Program of Immunization.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
DTP + Hib	Haemophillus influenzae type B, dipthteria, tetanus and pertussis vaccine	5 doses/vial	2.5 ml
Hib	Haemophillus influenzae type B vaccine	1 and 5 doses/amp	0.5 ml
Yellow Fever	Yellow fever vaccine	5,10 and 50 doses/vial	0.5, 1.0 and 25 ml
Polysaccharide Meningite AC	Polysaccharide Meningiti AC vaccine	10 doses/vial	1.5 ml
OPV	Oral poliomyelitis virus vaccine	25 doses/tube	2.5 ml
MMR	Measles, mumps and rubella triple vaccine	10 doses/amp	5.0 ml
Rotavirus	Rotavirus vaccine	1 dose/vial	2.0 ml
10-valent Pneumococcal	10-valent Pneumococcal vaccine	1 dose/vial	0.5 ml

Vaccines pipeline:

- a. IPV vaccine
- b. DTP/HB/Hib vaccine
- c. Polysaccharide Meningitis ACW-135 vaccine
- d. Conjugate Meningitis ACW-135 vaccine
- e. Dengue tetravalent vaccine (recombinant)
- f. Dengue tetravalent vaccine (inactivated)
- g. Dengue inactivated vaccine
- h. Yellow fever vaccine (attenuated)
- i. Yellow fever vaccine (inactivated)
- j. Yellow fever vaccine (one dose)

- k. Hepatitis A vaccine (inactivated)
- I. Influenzae pandemic vaccine (recombinant)
- m. Malaria vaccine (recombinant)
- n. Leptospirosis vaccine (recombinant)
- o. Leishmaniases human vaccine
- p. Polysaccharide Meningiti B vaccine
- q. Conjugate Meningite C vaccine
- r. Pneumo proteic vaccine
- s. Double Viral vaccine
- t. TVV vaccine

Stage of development of vaccines, biopharmaceutical, kits for laboratory diagnosis:

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Bacterial Vaccines	3	-	2	1	-
Viral Vaccines	8	-	-	-	-
Biopharmaceuticals	3	-	-	-	-
Kits for lab diagnosis	2	-	-	3	-
TOTAL	16		6		-

#### Areas of Interest for Collaboration

- Fermentation
- Prokaryotic expression
- Eukaryotic expression
- o Conjugation
- Plant-based development (Dengue, Malaria, Men B, Men C, YF, Influenza, HAV)

#### Contact Details

Name of contact person : Mrs. Denise Maria Lobo Crivelli

Address : Avenida Brasil, 4365 - Manguinhos

Phone: +55 21 3882-9329

City : Rio de Janeiro

State : Rio de janeiro

Country: Brazil

Postal code: 21040-360

#### Mobile :

Fax: +55 21 3882-7176

email:dlobo@bio.fiocruz.br

Website: http://www.bio.fiocruz.br



## BioNet

Name of the company : BioNet-Asia Co., Ltd.

Head of Institution: Mr. Vitoon VonghangoolEstablished: 2001Country: Thailand

#### - Overview of the company

BioNet-Asia Co.,Ltd is a biotech company which focuses on the networking, development, manufacturing and supply of vaccines in emerging countries.

#### A pioneer in the vaccine development in Thailand

BioNet-Asia opened its R&D Centre in 2009 and has several development programs on vaccines against pertussis, meningitis and dengue diseases. BioNet has built some fruitful collaboration in the research and development of future vaccines with Thai and foreign



entities. We are exploring any new development opportunities for partnerships in the field of Japanese Encephalitis, Chikungunya, Influenza, hepatitis and Pneumococcus vaccines.

A leading international Bio Network

Our global Biotech Network of manufacturers, distributors, consultants and academics aims at promoting the development, manufacturing and supply of vaccines in the emerging countries.

Through its unique networking architecture, BioNet-Asia has helped vaccine producers to expand their business in Thailand and internationally.

Bionet has also supported its manufacturing partners to enlarge their product portfolio and pipeline through unprecedented strategic alliances and technology transfers.

For more than 10 years, BioNet has been the promoter of key vaccine partnerships for the production and supply of billions of doses of pediatric vaccines, contributing to save the lives of millions of children all around the world.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Recombinant Acellular Pertussis Vaccine			

- a. Polysaccharide and conjugate vaccinesb. Recombinant Dengue Vaccine

Product Name	Pre Clinical	Clinical Phase 1 Phase 2	Phase 3	Expected launch date Quarter / Year
<ul> <li>Technology transfer</li> <li>Joint-development</li> </ul>		,	Areas of Inte	erest for Collaboration
<ul> <li>Licensing</li> <li>Marketing distribution</li> </ul>				
Contact Details				•
Name of contact person : Mr.Veerachai	Tarnmaneewongs	e		
Address : 19 Soi Udomsuk 37, Sukhumvit 103 Road, Bangjak, Prakanong, Bangkok 10260, Th	nailand	Phone : +66 2361	8110	
City: Bangkok		Mobile : +66 8 56	61 3177	
State :		Fax : +66 2361 81	05	
Country: Thailand		e-mail : veerach	ai@bionet-asia.c	com
Postal code: 10260		Website: www.bi	onet-asia.com	
DEVELOPING COUNTRIES VAC	CCINE MAN	IUFACTURERS	NETWORK	dcvmn



Name of the company : Cadila Pharmaceuticals Limited

Head of Institution	: Shri I.A.Modi, Chairman
Established	: 28-02-1991
Country	: India

#### Overview of the company

Cadila Pharmaceuticals is one of the largest privately held pharmaceutical companies in India. Over the last few decades, it has been developing and manufacturing pharmaceutical products and selling and distributing these in India and in over 90 countries around the world. It is a research-driven integrated healthcare solutions provider with a pharmaceutical product basket of 450 plus in therapeutic areas that include cardiovascular, gastrointestinal, analgesics, haematinics, anti-infectives and antibiotics, respiratory agents, antidiabetics and immunologicals. The state-of-the-art Research and Development (R&D) facility at Cadila Pharmaceuticals is manned by more than three hundred and fifty scientists.



The company also participates in Public-Private partnerships for developing preventive and curative pharmaceutical and diagnostic products. Over the last decade, Cadila Pharmaceuticals has focused on novel approaches to cancer management and is the first Indian company to get multiple investigational new drugs applications (INDs) cleared by USFDA.

The company has manufacturing facilities conforming to the most stringent international norms at Dholka, Ankleshwar, Kadi and Hirapur in Gujarat; Samba in Jammu and Kashmir and Addis Ababa in Ethiopia.

Cadila Pharmaceuticals has recently emerged on the World map with the development of world's first introductions like 'Polycap'- a novel drug combination for prevention of Cardiovascular Heart Disease; and 'Risorine', a boosted Rifampicin dosage for TB treatment. Cadila Pharmaceuticals also has a strong footprint in micropropagation and bioformulation through its Agro division.

Cadila Pharmaceuticals Ltd. has also formed a joint venture with Novavax, Inc. USA. The JV-CPL Biologicals will be developing and manufacturing vaccines, biological therapeutics and diagnostics in India.

Product Name	Description	Type Vial/PFS	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Pandemic Influenza	H1N1 vaccine produced from VLP technology	Vial/PFS	0.5 ml/2ml vial
Seasonal Influenza Vaccine	Trivalent Influenza vaccine produced from VLP technology	Vial/PFS	0.5 ml/2ml vial
Rabies vaccine	Recombinant G-Protein produced by VLP technology	Vial/PFS	0.5 ml/2ml vial

- a. HPV Vaccine
- b. Malaria Vaccine
- c. Hepatitis B
- d. Hepatitis E
- e. Pneumococcal conjugate vaccine

Product Name	Pre Clinical		Clinical		Expected launch date
HouderName		Phase I	Phase II	Phase III	Quarter / Year
Pandemic Influenza					2012
Seasonal Influenza					2013

Areas of Interest for Collaboration

- Vaccine-recombinant
- Vaccine- cell culture based
- O Conjugate vaccine
- Adjuvant (Biological and small molecules)
- O Recombinant proteins and Monoclonal antibody for therapeutic use
- O In licensing / out licensing

#### Contact Details ·

Name of contact person : Dr. Bakulesh M Khamar, Executive Director-Research

Address	: Cadila Pharmaceuticals Limited "Cadila Corporate Campus" Sarkhej-Dholka Road, Bhat	Phone : +91-2718-225001
City :	Ahmedabad	Mobile : +91-98253 25010
State : C	Gujarat	Fax:+91-2718-225039
Country:	India	e-mail : bmk@cadilapharma.co.in
Postal co	ode: 382210	Website: www.cadilapharma.com





Head of Institution

Established

Country

Name of the company : "Cantacuzino" National Institute of Research and Development for Microbiology and Immunology

> : Dr. Gabriel Ionescu, General Director : 1921

: Romania

#### Overview of the company

Headquarters in Bucharest, a branch in lasi and an experimental unit in Baneasa. Main public health unit in Romania. Based on integration concept - national references laboratories, research and production has a long production history, since its beginning. The institute is a member of the International Network of Pasteur Institutes (RIP). The institute is collaborating with other institutions and universities from France, Germany, Italy, United Kingdom, The Netherlands, USA, Hungary, Greece, Japan, Moldavia, Russia, Ukraine. Basic and practical research in microbiology and immunology.



Microbiological surveillance by the National Reference Centres recognized by the Ministry of Health for diagnosis and surveillance of communicable diseases. Services of technical and methodological consulting granted to all profile units across the country, expertise, participation in national and international epidemiological surveillance networks. Production of vaccines, bacterial immunomodulators, diagnostic reagents, bacteriological and cell cultures media. The seasonal influenza vaccine is produced since the year 1971.

Teaching activities Laboratory investigations for health inssurance companies, population and different other units. Breeding and marketing of laboratory animal and developing experimental models

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Trivalent purified inactivated Influenza vaccine	Trivalent Influenza vaccine prepared on embryonated chicken eggs	Ampoule	0.5 ml
Adsorbed tetanus vaccine	Tetanus toxoid adsorbed on aluminium phosphate	Ampoule	0.5 ml
PPD IC 65 2 UT and 10 UT	In vivo diagnostic reagent for TB (Purified protein derivative)	Ampoule	2.0 ml /20 doses of 2UT or 10UT
Natural SOD	Natural juice extracted from green barley containing Superoxide dismutase (SOD)	Ampoule	10 ml

Produ	uct Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
o Immunomoc o Vaccines	dulators				Areas of Ir	nterest for Collaboration
Contact Detail	ls					•
Name of contact	person : Francisc Czc	bor				
Address : Splaiul	Independentei 103, Se	ctor 5	Phone	e: +40 21 3	06 9218	
City : Bucharest			Mobil	e: +40 788	546 612	
State :			Fax :	⊦40 21 306 9	9307	
Country: Roman	ia		email	: czobor@c	cantacuzino.	<sup>7</sup> 0
Postal code: 0500	996		Webs	ite: www.ca	antacuzino.ro	
DEVELOPING	COUNTRIES VA		ANUFAC	<b>URERS</b>	NETWORK	dcvm

17/1/	Name of the company	y: Center for Genetic Engineering and Biotechnology
$\Lambda$	Head of Institution	: Dr. Luis Herrera Martínez. Director General
	Established	: 1986
	Country	: Cuba

#### Overview of the company

The Center for Genetic Engineering and Biotechnology (CIGB) since 1986 has become one of the most important research-production facilities at the "Western Havana Bio-Cluster", equipped and staffed to close the cycle from biological research, which means from biotech product and process development, to production, registering, and commercialization. The CIGB has 20 years of experience in the production of recombinant biopharmaceutical molecules such as interferon, Hepatitis B vaccine, Synthetic Haemophilus influenzae type b vaccine, Tetra- and Penta-valent Combined vaccines, streptokinase, epidermal growth factor formulated in different forms, monoclonal antibodies and other products, which are already producing a positive impact on public health in Cuba and a positive cash flow from sales to more than 50 countries.

The CIGB with about 550 scientists and engineers work in more than 50 research and development projects, which involve new vaccines,



therapeutic recombinant proteins and peptides, therapeutic monoclonal antibody and diagnostic systems. CIGB project/product portfolio is covered by more than 70 patent applications and manufacture of those arriving into production stage take place under the most stringent GMP conditions leading into international recognition by different authorities.

CIGB is open to implement a coordinated and targeted alliance-building policy, in order to speed up projects, to complement our capacities with those of our new partners, and to open new channels to the most sophisticated markets.

A component of that policy is to anticipate negotiation time and to start alliance building earlier in the product's life cycle. Thus, immersed in this movement, you will find in this document general data about the institution and summaries of eleven projects, which we considered most attractive for negotiation with your organization, However, while the mail proposed focus is set within these propositions, discussions can be opened around other projects of mutual interest as well.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Heberbiovac HB	HB Vaccine	Vial (liquid)	Pediatric and adult doses, single and multidose
Quimi- Hib	Hib Vaccine	Vial (liquid)	Pediatric, single dose
Trivac HB	Tetravalent Vaccine (DPT-HB)	Vial (liquid)	Pediatric and adult doses, single and multidose
Heberpenta L	Pentavalent Vaccine (DPT-HB-Hib). Fully liquid in one vial	Vial (liquid)	Pentavalent Vaccine (DPT-HB+Hib)
Heberon	Interferon's	Vial (liquid& freeze dried)	Several presentations
Hebekinasa	Streptokinase	Vial (freeze dried)	Several presentations
Heberprot-P	Heberprot-P <sup>®</sup> is a novel and unique medicine indicated for diabetic foot ulcer treatment (DFU). This innovative product contains epithermal growth factor (EGF) as active pharmaceutical ingredient (APhI) to be applied by intra-lesional infiltration directly in the wound site	Vial (freeze dried)	25 and 75 mcg/vial

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Heberprot - P					
HBV vaccine (NASVAC)					
HCV vaccine ( CIGB - 230 )					
CIGB - 500 ( Cytoprotective Agent)					
CEA recombinant antiboby fragment (CIGB - M3)					
HPV vaccine					
Prostate cancer vaccine					
CIGB - 370 ( Anti- tumor agent)					
CIGB - 166 (anti- VEGF antibody)					
CIGB_247 (VEGF vaccine)					
CIGB - 552 (anti -tumor peptide)					
Dengue vaccine					
Dengue anti-viral molecules					
CIGB - 845 (neure-protective agent)					
Peptide for Rheumatoid Arthritis					

## Areas of Interest for Collaboration

• Business Strategy for International Partnership in R&D CIGB's Projects

• CIGB is open to implement a coordinated and targeted alliance-building policy, in order to speed up projects, to complement our capacities with those of our new partners, and to open new channels to the most sophisticated markets

#### Contact Details -

Name of contact person : Dr Luis Herrera Martinez

Address : ave 31. entre 158 y 190. Cubanacan Playa

City : Havana

State : Havana City

Country: Cuba

Postal code: PO Box 6162

Phone : +53 7 271 6013 +53 7 271 6022 Mobile : +91 98495 57083

Fax: +53 7 33 6008

email: luis.herrera@cigb.edu.cu

Website: www.cigb.edu.cu



**DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK** 



Name of the company : China National Biotec Group (CNBG)

Head of Institution	: Dr. YANG Xiaoming, President
Established	: 1989
Country	: China

#### Overview of the company

CNBG is a state-owned company and one of the subsidiaries of China National Pharmaceutical Group Corporation (Sinopharm). It is the largest vaccine and blood products manufacturer and supplier in China. CNBG consists of six institutes of biological products which are located in Beijing, Changchun, Chengdu, Lanzhou, Shanghai and Wuhan respectively. CNBG



is also the major shareholder of Beijing Tiantan Biological Products Co., Ltd. And Beijing Vigoo Biological Co., Ltd.

CNBG has nearly 10,000 employees, among which more than 4,000 are scientists and technicians. CNBG owns dozens of achievements with independent intellectual properties rights and are currently operating more than a hundred SFDA cGMP certified manufacturing lines enabling to manufacture over 200 types of biological products for disease prevention, therapeutic and diagnostic use, also including all the vaccines for Chinese EPI program.

CNBG has successfully integrated a flow of R&D, manufacturing, marketing and post-marketing activities for biological products and has become one of the few companies in the world that could offer the widest range of vaccines with large quantities.

Product Nam	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
	Hepatitis B Vaccine (Yeast)/(CHO)	Ampoule/ Vial	5, 10, 20 µg
	BCG Vaccine for Intradermal Injection	Ampoule	0.25 mg
	Live Attenuated Oral Poliomyelitis Vaccine (Dragee Candy)	Pill	1g
Shanliantai	Diphtheria Tetanus and Acellular Pertussis Combined Vaccine (DTaP) ,Adsorbed	Ampoule/Vial	0.5, 2.0 ml
	Measles, Mumps and Rubella Combined Vaccine,Live (M/R/MR/MM)	Vial	0.5 ml
CD.JEV	Japanese Encephalitis Vaccine Live / Inactivated Vero cell	Vial	0.5 ml
	Group A Meningococcal Polysaccharide Vaccine	Ampoule	5 doses,150µg 10 doses 300µg
Menglingkang	Group A+C Meningococcal Polysaccharide Vaccine	Ampoule	100µg/4 doses 400µg
Havac	Live Attenuated Hepatitis A Vaccine	Vial	1ml
Hanpuwei	Hpemorrhagic Fever with Renal Syndrome Bivalent Purified Vaccine, Inactivated	Ampoule	1ml
	Leptospirosis Vaccine	Ampoule	5ml
Yingfuning/Shipulier	Split Influenza Virus Vaccine	Injector/Vial	0.25, 0.5ml
Huiyikang	23-Valent pneumococcal polysaccharide vaccine	Vial	0.5 ml
	Typhoid Vi Polsaccharide Vaccine	Ampoule	2 doses 1ml
Luotewei	Live Rotavirus Vaccine (Oral)	Vial	3.0 ml
Keerbei	Haemophilus Influenzae Type b Conjugate Vaccine	Vial	0.5 ml
Xinning	Rabies Vaccine for Human Use, Freeze-dried (Vero cell)	Vial	0.5 ml
Shengdousi	Freeze-dried Live Attenuated Varicella Vaccine	Vial	0.5 ml
-	Yellow Fever Vaccine,Live	Ampoule	6 doses 0.3 ml
	Tick-borne Encephalitis Purified Vaccine	Ampoule	1.0 ml

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Bovine Rotavirus Vaccine					
Trivalent Ovine Rotavirus Vaccine					
Meningococcal A+C Conjugate Vaccine					
Meningococcal ACWY Vaccine (Polysaccharide	:)				
Hepatitis B Vaccine for Therapeutic use					
Varicella Vaccine (Beijing Strain)					
Influenza (Subunit)					
Ev71 Vaccine					
Hib Polysaccharide Conjugate Vaccine					
DTP-Нер В					
DTaP-Hib					
Measles-Mumps-Rubella, Varicella Combined Vaccine					

- o Adjuvant
- O Combined Vaccine
- O Cell line
- O New Antigen
- O Large-scale Production Technology

#### Contact Details

City : Beijing

Country: P.R. China

Postal code: 100029

State :

Name of contact person : Ms.TANG Ying ; Ms.QU Liang

Address : 26<sup>th</sup> Floor, Fortune Tower A, No.4 Huixin-East Street, Chaoyang District Phone : +86 10 8466 3879 +86 10 8466 3787

Fax: +86 10 8466 3322

Mobile : +86 135 0108 1655 +86 136 2110 6475

email : tangying@cnbg.com.cn quliang@cnbg.com.cn

Website: www.cnbg.com.cn



Areas of Interest for Collaboration

**DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK** 

Name of the company : Finlay Institute



Head of Institution	: Dra. Concepción Campa Huergo, President/General Director
Established	: 1991
Country	: Cuba

#### Overview of the company

The FINLAY INSTITUTE, founded in 1991, is a scientific organization, dedicated to research, development, production and commercialization of human vaccines, internationally recognized in this field. This institution is a world leader in the field of meningococcal vaccine and other classic vaccines included in the Extended Immunization Program (EIP). VA-MENGOC-BC®, created and produced by the Finlay Institute was the first effective vaccine against serogroup B meningococcus.



The almost 1000 members of Finlay's staff constitute the largest capital of Finlay Institute and they have been recognized for their experience in the field of vaccines, more than 60% of them have high technical and professional qualification in the field of vaccine research, development, production and quality control. Many of them have more than 20 years of experience in these specialties, which guarantees the preparation and continuity of the projects with the inclusion of new talents graduated from the universities.

The facilities engaged in the production of vaccines and active pharmaceutical ingredients were designed, built, equipped and they are operated according to cGMP. Some products manufactured in these facilities have been prequalified by WHO.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
VA-MENGOC-BC®	Meningococcal BC vaccine	Vial	0.5/2.5/5.0 ml
vax-MEN-AC®	AC Meningococcal polysaccharide vaccine	Vial	5.0 ml
vax-SPIRAL®	Trivalent leptospirosis vaccine	Vial	0.5/5.0 ml
vax-TyVi®	Vi Polysaccharide typhoid vaccine	Vial	0.5/5.0/10.0 ml
vax-TET®	Tetanus vaccine	Vial	0.5/5.0/10.0 ml
VA-DIFTET®	Diphtheria-Tetanus vaccine for children	Vial	0.5/5.0/10.0 ml
Diphtheria-Tetanus ®	Diphtheria-Tetanus vaccine for adults	Vial	0.5/5.0/10.0 ml
DTP- vax®	Diphtheria-Tetanus-wPertussis	Vial	0.5/5.0/10.0 ml

- 1. Meningococcal ACW135 vaccine (plain)
- 2. Meningococcal ACYW135 vaccine (plain)
- 3. Meningococcal ACYW135X vaccine (plain)
- 4. Conjugated Pneumococcal vaccine
- 5. Conjugated Vi polysaccharide vaccine

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Meningococcal ACW <sub>135</sub> vaccine (plain)	Q4/2010	Q1/2011	1Q/11		Q2/2011
Meningococcal ACYW <sub>135</sub> vaccine (plain)	Q2/2011	Q3/2011	3Q/11		Q1/2012
Meningococcal ACYW <sub>135</sub> X vaccine (plain)	Q1/2012	Q3/2012	2Q/12		Q1/2013
Conjugated Pneumococcal vaccine	Q1-3/2010	Q4/10-Q1/11	Q4/11-Q2/12		Q1/2013
Conjugated Vi polysaccharide vaccine	Q3/2011	Q3-4/2011	Q1-3/2012		Q1/2013

#### Areas of Interest for Collaboration

- O Cooperated manufacturing
- Vaccine technologycal transfer
- Bacterial vaccines development based on outer membrane vesicles and based on capsule polysaccharides
- Application of novel adjuvants based on serogroup B Neisseria meningitidis outer membrane vesicles and proteoliposome-derived cochleate structure for vaccine development

#### Contact Details

Name of contact person : Dra. Concepción Campa Huergo

Address : Ave 27 No. 19805, La Coronela, La Lisa	Phone : + 53 7 208 6086 + 53 7 208 7986
City : La Habana	Mobile : + 535 285 0016
State :	Fax : + 53 7 208 6075
Country: Cuba	email : ccampa@finlay.edu.cu
Postal code: 11600	Website: www.finlay.sld.cu





Name of the company : Indian Immunologicals Limited

Head of Institution	: Shri K.V.Balasubramaniam, Managing Director Dr. Anand Kumar, Deputy Managing Director
Established	: 1982
Country	: India

#### Overview of the company

National Dairy Development Board set up Indian Immunologicals Limited in 1982. IIL's veterinary and human vaccine manufacturing facilities at Hyderabad and Ooty in India are among the largest vaccine producing plants in the world.

IIL is a major player in the human vaccine market in India, holding the fourth position and focusing on the paediatric and rabies segment with its flagship product "Abhayrab". IIL is also a major supplier of vaccines to India's large Universal Immunization Programme. IIL strongly believes that its mission of "Biotechnology in health care made affordable and accessible" can be actively pursued only with its sound technology base in modern biotechnology.



IIL's concept of "Abhay Clinic", which provides vaccination service by qualified medical practitioners working on franchise basis, and supported by sound cold chain system, is unique. Further through "Abhay Shoppe" IIL has been able to reach out to a large number of doctors with its unique service proposition of "vaccine on call". Through its new initiative of "Abhay Mart", IIL services the vaccine needs of organized pharmacy chains and corporate hospitals.

IIL research efforts are directed at developing frontier technologies in biologicals, diagnostics and vaccines. Vaccines for tropical diseases which are of little interest to western countries but very relevant for a country like India are a major focus of research. IIL has research collaborations with several reputed national and international institutes.

IIL exports its products to more than thirty five countries across the world with customer focus in Middle East, Asia Pacific region, Africa and CIS countries.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Abhayrab	Vero cell culture Rabies vaccine	Freeze dried vial with diluent ampoule	0.5 and 1ml
Abhay M	Measles vaccine	Freeze dried vial with diluent ampoule	0.5, 2.5 and 5 ml
Elovac B	Recombinant Hepatitis B vaccine	Vial	0.5, 1, 5 and 10 ml
Abhay TAG	Diphtheria, Pertussis and Tetanus vaccine	Vial	0.5 and 5 ml
Abhay DAG	Diphtheria and Tetanus vaccine	Vial	0.5 and 5 ml
Abhay TOX	Tetanus vaccine	Vial	0.5 and 5 ml
Abhayvac 3	MMR vaccine	Freeze dried vial with diluent ampoule	0.5 and 2.5 ml
Abhay RIG	Equine Rabies immunoglobulins	Vial	5 ml

- a. Tetravalent vaccine (DPT+H)
- b. Pentavalent vaccine (DPTH+HiB)
- c. Japanese Encephalitis vaccine
- d. HiB vaccine
- e. Chikungunya vaccine
- f. Human Papilloma virus vaccine

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Tetravalent vaccine (DPT+H)					02/2012
Pentavalent vaccine (DPTH+HiB)					04/2012
HiB vaccine					01/2012
Japanese Encephalitis vaccine					01/2013
Chikungunya vaccine					04/2012
Human Papilloma virus vaccine					04/2013

#### Areas of Interest for Collaboration

- O IPV vaccine technology
- Varicella vaccine technology
- Acellular Pertussis Vaccine
- O Dengue Vaccine

#### Contact Details ·

Name of contact person : Dr. Anand Kumar, Ph.D

Address : Indian Immunologicals Limited, Rakshapuram, Gachibowli Post	Phone : +91 40 2354 4585
City : Hyderabad	Mobile : +91 96663 39987
State : Andhra Pradesh	Fax: +91 40 2354 4007
Country: India	email : anandkumar@indimmune.com
Postal code: 500 033	Website: www.indimmune.com



**DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK** 



Name of the company : Institute of Vaccines & Medical Biologicals

Head of Institution	: Dr. Le Van Be
Established	: 1978
Country	: Vietnam

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#### Overview of the company

The Institute of Vaccines and Medical Biologicals(IVAC) was established on November 23rd, 1978 by the Ministry of Health with functions: Apply new technology for production of vaccines, sera and other medical biologicals to supply the Nationwide need, that includes the National Programme for Prevention and Treatment of infectious diseases such as the Expanded Programme on Immunization (EPI).

- 1986: Inauguration the large scale vaccines production lines for the EPI (in collaboration with the UNICEF).- 1993, 1998, 2002:



Receipt of the Third-class, Second-class, and First-class Labour medal respectively.- 1996: Receipt of VIFOTEC and KOVALEPSKAIA awards. Inauguration of ORESOL production line for the Control of Diarrheas Disease Programme (CCD).- 1999: Industrialize the antisera purification process, Holland sponsorship.-2001:Receipt of the silver memorial award of UNICEF.- 2007: UNICEF certified IVAC as a topquality producer for the essential vaccine. Start building up an influenza vaccine facilities at Suoi Dau Center. WHO grant.- 2008: Receipt of the Third-class Independent medal

Currently, IVAC is the largest vaccine manufacturer in Vietnam with more than 31 years of experience in production of different kinds of vaccines and sera. IVAC executive two centers: main center in Nha Trang with an area of 13.936 m<sup>2</sup>; second center in Suoi Dau, which is 22 km from Nha Trang center, has an area of 126 ha.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
DTP	Diphtheria Tetanus and Pertussis vaccine adsorbed, 20 dose	Vial	10ml
Π	Tetanus Toxoid adsorbed, 1 & 20 doses	Vial & ampoule	0.5mal & 10ml
Td	Tetanus & Diphtheria vaccine, 1 & 10 doses	Vial & ampoule	0.5ml & 5ml
BCG	Live freeze - dried BCG vaccine, 10 doses	amber ampoule	1ml
SAT	Tetanus Antitoxin, 1500IU and 1000 IU	ampoule	1ml
SAR	Equine Rabies Immune Globulin,1000IU	Vial	3ml
SAV - Naja	Antivenin against Naja kaouthia, 1000 $LD_{50}$	Vial	7ml
SAV - Tri	Antivenin against T.albolabris, 1000 $LD_{50}$	Vial	7ml
SAD	Diphtheria Antitoxin, 2500IU	Vial	5ml
Superferon	Interferon $\alpha$ - 2b, 3MIU and 1.5MIU	Vial	1ml
lm.BCG	Immune BCG (Freeze - Dried, used for cancer treatment), 37.5mg	amber ampoule	37.5ml

1.Inactivated influenza vaccine (H5N1, H1N1, Seasonal Flu) 2.DPT-Heb-Hib

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
H5N1	Q2/2011	Q1/2012	Q3/2012		Q2/2013
H1N1	Q2/2011	Q1/2012	Q3/2012		Q2/2013
Seasonal Flu	Q4/2011	Q3/2012	Q1/2013		Q4/2013
DPT-Heb-Hib	Q4/2011	Q3/2012	Q1/2013		Q4/2013

Areas of Interest for Collaboration

- o Adjuvant
- Compo vaccine
- Immune technique for production and QC
- O Quality Management
- O Business Trading Marketing

#### Contact Details -

Name of contact person : Dr. Le Kim Hoa

Address :	9	Pasteur	Street
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City : Nha Trang

State : Khanh Hoa province

Country: Vietnam

Postal code: 84

Phone: +84 58 3 822 408

Mobile : +84 90 3 504 198

Fax: +84 58 3 823 815

email: lekimhoa@dng.vnn.vn

Website: www.ivac.com.vn





Name of the company :Instituto ButantanHead of Institution:Jorge KalilEstablished:1901Country:Brazil

#### Overview of the company

Instituto Butantan is a Public research center associated with the Secretary of Health of the State of São Paulo dedicated to Biomedical Research with the mission to investigate, develop and provide to the Brazilian population essential products for Public Health. It has a centenary tradition in the investigation on snakes and poisonous animals, and is currently the leading national producer of vaccines and anti-venom sera. Fundação Butantan is a Private foundation created to support the activities of the Institute, allowing technological development, the operation of industrial production units and



commercialization of the products. The Ministry of Health is a partner of the ensemble and its major client.

In 2009, Butantan provided the Ministry of Health with ~270 million doses of vaccines/year, such as DTP, Hepatitis B and Rabies and ~1 million doses of hyperimmune sera. It has a surplus production capacity which can be made internationally available. Butantan constitutes a unique association where basic research, technological development and production allows Brazil within the National Programs of Public Health to provides state of art immunobiological products in the frontier of knowledge, in a rapidly expanding program of self-sufficiency.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
DTP vaccine	Diphtheria, tetanus and whole cell pertussis vaccine	Vial	5.0 ml
dT vaccine	Adult diphtheria and tetanus vaccine	Vial	5.0 ml
HepB vaccine	Recombinant Hepatitis B vaccine	Vial	5.0 ml
Rabies vaccine	Rabies vaccine produced in Vero cell culture for human use	Vial	5.0 ml
Anti-Diphtheria Hyperimmune sera	Anti-diphtheria toxoid hyperimmune sera	Vial	10.0 ml
Anti-Tetanus Hyperimmune sera	Anti-tetanus toxoid hyperimmune sera	Vial	5.0 ml
Anti-Venoms Hyperimmune sera	Bothropic (5 valent), Bothropic-Crotalic, Botropic-Lachetic, Crotalic (2 valent), Lachetic, Elapidic, Escorpionic, Aracnidic (Loxocelles and Phoneutria),Botulinic AB or E, Rabic	Vial	5,10, 20 ml
Influenza vaccine	Influenza vaccine seasonal and H1N1 produced in eggs	Vial	5.0 ml

- a. Lung surfactant
- b.  $\text{DTP}_{\text{low}}$  vaccine
- c. Influenza/adjuvant
- d. Rotavirus vaccine
- e. Human IgG
- f. Dengue vaccine
- g. Recombinant OncoBCG

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Lung surfactant					01/2012
Influenza/adjuvant					03/2013
DTP low					01/2012
Rotavirus vaccine					

Areas of Interest for Collaboration

- **O** Adjuvants
- **O** Fermentation
- $\boldsymbol{O}$  Conjugation

#### Contact Details

Name of contact person : Jorge Kalil

Address : Av. Vital Brasil 1500

City : São Paulo

State : SP

Country: Brazil

Postal code: 05503-900

Phone: +55(11) 2627-9502/3

Fax: +55(11) 2627-9505

email : jkalil@butantan.org.br

Website: www.butantan.gov.br





Birmex is a government-owned company that produces, imports and commercializes vaccines, antisera and biological reagents.

Our personnel possess a vast expertise in biologics production which combines with a stringent quality control of the production procedures. This expertise results in the successful updating of facilities, production procedures, and programs aimed to meet Good Manufacturing Practices as certified by the National Regulatory Agency.

Over the years Birmex has evolved into a reliable guarantee of experience and know-how for its customers, incorporating into each product and service:



- The confidence of high quality

- The pledge of an end-to-end service with full tracking and control over shipments at all times, whether by land or air

- The security of on-time distribution to any point in the country – this because Birmex is the only laboratory that delivers to all Mexico's 32 states

- The innovation, competitiveness, honesty and integrity in each process focused on offering solutions that meet the customer's needs

- And finally, the assurance of being with a laboratory whose experience, market knowledge and degree of specialization today make it the leading vaccine manufacturer in Mexico and one of the three principal vaccine-manufacturing countries in Latin America.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
topv	Trivalent Sabin Oral Polio Vaccine	Dropper	2.0 ml
Td vaccine	Tetanus and Diphteria Toxins	Vial	5.0 ml
Snake Antiserum	Vial with freeze dried to be reconstituted with 10 mL of Water for Injection as diluent. This serum is made with venoms from the species Crotalus basiliscus and Bothrops asper, and it has also cross reaction against venoms of the species Akgistrodon and Sistrurus.	Vial	10.0 ml
Scorpion Antiserum	Vial with freeze dried to be reconstituted with 5 mL of Water for Injection as diluent. This serum is made with venoms from the species Centruroides	Vial	5.0 ml

- 1. Monovalent oral polio vaccine (types 1, 2 and 3).
- 2.Influenza vaccine in cell culture systems.
- 3. Influenza vaccine in embrionated chicken eggs.

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Monovalent oral polio vaccine (types 1,2 & 3	3)				4 / 2013
Influenza vaccine in cell culture systems					3 / 2018
Influenza vaccine in embrionated chicken egg	IS				2 / 2014

Areas of Interest for Collaboration

- Cell cuture-based vaccines
- Scale-up processes
- **O** Technology transference
- O Pilot plant design
- From bench to patient (the vaccine development production proccess)

#### Contact Details ·

Name of contact person : Sonia Villaseñor Bustamante, International Business Manager

Address : Amores No. 1240, Col. Del Valle

Phone:+52/(55) 54-22-28-73

email: svillasenorb@birmex.gob.mx

Website: www.birmex.gob.mx

State : D.F.

Country: Mexico

Postal code: 03100





Name of the company : LG Life Sciences Ltd.

Head of Institution	: II Jae JUNG
Established	: 1947
Country	: Republic of Korea

#### Overview of the company

LG Life Sciences(LGLS) has developed and commercialized an array of pharmaceuticals for human and animal applications over the years. Especially for vaccines, LGLS successfully developed hepatitis B vaccine (EUVAX B<sup>™</sup> Inj.) which has been exported to more than 80 countries through UN-sponsored programs and represented the major portion of overseas sales. Further to hepatitis B vaccine, LGLS successfully developed tetravalent DTP-based combined vaccines. These include DTaP-HepB(Eutravac<sup>™</sup> Inj.) and DTwP-HepB(Euforvac<sup>™</sup> Inj.). Both of them were approved by Korean FDA in year 2008 and showed



superior efficacy and safety. LGLS also developed a Hib vaccine(Euhib<sup>™</sup> Inj.), as a component of pentavalent vaccine by reconstitution with DTwP-HepB-Hib(Euforvac-Hib<sup>™</sup> Inj.). In addition, LGLS is developing a fully-liquid pentavalent vaccine(DTwP-HepB-Hib), based on the accumulated technology and knowhow, for UN vaccine market. And year 2011, LGLS is selected by WHO as one of tech transfer recipient of sabin IPV. Based on this new technology, LGLS will continue to develop hexavalent and further combined vaccines. Through the long development history on vaccines LGLS accumulated a lot of experiences on vaccines and came to have very strong capability on vaccine development area. In the future, LGLS will remain a leader in life sciences and biotechnology-value added areas that are knowledge intensive.

#### **Current Product Pipeline**

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml	
Euvax B™lnj.	Recombinant Hepatitis B vaccine	Vial Liquid	0.5/1.0/5.0ml	
Euforvac <sup>™</sup> lnj.	Adsorbed diphtheria, tetanus, whole cell pertussis & hepatitis B combined vaccine	Vial Liquid	0.5/1.0/5.0ml	
Eutravac™lnj.	Adsorbed diphtheria, tetanus, aceulluar pertussis & hepatitis B combined vaccine	Vial Liquid	0.5ml	
Euhib™lnj.	Haemophilus influenzae type b vaccine	Vial Lyophilized	0.5/1.0ml	
Euforvac-Hib <sup>™</sup> Inj.	Adsorbed diphtheria, tetanus, whole cell pertussis, hepatitis B and Haemophilus influenzae type b combined vaccine	Vial Lyophilized	0.5/1.0ml	

\* More detailed information of LGLS' full list of current product pipeline & future product pipeline is available at <u>www.lgls.com</u>.

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
hGH					
EPO (Espogen®)					
SR-hGH(adult GHD)					
SR-hGH(Pediatric GHD)					
MAb(LBEC0101)					
MAb(LBIM0101)					
MAb(LBAL)					
Euforvac-Hib <sup>™</sup> Inj.					
DTwP-HepB-Hib (Fully liquid)					
sIPV(sabin strain)					
DTP-HepB-Hib-IPV(fully liquid)	On going				
Cell culture influenza vaccine					
HA IDF 1(Skin Rejuvenation)					
HA IDF 2(Skin Rejuvenation)					
LBSA0103(Osteo Arthritis)					
Anti-Adhesion Barrier (Post Operation Adhesed)	sio)				

DS: Discovery, PC: Preclinical Studies, MKT: Market, GHD: Growth Hormone Deficiency, TS: Turner's Syndrom, CRI: Chronic Renal Insufficiency, SGA : Small for Gestational Age, SR : Sustained Released , CRF: Chronic Renal Failure, IVF: In vitro Fertilization, CML: Chronic Myeloid Leukemia, HA: Hyaluronic Acid, IDF: Injectable Dermal Filler

Phone: +82(0)2 6924 3147

email: kimhs@lgls.com

Website: www.lgls.com

Mobile :

- O Development and marketing partnership for novel vaccine products
- Marketing alliance for biologics, SR-hGH, EPO, rFSH, etc.
- O Global marketing partnership or distributionship for HA based products
- O Global marketing partnership or distributionship for Fative®

#### Contact Details -

Name of contact person : Vaccine Biz.

Address : LG Gwanghwamun Bldg. 92, Sinmunno 2-ga, Jongno-gu

City : Seoul

State : Fax : +82(0)2 6924 3059

Country: Republic of Korea

Postal code: 110-062

Areas of Interest for Collaboration



DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK



Name of the company : National Administration of Laboratories & Institutes of Health ANLIS "Dr. Carlos G. Malbrán"

Head of Institution	: Dr. Gustavo Ríos
Established	: 1996
Country	: Argentina

#### Overview of the company

The National Administration of Laboratories and Institutes of Health ANLIS "Dr. Carlos G. Malbrán" agency dependent of The Secretary of Policy, Regulation and Institutes of the Ministry of Health of Argentine Nation nucleates eleven institutes and centers located in different places in our country (all of them of recognized performance in their areas of competence).

Its fundamental function understands in science and technical policy associated with various substantive aspects of actions in public health. The Institutional Plan recognizes 6 strategic areas:



## 1. Research and Technological Development in Health.

- 2. Health Surveillance and outbreak control.
- 3. Prevention and Control Disease Programs.
- 4. Production and Supply of Health Strategic Inputs.
- 5. Education and Training of Health Human Resources.
- 6. Information and Communication in Health.

Planned activities in the Production and Supply of Strategic Inputs Area will focus to achieve more equitable access (regarding availability and prices) to technologies and essential medical supplies, with guaranteed quality, safety, effectiveness and cost effectiveness and to promote reasonable and effective use according to their costs.

The global products portfolio of interest includes: viral and bacterial vaccines, immunotherapics (antidotes and antitoxins sera), diagnosis kits and reagents, inputs for reference and proficiency tests sera panels and reference biological standards, biopharmaceuticals and strategic medicines and laboratory animals.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Candid # 1	Virus Junin live attenuated vaccine against Argentine Hemorrhagic Fever	10 doses Vial	Lyophilized
Viper venom antiserum, Bothrop	os bivalent	vial	10.0 ml
Viper venom antiserum, Bothrop	os tetravalent	vial	10.0 ml
Viper venom antiserum, Crotalu	us durissus terrificus	vial	10.0 ml
Viper venom antiserum, Micruru	ıs pyrrhocryptus	vial	5.0 ml
Spider venom antiserum, Loxoso	celes SP	vial	5.0 ml
Spider venom antiserum, Latroc	lectus SP	vial	2.0 ml
Scorpion venom antiserum, Tity	vial	2.0 ml	
Rabies vaccine, FP, human use	vial	2.0 ml	
Rabies vaccine, FP, veterinary u	ise	vial (multidose)	50.0 ml
Tuberculin purified protein derivate, human use		vial (multidose)	3.0 ml
BCG for immunotherapy	vial	5.0 ml	
Serotyping antisera (Enterobac	vial	Miscellaneous volumes	
Tetanus toxoid - API		N/A	N/A
Diphteria toxoid – API	N/A	N/A	
Pertussis (cellular component) -	API	N/A	N/A

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Yellow Fever Vaccine					Implementation of a Quality System training to staff ANLIS in Argentina November 2011
dT vaccine - Diphteria and Tetanus vaccine					Adaptation, renovation and design of the productive areas of the components or API's (used to produce DTP and dT)
DTP vaccine - Diphteria, Tetanus and Pertussis vaccine					and acquisition of necessary equipment and instrumentation Execution of the work of the filling and packaging plant and submission a file that includes all equipment and instruments needed in the plant. 2011
Pentavalent vaccine DTP-HB/Hib					In technology transference management

Kits for diagnosis use: Rotavirus, Neisseria meningitidis, Streptococcus pneumonie, Toxoplasmosis, Chagas, Leptospirosis, Brucellosis, etc.

#### • Production technologies

- O Quality Control
- O Quality Assurance
- O Management
- O Good Manufacturing Practices
- ${\bf O}$  Clinical trials
- O Ethical issues

#### • Vaccine development

- **O** Vaccine patents politics
- O Regulatory issues

#### Contact Details ·

Name of contact person : Flavia M. Consalvo

Address : Av. Vélez Sarsfield Nº 563

City : Ciudad Autónoma de Buenos Aires

State : Ciudad Autónoma de Buenos Aires

Country: Argentina

Postal code: C1282AFF

Phone: +54 011 4303 1804 ext. 159

Mobile : +54 011 5594-5332

Fax: +54 011 4303 1804

email: fconsalvo@anlis.gov.ar

#### Website: www.anlis.gov.ar



Areas of Interest for Collaboration

**DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK** 



Name of the company : Panacea Biotec Ltd

Head of Institution	: Mr.Soshil Kumar Jain
Established	: 1984
Country	: India

#### Overview of the company

Panacea Biotec India's leading research based Health Management Company engaged in research, manufacturing and marketing of pharmaceuticals, biopharmaceuticals and vaccines occupies position of  $3^{rd}$  largest biotechnology\* and  $39^{th}$  largest pharmaceutical Company<sup>#</sup> in India.

#### Pharmaceuticals

Innovative portfolio and pipeline in niche therapeutic segments like renal disease management, organ transplantation and oncology is result of focus on Novel Chemical Entities and Drug Delivery Systems in 'State of Art' R&D centers. cGMP certification of



ate of Art R&D centers. CGMP certification of manufacturing facility at Baddi by regulatory agencies including US-FDA facilitates global presence.

**Biologicals** 

Focus on research resulted in development of innovative fully liquid vaccines Easyfour (DTwP-Hib), Easyfive (DTwP – Hep B– Hib), NovoHib (Hib) also Ecovac 4 (DTwP – Hep B), Enivac HB (rHep B), OPVs (trivalent, monovalent and bivalent), Polprotec (eIPV), Pandyflu (inactivated HINI) and rich vaccine and bio- therapeutics pipeline.

Capacity of two Vaccine Formulation and filling facilities (VFP) at Delhi and Baddi is over 2 billion doses p.a in PFS and Vials. Bulk antigen production facility at Panjab has dedicated blocks for manufacture of Recombinant, Bacterial, Tetanus Toxoid bulk, Viral Vaccines / proteins and non – viral recombinant bio - therapeutics.

Panacea Biotec has collaborations with leading research organizations and corporations like Novartis Vaccines and Diagnostics , Sanofi Aventis.

- \* = ABLE survey 2011
- # = ORG IMS TSA March 2011

Product Name	Description	Type Vial/PFS	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
DTwP	Diphtheria , Tetanus and whole Cell pertussis Vaccine	Vials	5 ml
ТТ	Tetanus Toxoid Vaccine	Vials	5 ml
Enivac HB	Recombinant Hepatitis B Vaccine	Vials	0.5ml
Ecovac 4	Fully Liquid Tetravalent Combination vaccine (DTwP- Hep B)	Vials	0.5ml
EasyFour	Fully Liquid Tetravalent Combination vaccine (DTwP- Hib)	PFS Vials	0.5 ml
Easyfive	Fully Liquid Pentavalent combination vaccine (DTwP – Hep B– Hib)	Vials PFS	0.5 ml
OPV	Monovalent OPV Type 1, Monovalent OPV Type 3, Bivalent –OPV, Trivalent OPV	Vials	2 ml/20 dose
PolProtec	Inactivated Polio Vaccine (eIPV)	PFS Vials	0.5 ml
Pandyflu	(Inactivated egg based H1N1 vaccine)	Vials	0.5 ml

- a. Novel Vaccines (PI. Refer list here below)
- b. New Chemical Entities: Novel DPP IV inhibitor, Novel Oxazolidinone
- c. Novel Therapeutic Peptides : Novel TNF Alfa Inhibitor, Novel Hair Growth Peptide
- d. Bio Similars : Darbepoetin , Trastuzumab , Bevacizumab and Etanercept
- e. Fully human monoclonal antibodies

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected Dossier Filing (Year)
Trivalent Seasonal Influenza Vaccine(Egg based)			NA		2013
Vero cell based Japanese Encephalitis Vaccine					2015
Recombinant \Chimeric recombinant Tetravalent Dengue Vaccine					2016
10 Valent Pneumococcal Conjugate Vaccine			NA		2014
Recombinant Anthrax Vaccine					2014

#### Areas of Interest for Collaboration

• In-Licensing of Pharma, Bio-Pharma & Vaccines

O Out-Licensing of Pharma, Bio-Pharma & Vaccine

#### Contact Details -

Name of contact person : Mr. R. K. SURI, Chief Executive-Biologicals

Address : B-1,Extn./ A-27, Mohan, Co-op Indl.Estate, Mathura Road	Phone : +91 11 4167 9057
City : New Delhi	Mobile : +91 98101 94483
State : Delhi	Fax : +91 11 4167 9027
Country: INDIA	email : rksuri@panaceabiotec.com
Postal code: 110 044	Website: www.panaceabiotec.com





Name of the company :PT Bio Farma (Persero)Head of Institution:Ministry State Owned EnterpriseEstablished:1890Country:Indonesia

#### Overview of the company

PT. Bio Farma engages in manufacturing and supplying vaccines, sera, and other biological and diagnostics products to support the expanded program on immunization in Indonesia and internationally. The company's products also comprise BIOTT vaccine for the immunization to produce antibody against tetanus and to prevent neonatal tetanus by immunizing women of child bearing age. In addition, it operates a polio and measles laboratory for polio eradication and measles reduction.



Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Π	Tetanus Toxoid	Vial, UniJect	0.5, 5.0 ml
DT, Td.	Diphtheria, Tetanus	Vial	5.0 ml
DTP	Diphtheria, Tetanus, Pertussis Vaccine	Vial	5.0 ml
DTP- HB	D, T, P, Hepatitis B Vaccines	Vial	5.0 ml
НВ	Hepatitis B Vaccine	UniJect	0.5ml, 1.0 ml
mOPV, bOPV	Monovalent, bivalent Polio Vaccine	Vial	1.0 ml
tOPV	Trivalent Oral Polio vaccine	Vial	2.0 ml
Measles	Measles vaccine	Vial	10 doses
BCG	Tubeculosis vaccine	Ampoule	20 doses
Flubio	Seasonal Flu vaccine	Vial	2.0 ml
- 1. DTP-HB-Hib
- 2. Pandemic Flu
- 3. IPV
- 4. Rotavirus
- 5. Acellular Pertussis

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
<ul> <li>GLP</li> <li>GCP</li> <li>Validation</li> <li>Marketing</li> </ul>				Areas of In	terest for Collaboration
Contact Details					•
Name of contact person : Iskandar					
Address : JI. Pasteur 28		Phon	e :+62 22 203	3 3755	
City : Bandung		Mobi	e :		
State :West Java		Fax:	+62 22 204 1	306	
Country: Indonesia		emai	: Iskandar@	biofarma.co	.id
Postal code: 40161		Webs	ite: www.bio	ofarma.co.id	A





#### Overview of the company

The Queen Saovabha Memorial Institute (QSMI), founded in 1922, has its mission in producing vaccines and snake antivenoms and conducting research on snakes, snake venoms, rabies and related topics.

It established a snake farm in 1923 and a horse farm in 1956. QSMI has been manufacturing snake antivenoms since 1923 and BCG vaccine since 1953. Work on snakes, snake antivenoms, rabies and equine rabies immunoglobulin has gained international reputation for many decades. The horse farm has approximately 400 horses. The Institute is recognized by WHO as WHO Collaborating Centres in both rabies and snake work. The activities of Queen Saovabha Memorial Institute cover 3 main areas : service, research and production as follows.



#### I. Service

- 1. Treatment of animal bites and vaccination against rabies
- 2. Animal clinic and Rabies diagnosis
- 3. Travelers immunization clinic
- 4. Other immunization
- 5. Snake farm for public
- Joint collaborative projects in clinical and laboratory diagnosis of human and animals suspect of being rabid, route of rabies vaccine dministration (with ministry of public health, livestock department, WHO and US communicable disease center).
- II. Research and Development
- 1 Research for improvement of product and diagnosis
- 2 Biomedical and clinical research in areas of rabies, snakes, snake venoms and horses
- 3 Collaboration and joint research projects between QSMI and other educational and research institute
- 4 Future plan : New tuberculosis vaccine
- III. Production
  - Biological products as in headline No.6

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
BCG Vaccine	lyophilized product of 10 doses per vial	vial	0.5 ml
Tuberculin test solution	injection liquid of 5 doses per vial	vial	0.5 ml
Equine Rabies Immunoglobulins	injection liquid of 1,000 IU per vial	vial	5.0 ml
Antivenoms for poisonous snake bite -King Cobra antivenin (Ophiophagus Hannah) -Cobra antivenin (Naja Kaouthia) -Banded Krait antivenin (Bungarus fasciatus) -Malayan Pit Viper antivenin (Calloselasma rhodostoma) -Russell's Viper antivenin (Daboia russelli siamensis) - Green Pit Viper antivenin (Trimeresurus albolabris) -Malayan Krait antivenin (Bungarus candidus) -Neuro polyvalent antivenin (Naja kaouthia, Ophiophagus hannah, Bangarus fasciatus, Bangarus candidus) -Haemato polyvalent antivenin (Calloselasma rhodostoma, Trimeresurus albolabris, Daboia russelli siamensis)	lyophilized product in 20 ml. vial with solvent of Water for injection 10 ml.	vial	10.0 ml

(bulk vaccine for formulation and filling): Estimate launch in year 2012

- a. Rabies vaccines : lyophilized product of 0.5 ml per vial
- b. Influenza vaccines : injection liquid of 1 ml per vial
- c. DTP-Hep -vaccines : injection liquid of 1ml per vial
- d. Td vaccines : injection liquid of 2 ml in vial

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Rabies vaccines					Q1/2012
Influenza vaccines					Q4/2012
DTP-Hep-vaccines					Q3/2012
Td vaccines					Q2/2012

• Research of new TB vaccine

Areas of Interest for Collaboration

#### Contact Details ·

Name of contact person : Prof. Sumana Khomvilai

Address :	Phone : +662 2520161
City : Bangkok	Mobile : 081 3759375
State :	Fax: +662 2540212
Country: Thailand	email : sumanaredcross@gmail.com
Postal code: 10330	Website: www.saovabha.com





Name of the company : Razi Vaccine & Serum Research Institute

Head of Institution	: Dr. Hadi Famil Ghadakchi
Established	: 1925
Country	: IR of Iran

## Overview of the company

Razi Vaccine and Serum Research Institute is known as one of the oldest and most reputed scientific centers in Iran. This Institute began its activities in the year 1925 with producing vaccine against Rinderpest under the supervision of Ministry of Agriculture. Rinderpest at the time had caused large casualties in the cattle population of the country, but Razi institute team very rapidly took up the research and production of the Rinderpest vaccine.

Presently, Razi institute is controlled by Ministry of Jihad-e-Agriculture and works closely with Ministry of Health and Veterinary



Organization. The institute is governed by a Board of Trustees with its Headquarter located in Karaj, Iran. RVSRI provides 110,000 square meter research with laboratory buildings. Razi Institute is a center of research, training and technical assistance for vaccines needed in developing countries and the Middle East.

The objectives are:

Research & Production of Medical Vaccines and Antisera

Research & Diagnosis of Veterinary and Poultry Diseases

Research & Production of Veterinary and Poultry Vaccines

Research and Diagnosis of Zoonotic Diseases

Biotechnology Research

Education & Training

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Trivalent DTP, dT, Td	Diphteria-Tetanus-Pertussis Vaccines	Vial	14 doses/7 ml
Measles	Live Attenuated vaccine (Lyo.)	Vial	10 doses/5 ml
Mumps, Rubella	Live Attenuated vaccines (Lyo.)	Vial	1 dose
Polio (type 1,2, and3)	Live Attenuated vaccine	Flakon	15 doses/1.5 ml
MMR , MR, MM	Live Attenuated vaccines (Lyo.)	Vial	10 doses/5 ml
Polyvalent Snake Antivenom	Antivenom	Ampoule	10 , 5
Polyvalent Scorpion Antivenom	Antivenom	Ampoule	5
Anti-Tetanus Serum	Anti Toxin	Ampoule	2
Anti-Diphtheria Serum	Anti Toxin	Vial	5
Anthrax	Live vaccine	Bottle	100
Blackleg (Cattle)	Inactivated vaccine	Bottle	250
Polyvalent Enterotoxaemia (Sheep & Goat)	Inactivated vaccine	Bottle	250
Brucella Melitansis Strain Rev. 1	Live vaccine (Lyo.)	Vial	100
Brucella Abortus Strain IRIBA	Live vaccine (Lyo.))	Vial	20
Agalactia & Pasterulosis (Cattle & Buffalo)	Inactivated vaccines	Bottle	100
Tetanus (Horse)	vaccine	Vial	20
Rinderpest, Sheep Pox, Goat pox	Live vaccines (Lyo.)	Vial	100
Foot and Mouth Disease (FMD)	Inactivated vaccine	Bottle	250
Bovine Theileriosis	Attenuated vaccine	Vial	12
Fowl Cholera	Inactivated vaccine	Bottle	100
Fowl Pox	Live vaccine (Lyo.)	Vial	1000 , 2000
Infectious Laryngotracheitis	Live vaccine (Lyo.)	Vial	1000 , 2000
Fowl Infectious Bronchitis H-120 & H-52	Live vaccines (Lyo.)	Vial	1000 , 2000
Newcastle La Sota , Newcastle B1	Live vaccines (Lyo.)	Vial	1000 , 2000,4000
Inactivated Influenza (oil-emulsion) H9N2	Inactivated vaccine	Bottle	250
Inactivated Newcastle (oil-emulsion) V4	Inactivated vaccine	Bottle	250
Combined oil-emulsion H9N2 & V4	Inactivated vaccine	Bottle	250
Combined IB (H-120) / ND (B1)	Live vaccine	Vial	2000

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Peste des Petits Ruminants (PPR)					
Combined Live IB (H-120) / ND (La Sota)					
Infectious Bursal Disease (IBD)					
Human Influenza Vaccine					
RS12					

Areas of Interest for Collaboration

- Training in the Fields of Production and QC Tests
- O Production of New Recombinant Vaccines (Human, Poultry and Veterinary)

## Contact Details ·

Name of contact person : Dr. Hadi Ghadakchi

Address : Razi Vaccine & Serum Research Institute<br/>Karaj, POBox 31975/148, IR, IranPhone : +98 26 1455 4658City : KarajMobile :State : TehranFax : +98 26 1455 4658Country: IR of Iranemail : int@rvsri.irPostal code: 3197619751Website: www.rvsri.ir





Name of the company: SERUM INSTITUTE OF INDIA LTD.,					
Head of Institution	: DR. CYRUS S. POONAWALLA, Chairman & Managing Director				
Established	: 1966				
Country	: INDIA				

#### Overview of the company

Serum Institute of India Ltd. (SIIL) founded in 1966 has established itself as the world's largest producer of Measles and DTP group of vaccines. It is estimated that 2 out of every 3 children immunized in the world are vaccinated by a vaccine manufactured by SIIL. In fact, it supplies a range of products to Intl. Health Agencies like WHO, UNICEF, PAHO and also to more than 140 countries across the globe. Currently our 15 vaccines i.e. TT, DT, Td, DTwP, BCG, Measles, Rubella, MR, MMR, Recombinant Hep B, DTwP + Hep B, DTwP + Hib, DTwP + Hib, Hib, Men. A Conjugate vaccines are prequalified by WHO for supplies to U.N. Agencies. SIIL has the aim of manufacturing life-saving immuno-biologicals, and make aVialable at affordable prices. SIIL believes that consistent Quality products of intl. standards are produced by Quality people through latest technology, process automation, cGMP,



regulatory requirements and training. SIIL is always working collectively to produce, distribute and make aVialable Immunobiologicals, which are safe, potent and efficacious, for customers especially children of the world, at affordable prices.

The production facilities of Serum Institute have the best in terms of equipment and human resources; essential to ensure high quality of vaccines. The manufacturing facilities conform to WHO current Good Manufacturing Practice (cGMP) requirements and are approved by WHO/Geneva. Our facilities are also approved by USFDA for oncology products. Serum Institute is recognized as a reliable source of High Quality but affordable priced vaccines and biologicals. The high service standards have resulted in several acknowledgments and appreciation from intl. agencies and local Govts and awards from Trade authorities.

Type

Presentation

Current Product Pipeline	Currer	i Proc	luct Pi	peline
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rioductivame	Description	Vial/Ampoule	0.5/ 1.0 / 5.0 / 10.0 ml
TT	Tetanus Vaccine	Ampoule	single dose 0.5 mL
DT	Diphtheria and Tetanus Vaccine (Paediatrics	Vial	10 doses 5 mL
Td	Diphtheria and Tetanus Vaccine for Adults & Adolescents	Vial	20 doses 10 mL
DTP	Diphtheria-Tetanus-Pertussis Vaccine	Ampolue/Vial	0.5,1.0,5.0,10.0 mL
BCG	BCG Vaccine	Vial	10&20 doses 5,10 mL
Measles	Measles Vaccine Live (Lyo.)	Vial	1,2,5,10dose(0.5per) mL
Rubella	Rubella Vaccine Live (Lyo.)	Vial	1,2,5,10dose(0.5per) mL
MR	Measles and Rubella Vaccine Live (Lyo.)	Vial	1,2,5,10dose(0.5per) mL
MMR	Measles, Mumps and Rubella Vaccine Live (Lyo.)	Vial	1,2,5,10dose(0.5per) mL
Rabies	Rabies Vaccine	Ampolue/Vial	1ml/1dose
IPV	Inactivated Poliomyelitis Vaccine	Prefilled syringe	0.5ml/dose
Nasovac	Influenza Vaccine, Live Attenuated (Freeze-dried), Pandemic (H1N1)	Ampolue/Vial	1&2doses(0.5mlper dose)
Enzavac	Influenza Vaccine, Inactivated (FD), Pandemic (H1N1)	Vial	1doses(0.5mlper dose)
Нер В	Recombinant Hepatitis B Vaccine	Ampolue/Vial	0.5,1.0,5.0,10.0ml
Qaduruple	DTP and Hepatitis B Vaccine (Adsorbed)	Ampolue/Vial	0.5,1.0,5.0ml
Quadravelent	DTP + Hib Vaccine (Lyo. & Liquid)	Vial	0.5,1.0,5.0ml
Pentavelent	DTP Hepatitis B + Hib Vaccine (Lyo. & Liquid)	Vial	0.5,1.0,5.0,10ml
Hib	Haemophilus type b Conjugate Vaccine (Lyo.)	Vial	1dose
MenAfriVac	Meningococcal A Conjugate Vaccine (Lyo.)	Vial	10dose
ATS	Tetanus Antitoxin	Ampolue/Vial	1,5.0ml
ADS	Dphtheria Antitoxin	Vial	10.0ml
ASVS	Anti-Snake Venom Serum (Lyo.) Asia & Central Africa	Vial	10.0ml
ARS	Anti-Rabies Serum	Vial	5.0ml

Description

Product Name Pre Clinical		Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
DTaP vaccine	08/10 to 01/11	02/11 to 10/11	-	11/11 to 07/12	Q3/2012
Pneumococcal vaccine	12/10 to 07/11	08/11 to 06/12	07/12 to 02/13	03/13 to 02/14	Q1/2014
Rabies Monoclonal antibody			-	10/10 to 07/11	Q3/2011
Measles Vaccine (Dry Powder)		09/10 to 04/11	-	07/11 to 08/12	Q3/2012
Rabies vaccine (Verorab)	Ongoing	04/10 to 11/10	-	07/11 to 02/12	Q1/2012
Aerosol Measles vaccine			-	12/10 to 02/11	Q1/2011
Meningococcal A vaccine				01/10 to 12/10	Launch for Africa before end 2010
Seasonal influenza vaccine(Live attenuated)	-	-	-	10/11	Q1/2011
Rotavirus Vaccine	Q3/08 to Q4/09	Q3/09 to Q4/10	Q1/11 to Q4/14	Q3/12 (Immunogenicity) Q4/13	Rotavirus Vaccine

\* Studies are planned as Phase II/III # Regulatory approvals are also considered.

## Areas of Interest for Collaboration

- Newer Vaccines development
- $\boldsymbol{O}$  Biosimilars
- O Monoclonal antibodies

## Contact Details ·

Name of contact person : DR. SURESH S. JADHAV, Executive Director

Address : 212/2, Hadapsar, Off. Soli Poonawalla Road, Hadapsar	Phone : +91 20 2660 2378 +91 20 2660 2379
City : Pune	Mobile : +91 98230 22248
State : Maharashtra	Fax : +91 20 2699 3945
Country : India	email : ssj@seruminstitute.com
Postal code: 411 028	Website: www.seruminstitute.com





:	Sinovac Biotech Ltd.
:	Weidong Yin
:	2001
:	China
	:

## Overview of the company

Sinovac Biotech Ltd. is a profitable biopharmaceutical company headquartered in Beijing, China. The Company focuses on the research, development, manufacture and commercialization of vaccines that protect against human infectious diseases including hepatitis A, seasonal influenza, H5N1 (bird flu) pandemic influenza and H1N1 influenza. Sinovac received approval in 2009 for its H1N1 influenza vaccine, PANFLU.1 and has commenced fulfilling orders from the Chinese Central Government pursuit to the government stockpiling program. Sinovac was the first company worldwide to receive



approval for H1N1 influenza vaccine.

Sinovac has a robust pipeline of new vaccine products under development. The Company is currently developing vaccines for Enterovirus 71 (EV 71), Pneumococcal Conjugate Vaccine, Hib, and Meningitis. Its wholly owned subsidiary, Tangshan Yian, is conducting field trials for an independently developed inactivated animal rabies vaccine.

Sinovac is open and flexible to discuss any possible collaborative opportunity of international business and has established a clear path to partnering. We are seeking the partners who share the same value as ours

Product Name	Product Name Description		Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Healive®	Inactivated Hepatitis A Vaccine	Vial	0.5 , 1.0 ml
Anflu	Split Influenza Vaccine	Vial	0.25, 0.5ml
Bilive	Hepatitis A and B Combined Vaccine	Vial	0.5 , 1.0 ml
PANFLU.1	H1N1 Influenza Vaccine (Split virion)	Ampoule	0.5, 1.0 ml

- 1. Ev71 Vaccine,
- 2. Japanese Encephalitis Inactivated Vaccine,
- 3. Human Rabies Vaccine,
- 4. Pneumococcal Conjugate Vaccine
- 5. HIB Vaccine,

- 6. Epidemic Meningitis Vaccine
- 7. Rotavirus Vaccine

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Ev71 vaccine					Q1/2013
Japanese Encephalitis Inactivated Vacci	ne ////////////////////////////////////				Q1/2012
Human Rabies Vaccine		1			Q1/2012
Pneumococcal Conjugate Vaccine					Q2/2012
HIB vaccine					Q1/2013

## Areas of Interest for Collaboration

- Oversea distribution
- O International business
- FDA registration for vaccines
- O Adjuvant technology
- Microcarrier technology
- Novel vaccine technology

Name of contact person : Ms. Helen Yang

Address :: 39 Shangdixi Road, Haidian District

City : Beiling

State :

Country: China

Postal code: 100085

Phone : +86 10 8279 9871

Mobile :

Fax : +86 10 6296 3661

email: info@sinovac.com

Website: www.sinovac.com





Name of the company :The Biovac InstituteHead of Institution:Dr Morena MakhoanaEstablished:2003Country:South Africa

## Overview of the company

The Biovac Institute "Biovac" is a Public Private Partnership (PPP) between a private consortium and the South African government. It was formed after the realization by the South African government of the need to have human vaccine manufacturing capability in the sub-saharan Africa.

Since its formation in 2003, The Biovac Institute has been importing vaccines to fulfill all of South Africa's EPI vaccine needs as well as exporting to neighbouring African countries, and at the same time building physical and human capital capability



at its manufacturing hub in Cape Town, South Africa.

The physical infrastructure comprises QC laboratories, R&D laboratories, Packaging, Clinical Trial Material manufacture, formulation and bulk filling (in the final phase of being built). The key human capital capabilities include expertise in the areas of conjugation, fermentation, quality control and analytical method development.

It is Biovac's vision to be a Centre of Excellence rooted in Africa for the development and manufacture of affordable vaccines for Africa and the developing world's needs.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
	Hepatitis B	Vial	0.5ml

- 1. Hib ( bulk)
- 2. Liquid pentavalent
- 3. Td
- 4. TT

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Hib					
Pentavalent					2014
Td		1			<mark>20</mark> 14
TT					<mark>2</mark> 013

Areas of Interest for Collaboration

- Sourcing relevant finished products for local market
- O Exporting bulk Hib
- O Opportunities around conjugation technologies/products

## Contact Details ·

Name of contact person : Morena Makhoana

Address : 15 Alexandra Road, Pinelands

City : Cape Town

State : Western Cape

Country: South Africa

Postal code: 1403

Phone : +27 21 514 5000

Mobile : +27 82 331 0431

Fax: + 27 86 518 1127

email: morena@biovacinstitute.co.za

Website: www.biovac.co.za





Name of the company : The Company for Vaccine and Biological Production No.1 (VABIOTECH)

Head of Institution Established Country Production No.1 (VABIOTECH) : Prof. Nguyen Thu Van Ph.D., D.M.Sci : March 2000 : Vietnam

#### Overview of the company

The Company for Vaccine and Biological Production No.1 was established under the decision No. 650/2000/QD-BYT dated March 2nd, 2000 by the Minister of Health, as a State-Owned Company belongs to The National Institute of Hygiene and Epidemiology, Hanoi-Vietnam. Since May 25<sup>th</sup>, 2007 the Company separated from the National Institute of Hygiene and Epidemiology and became an independent company under the Ministry of Health of Vietnam.



The functions of the Company are manufacturing and trading vaccines and biological products for human use, analyzing samples of new developing vaccines and biological products (including diagnostic kits and prophylaxis treatment products, pharmaceuticals; Healthcare services). Annually these vaccines are provided to the National Expanded Program on Immunization and domestic demand.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
r-HBvax	Hepatitis B Vaccine (Yeast derived, Recombinant)	Vial	0.5ml, 1.0 ml
Gen-HBvax	Hepatitis B Vaccine (Yeast derived, Recombinant)	Via	0.5 ml, 1.0 ml
JEVAX	Japanese Encephalitis Vaccine (Mouse brain derived, Nakayama strain)	Vial	1.0ml, 5.0 ml
JEBEVAX	Japanese Encephalitis Vaccine (Mouse brain derived, Beijing-1 strain)	Vial	1.0ml, 5.0 ml
ORCVAX	Oral Cholera Vaccine (Bivalent, Killed Whole Cell, Formulated based on OD)	Vial	1.5ml, 7.5 ml
mORCVAX	Oral Cholera Vaccine (Bivalent, Killed Whole Cell, Formulated based on LPS content)	Vial	1.0ml, 5.0 ml
HAVAX	Hepatitis A Vaccine (Inactivated, Purified, Primary monkey kidney cell based)	Vial	1.0 ml

- 1. Hib Conjugate Vaccine
- 2. Rabies Vaccine (Vero cell based)
- 3. Japanese Encephalitis Vaccine (Vero cell based)
- 4. Hepatitis A Vaccine (MRC-5 cell based)
- 5. Influenza A/H5N1 Vaccine (Cell culture based)
- 6. Pandemic influenza A/H1N1Vaccine (Cell culture based) 13. EV71 Vaccine
- 7. Seasonal Influenza Vaccine (Cell culture based)
- Varicella Vaccine 8.
- 9 Rubella Vaccine 10. Dengue Vaccine
- 11. Mumps Vaccine
- 12. Vi Typhoid Conjugate Vaccine
- 14. Pentavalent combination Vaccine (DTwP- Hep B- Hib)

Areas of Interest for Collaboration

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Hib Conjugate Vaccine					2014
Rabies Vaccine (Vero cell based)					2014
Japanese Encephalitis Vaccine (Vero cell based)					2014
Hepatitis A Vaccine (MRC-5 cell based)					2014
Influenza A/H5N1 Vaccine (Cell culture based)					2013
Pandemic influenza A/H1N1Vaccine (Cell culture based)					2013
Seasonal Influenza Vaccine (Cell culture based)					2014
Varicella Vaccine					2015
Rubella Vaccine					2015
Dengue Vaccine					2016
Mumps Vaccine					2015
Vi Typhoid Conjugate Vaccine					2015
EV71 Vaccine					2015
Pentavalent combination Vaccine (DTwP- Hep B- Hib)					2015

O Technology transfer

• Filling and packaging

O Bio-Pharmaceutical products

#### Contact Details

Name of contact person : Prof. Nguyen Thu Van, Ph.D., D.M.Sci.

Address : 1, Yersin Street

Phone: + 84 4 38211500

Mobile :

City : Hanoi

State :

Country: Vietnam

Postal code: 10000

Fax: + 84 4 39717711

email: thuvan@vabiotech.com.vn

Website: http://www.vabiotech.com.vn



**DEVELOPING COUNTRIES VACCINE MANUFACTURERS** 

**NETWORK** 



Name of the company : The Government Pharmaceutical Organization

Head of Institution	: Dr. Witit Artavatkun MD.Managing Director
Established	: 1966
Country	: Thailand

#### Overview of the company

The Government Pharmaceutical Organization (GPO) of Thailand is a state enterprise under Ministry of Public Health. It was founded in the year 1966 by merging of a pharmaceutical manufacturing plant (founded in 1939) and Pharmaceutical Department (founded in 1901) according to the GPO Act of 1966. The annual revenue of year 2009 is approx. 260 mUSD. The total pharmaceutical product items are more than 300. The total staff is about 2,100.

The main responsibility of GPO is to produce medicines and pharmaceutical products to support the country's public health. GPO was assigned to serve the national public health policy.

Biological Product Department of GPO is, one of the Production Cluster, responsible for production of vaccines and antisera.



At present, staff under this department is about 150. Our current products are JE(MB) vaccine, antiserum of tetanus and snake venoms. The coming vaccines of dT, TT, DTP and DTP-HB are under reproduced. The under developed influenza vaccine by WHO Grant and the Government including domestic and international networks. The H1N1 2009 PLAIV is now in phase II CT and will finish soon. The new strain under prepared for pandemic preparedness. The IIV for seasonal program will be scaled up in the industrial plant supported by Thai Government Budget.

Since the pandemic of H5N1 Avian Influenza, Thai Government take serious awareness for the possibility of Influenza pandemic situation.

The construction of new Influenza vaccine plant supported by the government is under construction and will be completed by next year. The plant is located in Saraburi Province (120 Km away from Bangkok).

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Japanese Encephalitis vaccine	Inactivated Japanese Encephalitis vaccine, Beijing strain	Vial	0.5 , 5.0ml
ТАТ	Tetanus Antitoxin	Ampoule/Vial	1.0,2.0ml
Antisnakevenom	Anti Cobra, Anti Malayan Pit Viper, Anti Russeli's Viper	Ampoule	10.0ml

- 1. Inactivated Influenza vaccine
- 2. Live attenuated Influenza vaccine
- 3. DTP-Hepatitis B vaccine
- 4. dT vaccine
- 5. Tetanus vaccine
- 6. Cell based JE

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
H1N1 2009 LAIV	Q4/2009	Q4/2009	Q4/2010		Q4/2010
H5N2 PLAIV	Q3/2010	Q1/2011	Q2/2011		Q3/2011
DTP-HB	Q4/2 <mark>010</mark>		Q2/2011		Q4/2012
Cell Based JE	Q1/2012	Q4/2012	Q2/2013		Q2/2014

Areas of Interest for Collaboration

- Development of new items of vaccine
- O Technology transfer
- $\mathbf{O}$  Research Collaboration

# Contact Details

Name of contact person : Mr. Sit Thirapakpoomanunt

Address : 75/1 Rama 6 Road, Ratchthewi,,Phone : +66 2 203 8500City : BangkokMobile : +66 8 5155 3304State :Fax : +66 2 644 8851Country: THAILANDemail : sit.thira@gpo.or.thPostal code:Website:



Name of the company: Xiamen Innovax Biotech Co., Ltd.



Head of Institution	: Mr. Steven Gao, General Manger
Established	: 2005
Country	: China

#### Overview of the company

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Xiamen Innovax Biotech CO., LTD. (INNOVAX) is a leading company in the field of developing, manufacturing and marketing innovative vaccines with its headquarter and manufacturing facility base in Xiamen, China.

In collaboration with the National Institute of Diagnostics and Vaccine Development in Infectious Diseases (NIDVD), INNOVAX has established a core- platform using DNA recombinant technology to express protein in E. coli for vaccine production. Based on this platform, Hecolin<sup>™</sup> (Hepatitis E Vaccine) is going to launch in the fourth quarter of 2011, a Cervical



Cancer Vaccine which is in the Phase II clinical trial and a Genital Warts Vaccine which has been submitted for registration have been developed. In addition, there are two products in the pre-clinical developmental stage: a new HPV vaccine and a pediatric HEV vaccine.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml

- a. HEV vaccine (adult)
- b. Cervical Vaccine (HPV16/18)
- c. Condyloma Acuminate Vaccine (HPV6/11)
- d. HEV vaccine (pediatric)

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
Hecolin <sup>™</sup> (HEV vaccine (adult))	2000-2003	2005	2005	2007-2009	The Fourth Quarter of 2011
Cervical Vaccine (HPV16/18)	2002-2 <mark>007</mark>	2010-2011	2011-2012	2012-2014	2015
Condyloma Acuminate Vaccine (HPV6/11)	2002 <mark>-2009</mark>	2012	2012	2013-2015	2016
HEV vaccine (pediatric)	2011-2012			2012-2014	2015

#### Areas of Interest for Collaboration

- O Licensing / Technology transfer
- Overseas distribution
- O Product co-development

## Contact Details ·

Name of contact person : Wendy Huang

Address : No.130 Xinyuan Road, Haicang district

City : Xiamen

State : Fujian Province

Country: China

Postal code: 361022

Mobile : +86-136 6609 6039 Fax : +86-592-653 6567

Phone: +86-592-653 6555

email : int@innovax.cn

Website: www.innovax.cn



#### Name of the company : Zhejiang Tianyuan



Bio-pharmaceutical Co.,Ltd.
Mr Ding Xlaohang, President & CEO
1989
People's Republic of China

#### Overview of the company

Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd. is a fast-growing developer, producer, and distributor of biopharmaceutical products in China. Since 1989 the company successfully established its national and international vaccine business with the intention to provide high quality vaccines of international standard, and contribute to the prevention of diseases in China and throughout the world. Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd. is a limited liability company, which is mainly invested by private capital in China. At present, the company is one of China's largest private manufacturers of influenza vaccine. The company is producing viral and bacterial vaccines in state-of-the-art manufacturing facilities meeting



both national and international quality standards. All manufacturing lines of Tianyuan have been granted with cGMP certificates from the State Food and Drug Administration (SFDA) of China. The company wants to further expand its market beyond China to other countries and strives for cooperation with international vaccine distributors. Since 2005 the company has sold its influenza vaccine in Macau and since 2006 it has been sold to Eastern European and South American markets. The product has been registered in several countries including India and Macedonia, where it got export permission. Tianyuan's approach for R&D includes the integration of knowledge and experiences from foreign experts. It is the company's goal to fast-track R&D and the optimization of our current processes to reach internationally competitive products.

Product Name	Description	Type Vial/Ampoule	Presentation 0.5/ 1.0 / 5.0 / 10.0 ml
Influenza virus vaccine, inactivated(Split)	To prevent influenza	Syringe/Vial	0.5ml/ 0.25ml / dose
Group AC and Group ACYW135 Meningococcal Polysaccharide vaccine	To prevent meningitis	Vial	0.5ml / dose
HFRS vaccine	To prevent HFRS	Ampoule	1.0ml / dose
japanese Encephalitis	To prevent Japanese encephalitis	Ampoule	0.5ml / dose

- 1. Diphtheria, Tetanus and acellular Pertussis (DTaP)
- 2. Typhoid Vi PS
- 3. Group A Meningococcal Polysaccharide vaccine
- 4. Pneumococcal PS vaccine
- 5. Conjugate Meningococcal AC

Product Name	Pre Clinical	Phase 1	Clinical Phase 2	Phase 3	Expected launch date Quarter / Year
DTaP					2010
Typhoid Vi PS					2010
Hib					
Pneumococcal PS vaccine					
Group A Meningococcal Polysaccharide vaccine	e				2010
Polysaccharide vaccine					
Conjugate Meningococcal AC					

6. Hib

Areas of Interest for Collaboration

- O Cooperation in Rabies vaccine
- O Cooperation in Varicella vaccine
- Cooperation in measles, mumps and rubella (MMR) vaccine

## Contact Details ·

Name of contact person : Mr Chen Xuekui

Address : No.56 Tianhe Road, Yuhang Economic Development Zone,	Phone : +86 571 2628 6027
City : Hangzhou	Mobile : +86 138 6808 4418
State : Zhejiang	Fax : + 86 571 2628 6008
Country: P.R.China	email : chenxuekui@126.com
Postal code: 311100	Website: www.ty-pharm.com



# List of Member Organizations

- Bharat Biotech International Limited
- Biological E. Limited
- Bio-Manguinhos Institute of Technology on Immunobiologicals
- BioNet-Asia Co., Ltd.
- Cadila Pharmaceuticals Limited
- "Cantacuzino" National Institute of Research and Development for Microbiology and Immunology
- Center for Genetic Engineering and Biotechnology
- China National Biotec Group (CNBG)
- Finlay Institute
- Indian Immunologicals Limited
- A Institute of Vaccines and Medical Biologicals
- Instituto Butantan
- Laboratorios de Biológicos y Reactivos de México, S.A. de C.V. (BIRMEX)
- LG Life Sciences Ltd
- National Administration of Laboratories and Institutes of Health ANLIS "Dr. Carlos G. Malbrán"
- Panacea Biotec Ltd
- PT Bio Farma (Persero)
- Queen Saovabha Memorial Institute
- Razi Vaccine & Serum Research Institute
- Serum Institute of India Ltd
- Sinovac Biotech Ltd.
- The Biovac Institute
- The Company for vaccine and biological production No.1 VABIOTECH
- The Government Pharmaceutical Organization
- The Holding Company for Biological Products & Vaccines (VACSERA)
- Xiamen Innovax Biotech Co. Ltd.
- Zhejiang Tianyuan Bio-pharmaceutical Co. Ltd.