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VACCINES FOR VIRAL DISEASES

Future Vaccines Research & Development Meeting

Amanda McMurray, Chief Executive Officer

21st May 2018

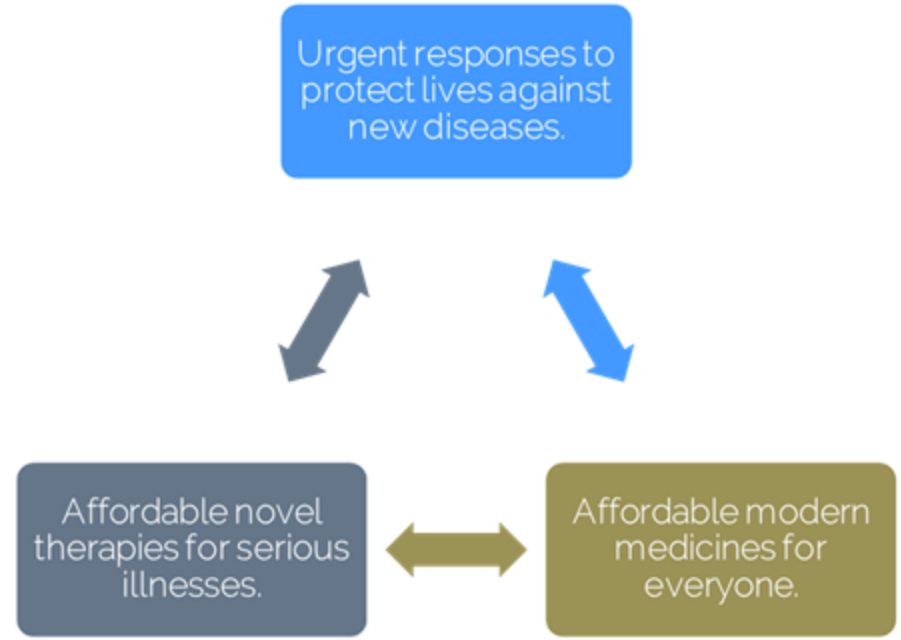
Innovate UK

Department of Health

Activirosomes develops effective, safe and affordable vaccines and virotherapies, to solve urgent and global health needs.

Our vision:

To bring affordable, accessible, modern medicine to mass markets, globally.



Amanda McMurray PhD MBA
Founder and CEO

Vishwas Joshi PhD
Founder and CSO

Seagull Biosolutions PvT Ltd
Strategic partner, laboratory and scientific team

7 billion people are at risk of infection and death from viral diseases, globally.

- Viruses change quickly;
  - can suddenly re-emerge causing life and economy-threatening diseases;
- No one is "safe":
  - Spread quickly and efficiently via global travel;
  - and through communities due to traditions and lifestyles;
- Vaccines aren't always fit for use in the areas they are needed;
- Vaccination "programmes" leave many unprotected;
  - As they don't fit people's lifestyles.
- Medicine development is expensive, risky and takes a long time.

Chikungunya – 7.1 billion at risk.

- 95% of the global population is at risk.
- 2013 epidemic ongoing, began in the Americas for first time.

Zika - 7.1 billion at risk.

- 95% of the global population is at risk
- 2016 epidemic ongoing, 4M cases projected, mainly across the Americas and Asia pacific

Ebola – 24M at risk

- 24M people at risk in Guinea, Sierra Leone and Liberia alone
- 2014-2017 epidemic - 30,000 cases, 11,315 deaths

Dengue – 7.1 billion at risk.

- 95% of world population is at risk
- 390M cases per year, globally.

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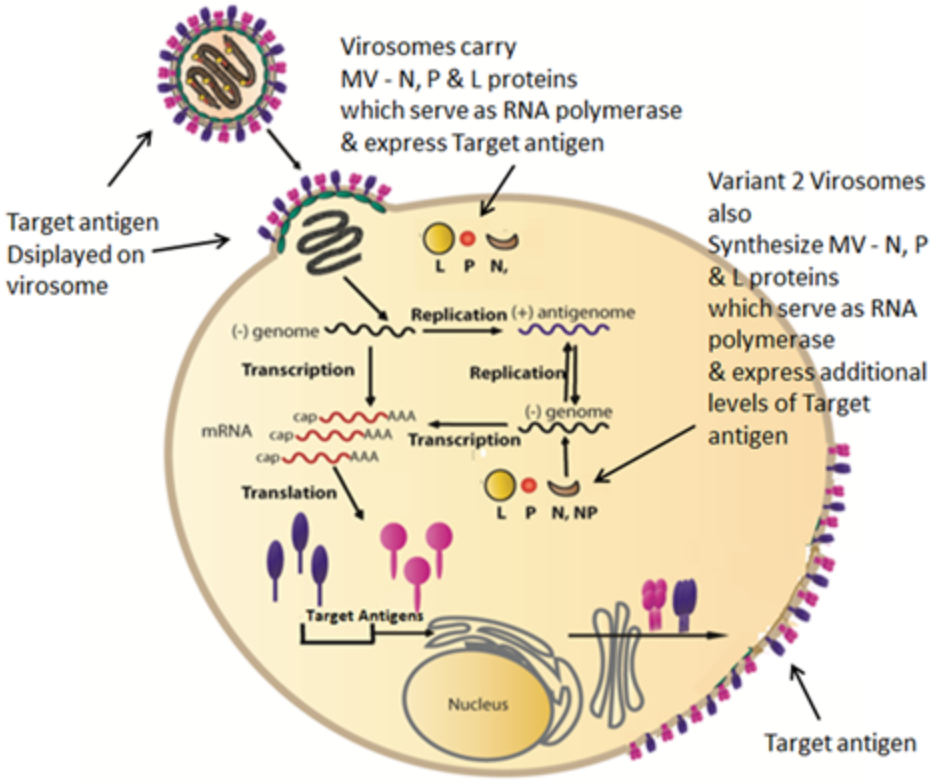
Active virosomes technology platform uses the effectiveness of the measles virus without the risks.

- Virosomes display Target Antigens & also carry a genome coding for Target Antigens.
- Virosomes infect human cells & deliver genes coding for "Target antigens" into the cell. These genes are expressed & the "Target antigens" are displayed on cell surface.
- SBPL technology incorporates ONLY vaccine relevant genes
  - Inherently safe, easy and cheap to produce;
  - very efficient at delivery into human cells.
- Cannot cause disease because virosome does NOT contain:
  - target virus polymerase & cis-acting Regulatory regions essential for Target virus replication.
  - the MV genes essential for MV replication.



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AVs have advantages over other vaccines technologies that addresses the problems of development time, cost and risk.

- Development of new vaccines and production can be completed within 3-4 months;
- the cost of development of an active virosome therapy candidate is <$1M
- Potent stimulators of cellular & humoral immunity;
- No need to grow the virus;
- Cassette construction gives us capability for production of multivalent vaccines;
- Low cost of production.

A simple 2-plasmid production and manufacture system

Prepare Cloning & Helper Plasmids

↓

Co-transfect into Packaging Cells

↓

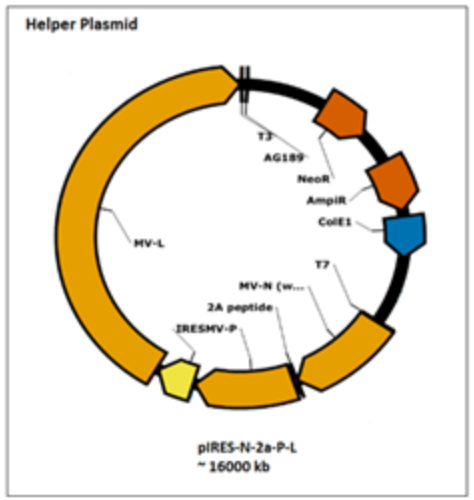
Double Selection Methotrexate + Geneticin

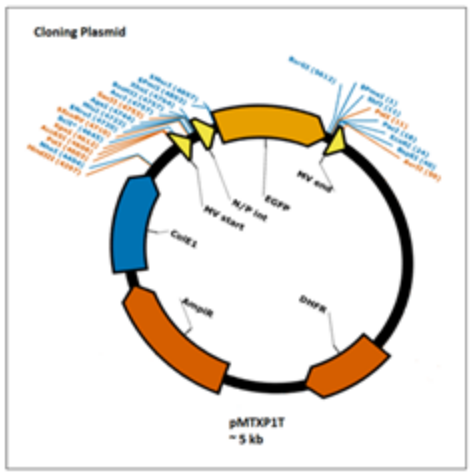
↓

Stably transfected cell lines

↓

Filtered through 100 kd filter





+

Packaging cell line
- $Vero_M$
- $Vero_{MFH}$

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Proof of concept studies completed on 5 vaccine candidates.

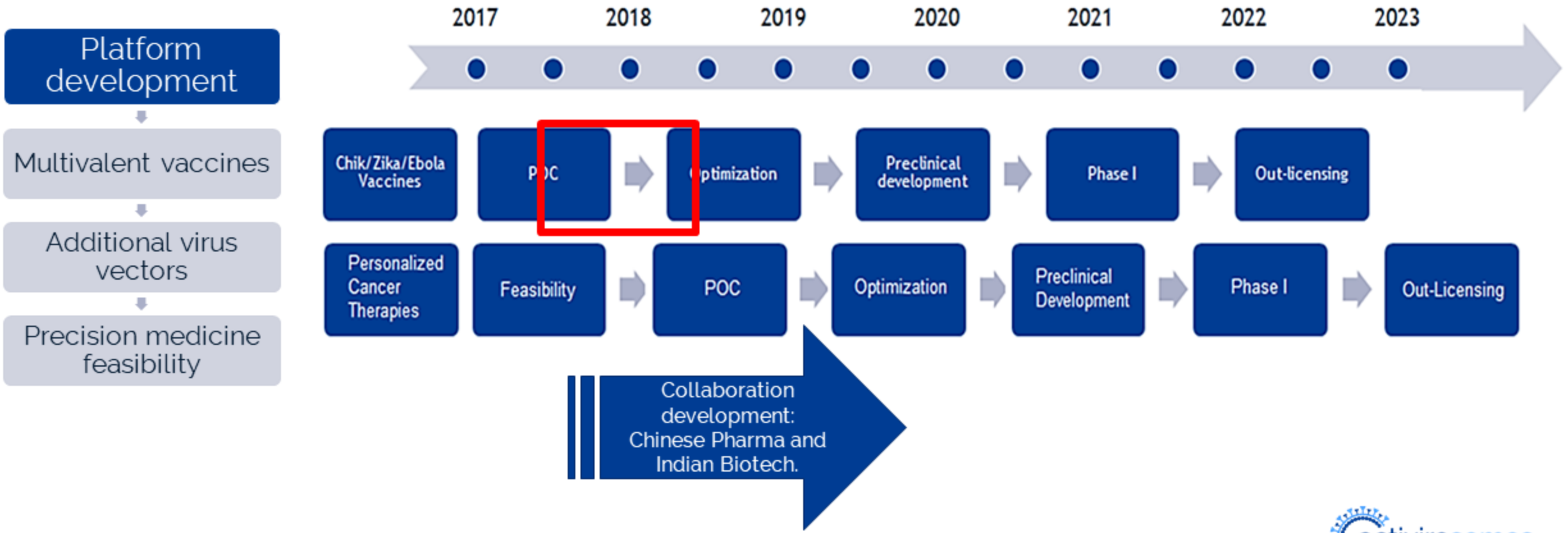
- Objectives – evaluation of vaccine candidates efficacy and vaccine platform scale up:
  - Produce Active Virosome Agents potentially useful as vaccine agents for prevention of Chikungunya, Ebola and Zika virus diseases.
  - Evaluate the immunogenicity of these Active Virosome Agents in lab animals & determine whether they produce protective immune response.
  - Determine the efficacy of these Active Virosome Agents.
  - Determine whether "Divalent Active Virosome formulations can be produced and are useful as vaccine agents.

- Funded by SBRI contract from the UK's Department of Health, £0.45M

Findings

- Monovalent AV agents displaying antigens from Chikungunya, Zika and Ebola viruses were produced.
- Divalent antigens were prepared and displayed antigens from
  - Chikungunya and Zika antigens.
  - Sudan Ebola virus and Zaire Ebola virus antigens.
- All antigens induced, measured by:
  - Cellular Immune responses.
  - PRNT antibodies.
- Animal protection studies:
  - Marginal, short lasting protection was observed in case of AV-Zika vaccine agent.
  - No protection was observed using Ebola virosomes.
  - Viral load was found to be reduced in mice immunized with Chikungunya antigens. This may indicate protective efficacy of Chikungunya virus AV agents.

Pipeline and platform development plan



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Active Virosome Technology – Applications

Value adding constituents of Other substances

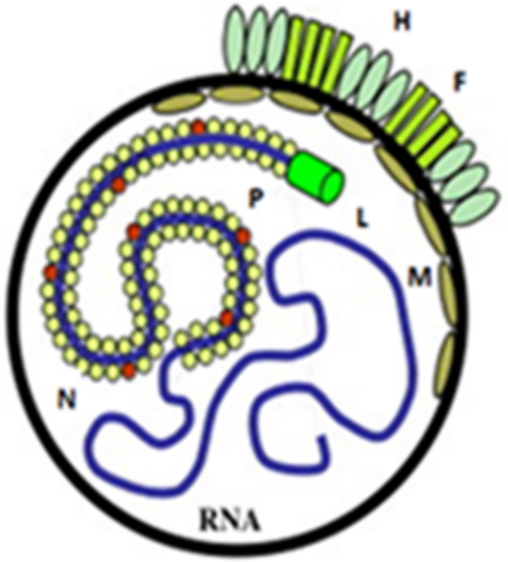
Others

Biocatalysis

Biosensors

Immunogenicity

Display Libraries



Antigen Display

Intracellular delivery

Car-T therapies

Si/Mi/Anti-sense RNA

Ribozymes

Immunotherapies

Vaccines

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Summary

- Activirosomes develops effective, safe and affordable vaccines and virotherapies, to solve urgent and global health needs.
- Flexible, robust and proven platform technology.
- Inherently safe and stable.
- Economical and simple to develop and manufacture.
- Proof of concept of multiple and multivalent vaccines.

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