

IMPROVE VACCINE EFFICACY AND GET RID OF THE JAB

Precision Delivery Solutions

PharmaJet[®]
Needle-Free Injection[™]

PharmaJet Team



Chris Cappello,
President and Chief Executive Officer
Chris.Cappello@PharmaJet.com



Darin Zehrung, MBA
Chief Business Development Officer
Darin.Zehrung@PharmaJet.com



Erin K. Spiegel, Ph.D.
Vice President, Clinical and Regulatory Affairs
Erin.Spiegel@PharmaJet.com



Paul LaBarre, MBA
Vice President, Global Business Development
Paul.LaBarre@PharmaJet.com



Kangethe (Ken) Ngure
Managing Director, Africa
kangethe.ngure@pharmajet.com



Ozge Goktekin
Managing Director, Asia
ozge.goktekin@pharmajet.com



PharmaJet®
Needle-Free Injection™

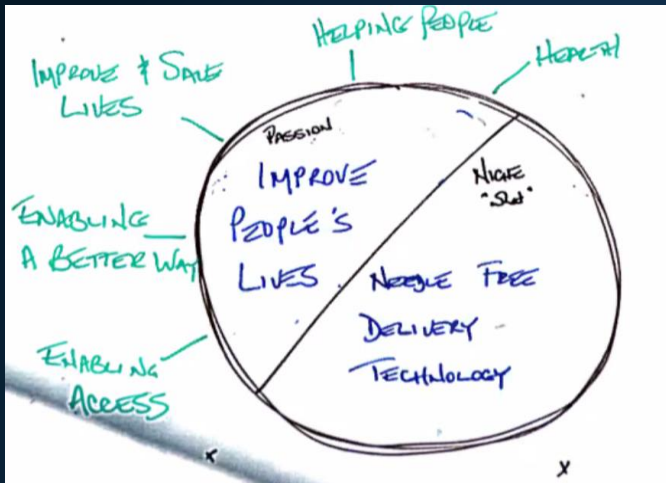


Mission:

We engineer precision delivery solutions that overcome the challenges of our vaccine and pharmaceutical partners.

Vision:

Enable greater access to life-saving vaccines and pharmaceuticals globally.



How:

- ✓ Equivalent or improved effectiveness
- ✓ Improved economics
- ✓ Better patient & caregiver experience

Most partners come to us for one/multiple of the following reasons:

IMPROVED STUDY RESULTS

Data from nucleic acid and other injectable studies has repeatedly shown:

- **Improved immunogenicity** compared to needle & syringe*
- Non-inferior immunogenicity compared to **electroporation***



HIGH ACCEPTABILITY

87% of Healthcare Workers prefer needle-free*

- No needle-stick injuries
- ID jet injection is easier than Mantoux

93% of Patients & Caregivers prefer needle-free*

- No needle-phobia, improving patient/caregiver experience
- More acceptable than electroporation



ID or Dose savings

Significant dose savings potential

- Injector sets the dose
- Transition from a 0.5 ml IM injection to a 0.1 ml ID and **maintain effective immunogenicity***



COMMERCIAL SUCCESS

- Ideal for mass vaccination campaigns in both urban & rural settings
- **More cost effective** than N/S*
- Differentiation in the marketplace
- Improved **vaccine compliance**

PharmaJet's Needle-Free Injection Systems

deliver a spring-powered injection in a 10th of a second by means of a narrow stream of fluid that penetrates the skin with a precise dose and depth.

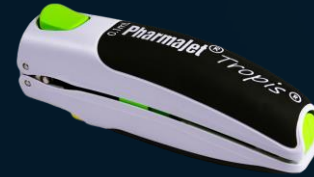
NO needle

NO external power source

- Fixed volumes
(variable dose devices in development)

Tropis® ID

Needle-Free Injection System for
0.1 ml Intradermal Injections



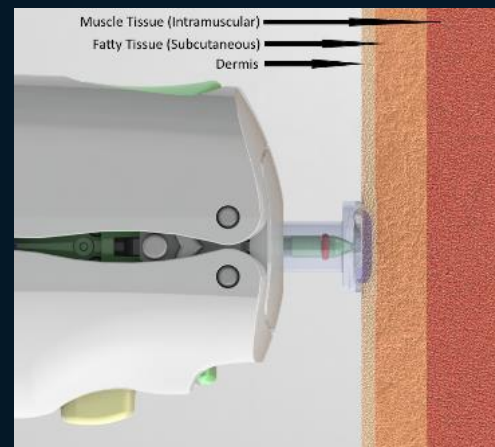
INJECTOR



0.1ml SYRINGE



ADAPTER



ID injection with Tropis

Stratis® IM/SC

Needle-Free Injection System for 0.5 ml
Intramuscular or Subcutaneous Injections



INJECTOR



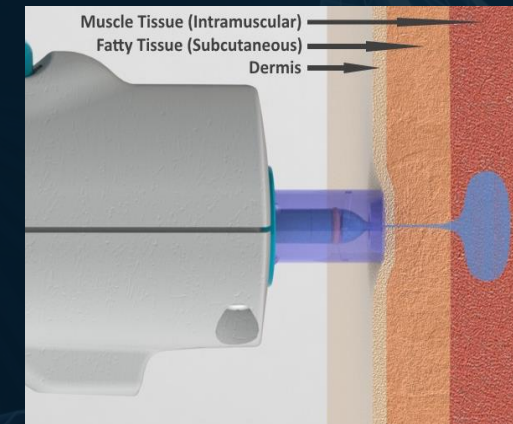
RESET STATION



0.5ml SYRINGE

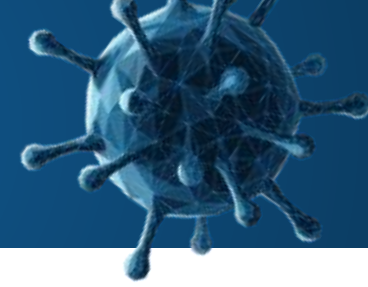


ADAPTER



IM injection with Stratis

Intradermal Delivery with Tropis



Mantoux Technique



- Technically difficult
- Slow
- Painful



Needle-Free Technique



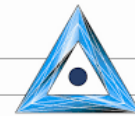
- Simple
- *Very* rapid (<0.1 sec)
- Consistent



Tropis®



- Spring-powered
- Handheld, provides safe, fast and easy 0.1 ml administration to the intradermal layer
- CE Mark; 1st and only needle-free system with WHO Prequalification



PERFORMANCE QUALITY SAFETY

Tropis Field Use for IPV



Ideal for mass vaccination campaigns



Improved vaccine compliance



Easy to roll out and train vaccinators



GAMBIA

fIPV Assessment (2016)

PMID:
[34951974](#)

Significant dose savings (10 full dose vial)

- 50 doses/vial with N/S
- **63 doses/vial** with Tropis



CUBA

fIPV Campaign Launch (2019)

- 130 vaccinators trained
- **92%** satisfaction
- **94%** likely to recommend



PAKISTAN

fIPV Large Scale Campaign Use (2019)

PMID:
[31983581](#)

- Cascade Training
- 2019: **500,000** children vaccinated in **5 days**
- 2020: **900,000** children vaccinated in **3 weeks**
- 2020-2021: **+2M Children** vaccinated
- 2022: **+2M** campaigns in Process
- **97.6%** of vaccinators prefer NFIS to N/S
- **99.6%** of caretakers prefer NFIS to N/S
- Mean coverage over previous IPV campaign improved by **18.4%**



NIGERIA

Campaign and Routine immunization

- CDC-funded Supplemental Immunization Campaign pilot
- USAID-funded Routine Immunization Evaluation with National Public Health Care Development Agency, PATH and JHPIEGO

Somalia 2021

Polio Immunization Campaign

110,000 children immunized using PharmaJet Needle-free Delivery



©2022 - PharmaJet, Inc – All rights reserved

Needle-free Makes Pharma Products Perform Better

55+
Development
Partners

80+
Studies in
Progress

65+
Completed
Studies

Many Applications:

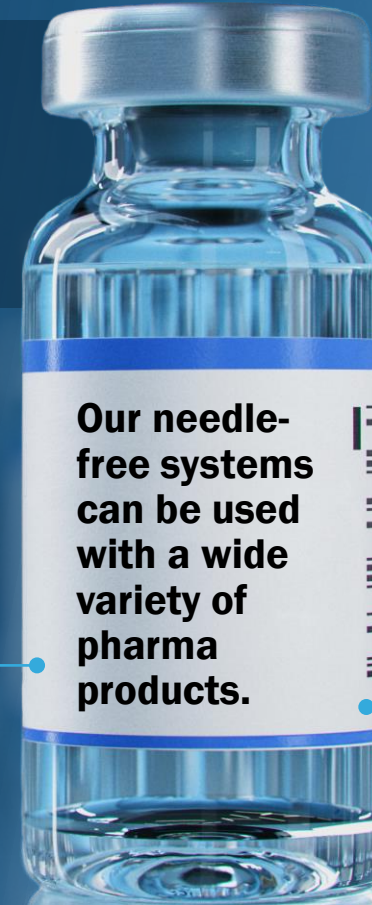
- Vaccines
- Therapeutics
- Select drug products

Any Level of Research:

- Bench testing
- Preclinical animal studies
- Clinical trials

Any Formulation:

- Viscosity up to 70 cP (mineral oil)
- Can use adjuvants and microcarriers
- Can do multiple injections per timepoint for larger doses



Nucleic Acid



Inactivated



Subunit



Live Attenuated



Viral Vector



Bacteria

Proven Benefits Of Needle-free Injection

IMPROVED STUDY RESULTS



Data from nucleic acid studies has repeatedly shown:

- Improved immunogenicity compared to N/S*
- Non-inferior immunogenicity to electroporation*



Significant dose savings potential

- Injector sets the dose
- Transition from a 0.5ml IM injection to a 0.1ml ID and maintain effective immunogenicity*

NO HASSLE



No needle means:

- No needle reuse or cross-contamination
- No sharps disposal



The PharmaJet systems are user friendly & quick to learn

HIGH ACCEPTABILITY



87% of Healthcare Workers prefer needle-free*

- No needle-stick injuries
- ID jet injection is easier than the Mantoux technique



93% of Patients & Caregivers prefer needle-free*

- No needle-phobia, improving the patient/caregiver experience
- Needle-free is more acceptable than electroporation

COMMERCIAL SUCCESS



Ideal for mass vaccination campaigns in both urban & rural settings



More cost effective than N/S*




















Differentiation in the marketplace







Improved vaccine compliance

Publications with PharmaJet Needle-free Injection




















RESPIRATORY VIRUSES

COVID-19	        	Phase 1/2
Influenza	   	Phase 1/2 Phase 4
RSV	 	(confidential data only)
Equine Influenza	 	
















ARBOVIRUSES

Zika	    	Phase 1
Dengue	  	Phase 1b
VEEV	 	






HANTAVIRUSES

ANDV	    	
DOBV	 	
HTNV	  	
PUUV	  	
SEOV	 	
SNV	   	







OTHER VIRUSES

Hepatitis B	 	
HIV	 	(confidential data only)
MMR		Phase 4
Polio		Phase 3/4 Phase 4
Pox	   	Phase 2
PRRSV	 	
Rabies	  	Phase 1







CANCER

Canine Cancer	 	(confidential data only)
HPV		Phase ?
Lymphoma		Phase 1
Solid Tumors		Phase 1












OTHER APPLICATIONS

Atherosclerosis	 	
Brucellosis	 	(confidential data only)
Canine Allergy	 	(confidential data only)

Injectable Type

	DNA
	RNA
	Inactivated
	Bacteria
	Live Attenuated
	Subunit

Preclinical Animal Model

	Mouse
	Rat
	Hamster
	Guinea Pig
	Rabbit
	Dog
	NHP
	Sheep
	Pig
	Cow
	Horse



PIPELINE

PRECLINICAL ANIMAL STUDIES

RESPIRATORY VIRUSES

- COVID-19 (15 studies)
- Influenza (4 studies)
- Pandemic Influenza
- Swine Influenza

ARBOVIRUSES

- Crimean Congo Hemorrhagic Fever
- Yellow Fever
- VEEV
- Zika

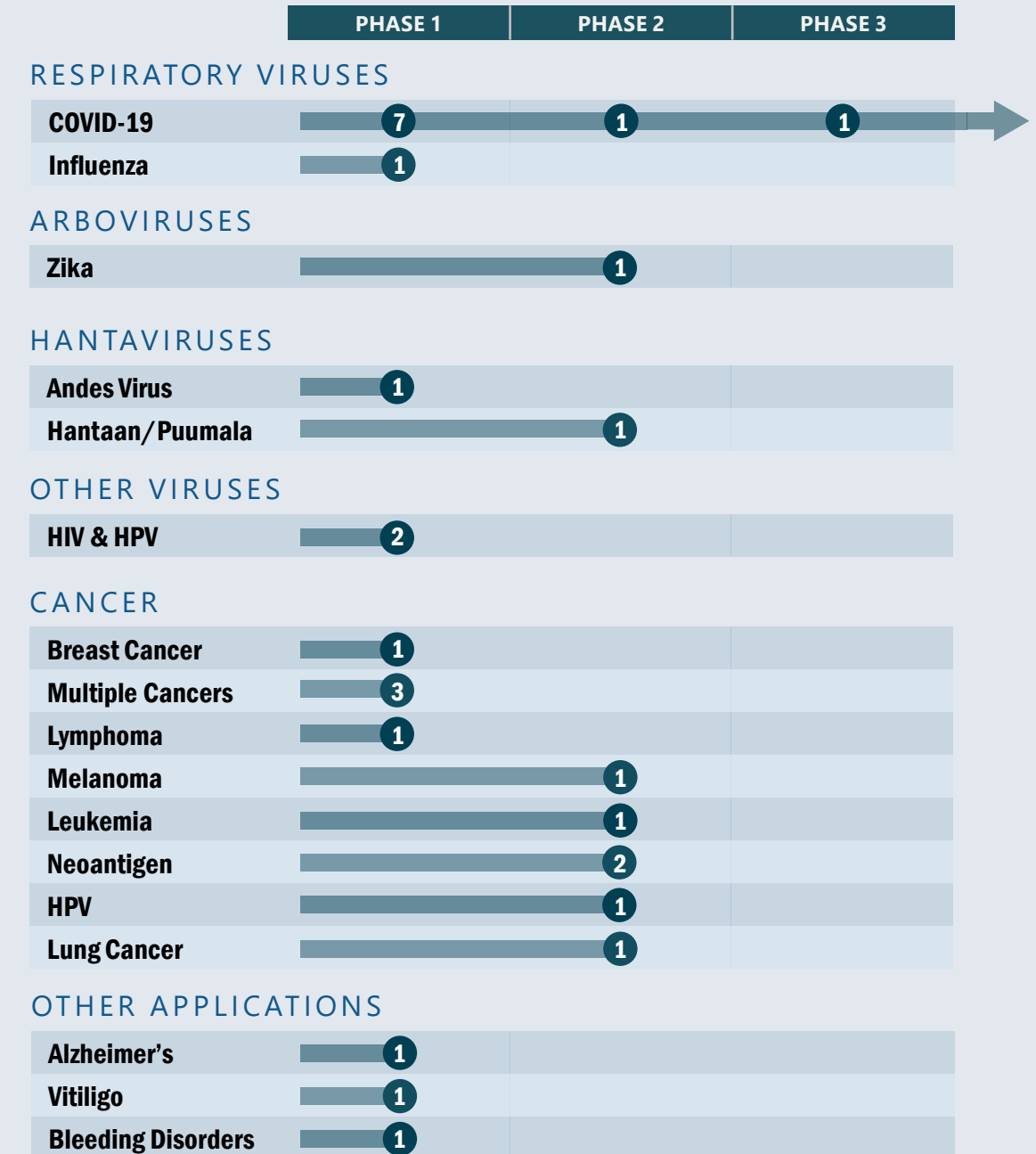
OTHER VIRUSES

- Hantaviruses
- Hepatitis B
- HIV / SIV (3 studies)
- Marburg Virus
- PRRSV
- Smallpox

CANCER & OTHER

- Canine Cancer
- Multiple Cancers (2 studies)
- Alzheimer's

CLINICAL TRIALS WITH PHARMAJET NFIS



PARTNER DATA

Transduction Efficiency

DNA vaccine
Intradermal (Tropis)
Swine
PRRSV



Antibody Response

DNA vaccine
Intramuscular (Stratis)
Phase 1 Clinical
Zika



EUA in India

Plasmid DNA vaccine
Intradermal (Tropis)
Phase 3 Clinical
COVID-19



Antibody Response

MVA-vectored vaccine
Buccal & Sublingual (Tropis)
Rhesus macaques
COVID-19



Heterologous Prime Boost

DNA vaccine
Intramuscular (Stratis)
Phase 1 Clinical
Influenza



T Cell Immunogenicity

dbDNA™ Vector
Intradermal (Tropis)
Minipigs
Influenza



Passive Immunotherapy

DNA LNP vaccine
Intramuscular (Stratis)
Rabbit, NHP, Cow
Andes & Zika



Strong T Cell Response

DNA therapeutic
Intramuscular (Stratis)
Phase 1/2a Clinical
HPV Cancerous Lesions



ZyCoV-D Vaccine Delivered Exclusively via Tropis

100% protection against moderate and severe COVID-19

COMPANY: Zydus Lifesciences

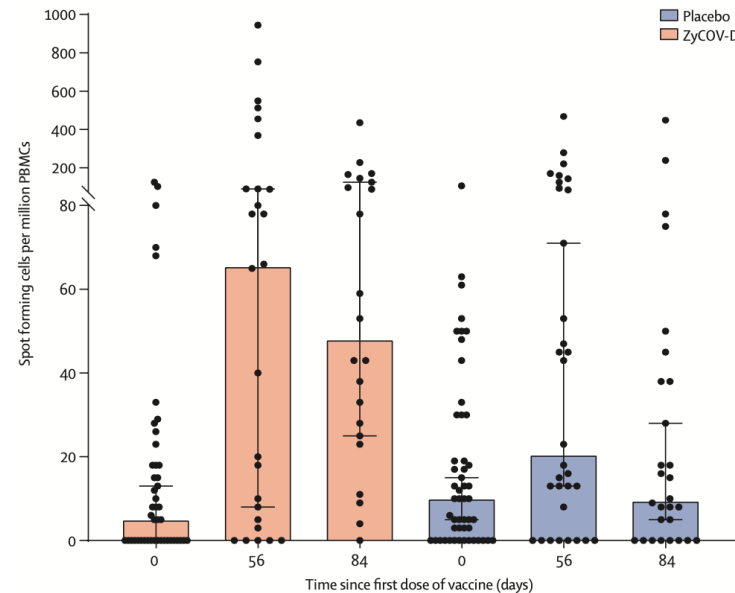
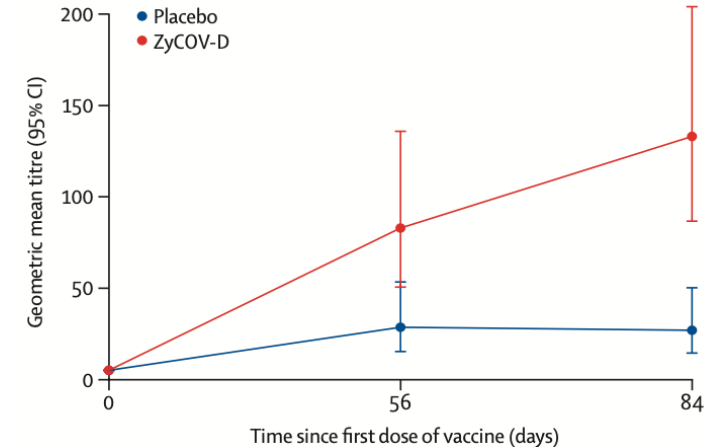
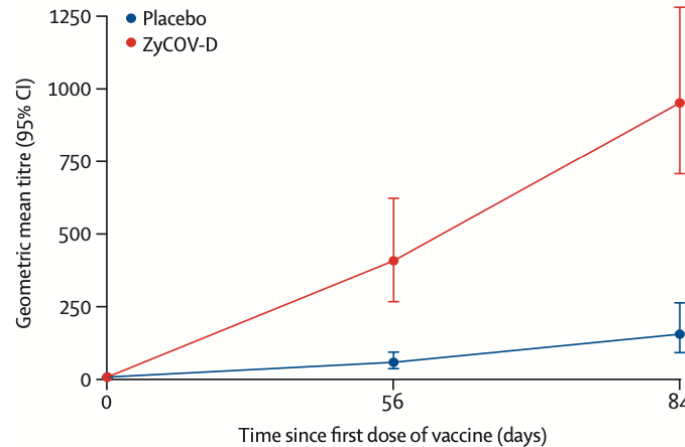
INJECTATE: COVID-19 DNA Vaccine

STUDY: Phase 3 Trial

ROUTE: Intradermal with Tropis

STATUS: EUA Roll-out in India

- ✓ **Safe and well-tolerated**
- ✓ **Significantly high immunogenicity**
 - Anti-spike binding and neutralizing antibodies
 - T cell response (IFN γ)
 - Higher in the 12-17 yr old group
- ✓ **Efficacious**
 - 100% protection against severe/moderate COVID-19
 - 65% protection against mild disease
 - Effective against Delta VOC



Khobragade, et al (2022). Efficacy, safety, and immunogenicity of the DNA SARS-CoV-2 vaccine (ZyCoV-D): the interim efficacy results of a phase 3, randomised, double-blind, placebo-controlled study in India. [https://doi.org/10.1016/S0140-6736\(22\)00151-9](https://doi.org/10.1016/S0140-6736(22)00151-9)

Emerging/Re-Emerging Infectious Disease Vaccines

Effectiveness in multiple animal models

INSTITUTION: USAMRIID

INDICATION: Andes or Zika Virus

INJECTATE: DNA-LNP Vaccine

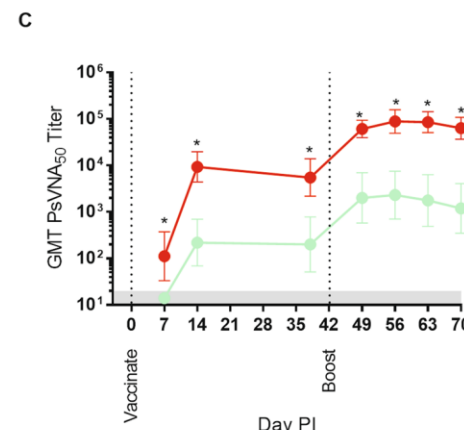
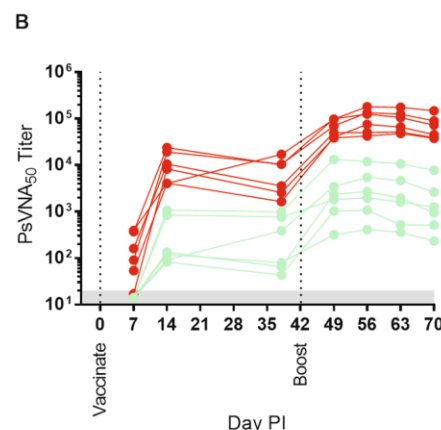
SPECIES: Rabbit, NHP, and Cow

ROUTE: Intramuscular with Stratis

- ✓ **Rabbits/ANDV:** Rapid, dose-dependent neutralizing antibody response
 - DNA-LNP faster, higher, less variable
- ✓ **NHP/ANDV:** DNA-LNP more immunogenic compared to un-formulated
- ✓ **Tc Cow/Zika:** Successful hyperimmunization to produce polyclonal human IgG for use as passive immunotherapy

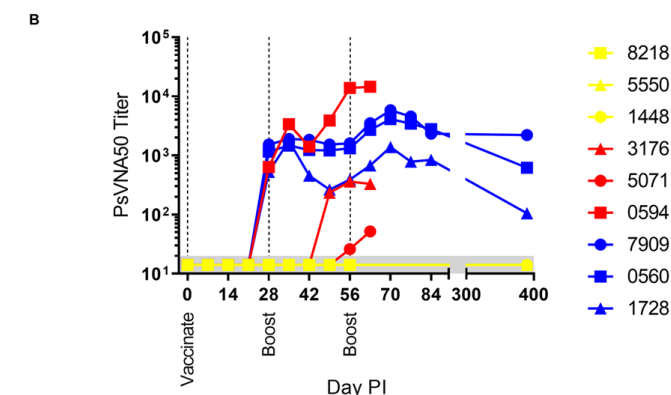
A

Group	Color	DNA	Dose	LUNAR	Prime	Boost	n
1	Red	AND-M	0.1 mg	YES	Day 0	Day 42	6
2	Green	AND-M	0.1 mg	NO	Day 0	Day 42	6



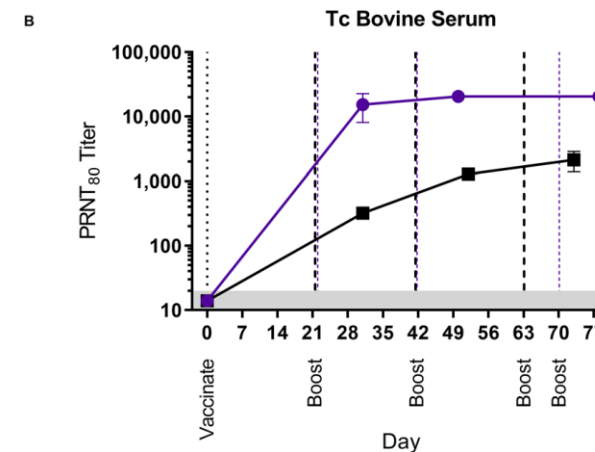
A

Group	Color	DNA	Dose	LUNAR	Prime	Boost	Boost	n
1	Yellow	AND-M	0.1 mg	NO	Day 0	Day 28	-	3
2	Red	AND-M	0.1 mg	YES	Day 0	Day 28	-	3
3	Blue	AND-M	2.0 mg	NO	Day 0	Day 28	Day 56	3



A

Group	Symbol	Vaccine	Dose	LUNAR	Vaccination Schedule	Reference
1	Purple	Zika DNA	1.2 mg	YES	0, 22, 42, 70	NA
2	Black	Zika DNA	12 mg	NO	0, 21, 42, 63	15



Mucker, EM, et al (2020). *Lipid Nanoparticle Formulation Increases Efficiency of DNA-Vectored Vaccines/Immunoprophylaxis in Animals Including Transchromosomal Bovines.*
<https://doi.org/10.1038/s41598-020-65059-0>

VB10.16 HPV16 Cancer DNA Immunotherapy

Strong T cell responses with significant correlation to lesion size regression

COMPANY: Nykode Therapeutics

INDICATION: HPV Cancerous Lesions

INJECTATE: DNA-based Immunotherapy

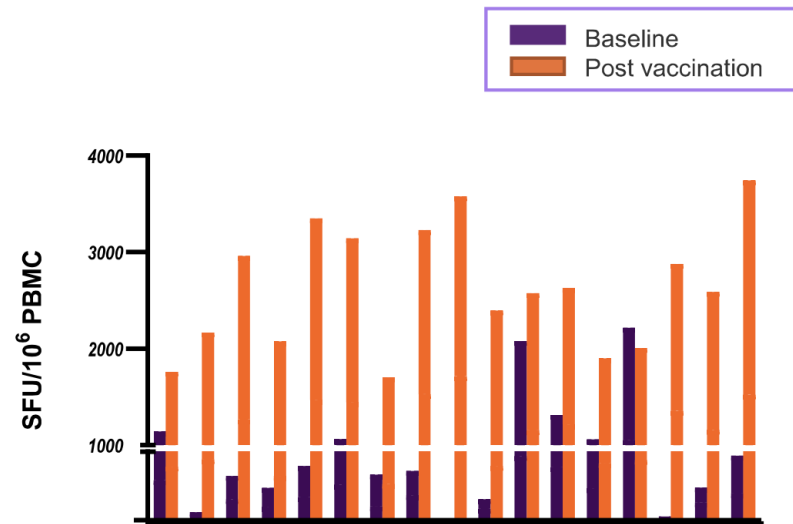
ROUTE: Intramuscular with Stratis

STATUS: Phase 1/2a Clinical Trial Complete

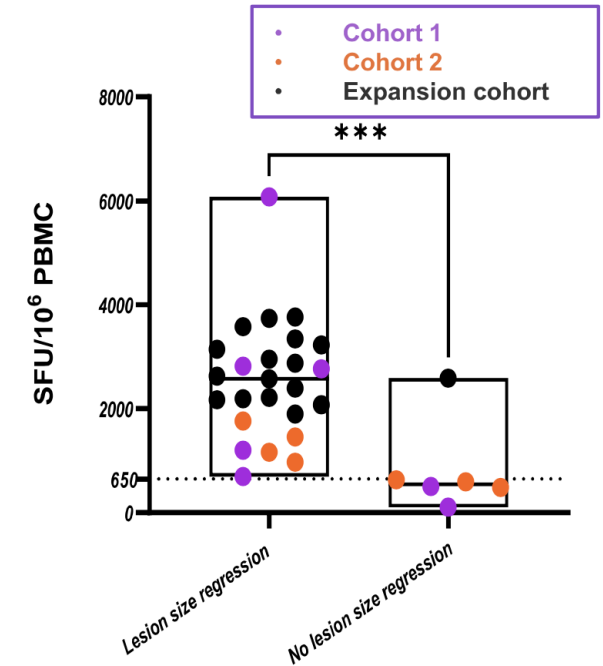
- ✓ All patients in expansion cohort produced a **strong HPV16-specific T cell response**
- ✓ Highly significant **correlation between vaccine-induced T cell responses and lesion size regression** in all cohorts



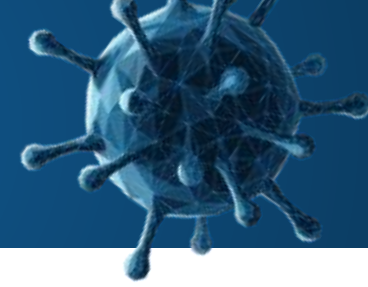
STRONG HPV16-SPECIFIC T CELL RESPONSES IN ALL PATIENTS IN THE EXPANSION COHORT



LESION SIZE REGRESSION CORRELATES WITH HPV-16 SPECIFIC RESPONSES



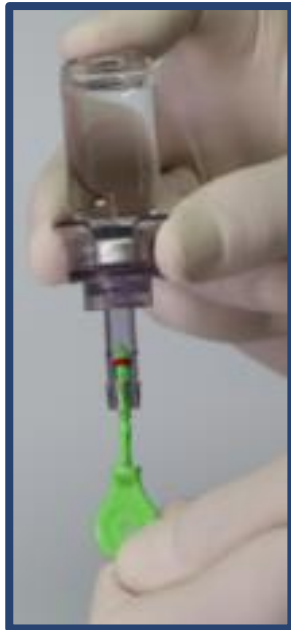
Tropis workflow



1. Prepare Injector



2. Fill Syringe



3. Load Injector



4. Give the injection



Workflow is comparable to needle-syringe.

Most users are self- or web-educated within 20 minutes

Partnering with PharmaJet



STRATEGIC ALLIANCES WITH:

Academia

Government

Pharmaceutical

Biotechnology

When you choose needle-free for your study, you have the PharmaJet team at your back.

We provide support from early development to large scale-ups, and our experienced clinical and regulatory teams will ensure that the implementation of needle-free is simple.

1

Establish Partnership

- Determine your needs & goals
- Share best practices & data from previous collaborations
- Execute MTA

2

Development & Support

- Learn how to use the devices with hands-on training sessions
- Get support with study design & site initiation

3

Planning & Proposal

- Receive assistance with funding
- Use our dossier for existing regulatory clearances
- Get support with IND application

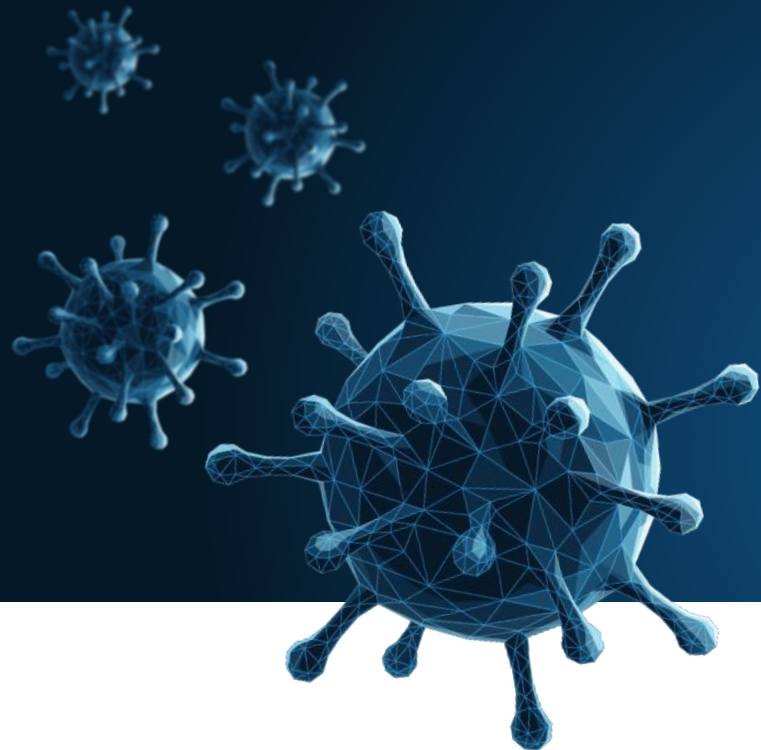
4

Commercialization

- Receive technical support & training
- Collaborate on data publication
- Get support with marketing and PR

Questions





THANK YOU



PharmaJet[®]
Needle-Free Injection[™]

PharmaJet Team



Chris Cappello,
President and Chief Executive Officer
Chris.Cappello@PharmaJet.com



Darin Zehrung, MBA
Chief Business Development Officer
Darin.Zehrung@PharmaJet.com



Erin K. Spiegel, Ph.D.
Vice President, Clinical and Regulatory Affairs
Erin.Spiegel@PharmaJet.com



Paul LaBarre, MBA
Vice President, Global Business Development



Kangethe (Ken) Ngure
Managing Director, Africa
kangethe.ngure@pharmajet.com



Ozge Goktekin
Managing Director, Asia
ozge.goktekin@pharmajet.com