

IAS webinar 3: Enabling biotech vaccine R&D, 2026/5/19

Translating basic science into a therapeutic HIV DNA vaccine candidate

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Outline

1. The HIV problem

2. **PD-1-Enhanced DNA Vaccines** developed by Immune Cure

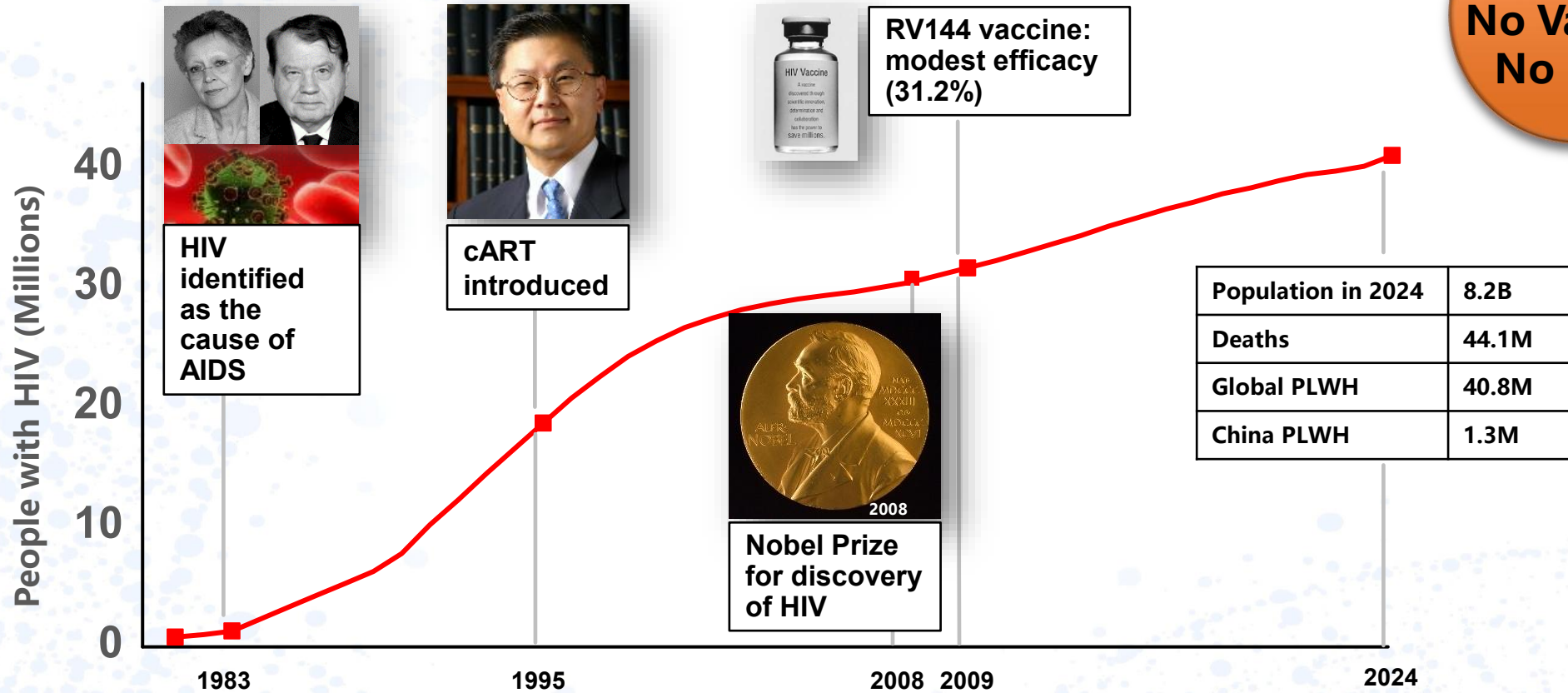
- The basic scientific concepts to be translated into a new vaccine
- Proof of concept study: HIV therapeutic vaccine Phase I data

3. The way forward

- Bridging Phase I and II: an investigator-initiated trial (IIT)
- Phase II trial plan

Meet the Grand Challenge of HIV/AIDS

44 years
No Vaccine
No Cure



Design ICVAX to induce strong T cell response to achieve functional cure

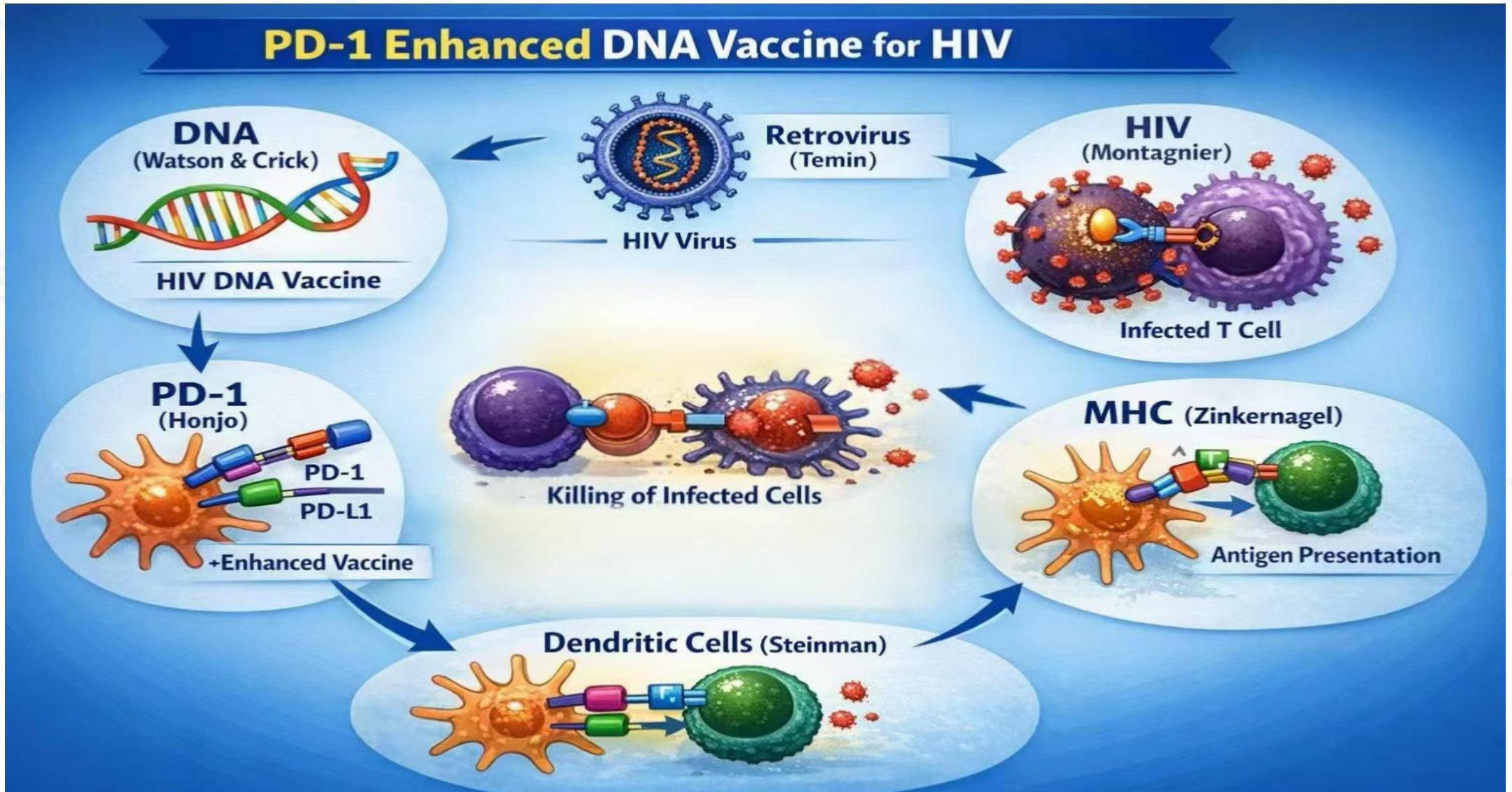
Core Product

ICVAX[®]

HIV Therapeutic DNA Vaccine

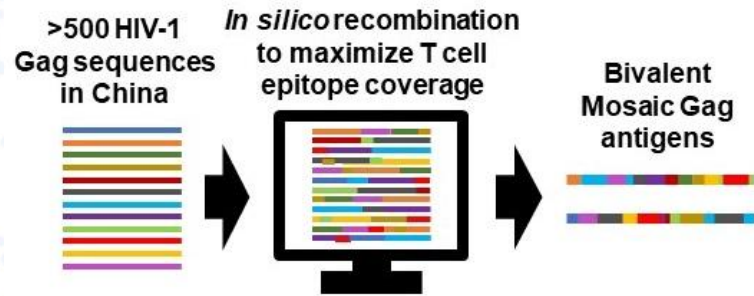


Integrating many aspects of basic research into the making of a product with potential

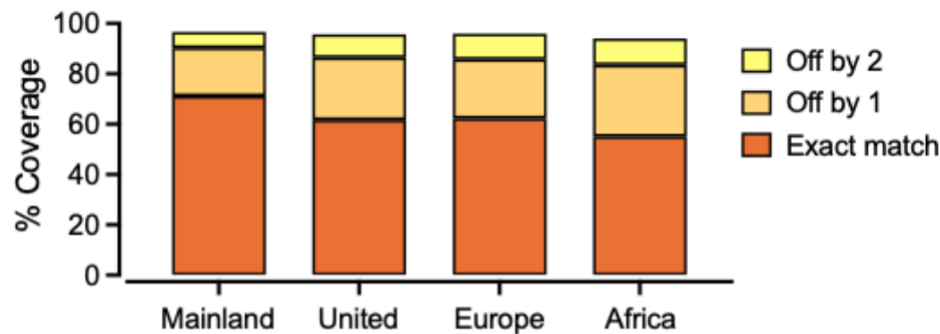


ICVAX[®]: A Novel Therapeutic DNA Vaccine for HIV

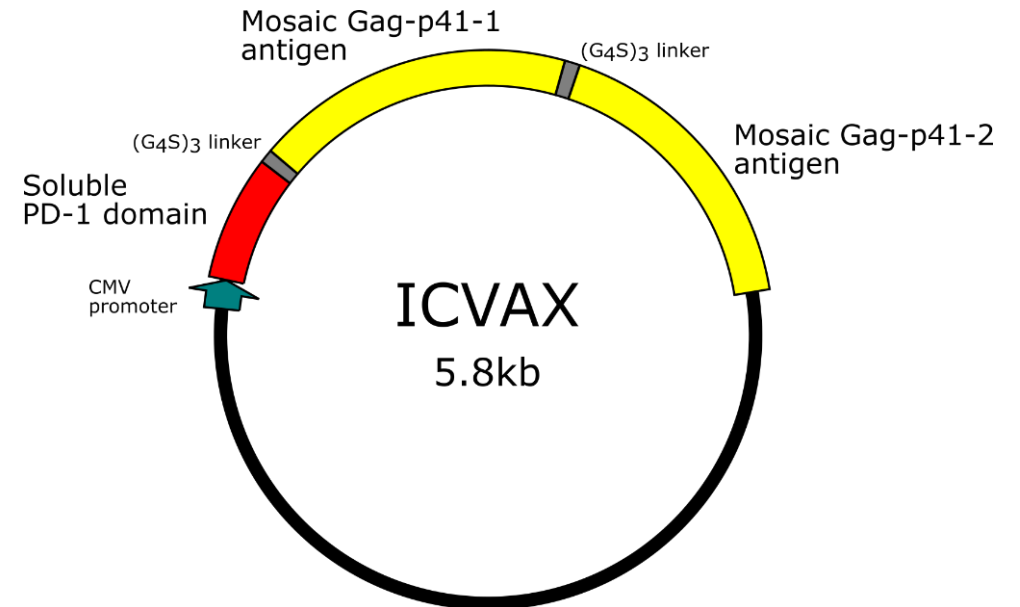
Mosaic antigen design to maximize global coverage



Great coverage against viral strains circulating in different geographical regions



Coverage: **96.6%** **95.7%** **95.9%** **94.0%**



NMPA-Approved ICVAX[®] Phase I Clinical Trial Design

Site:

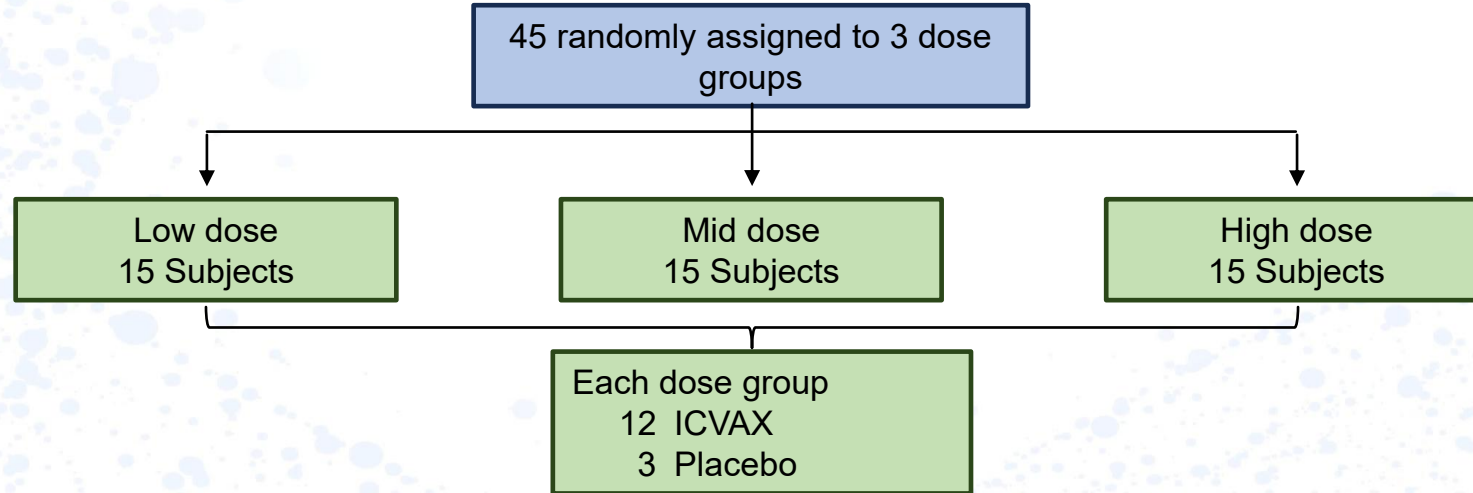
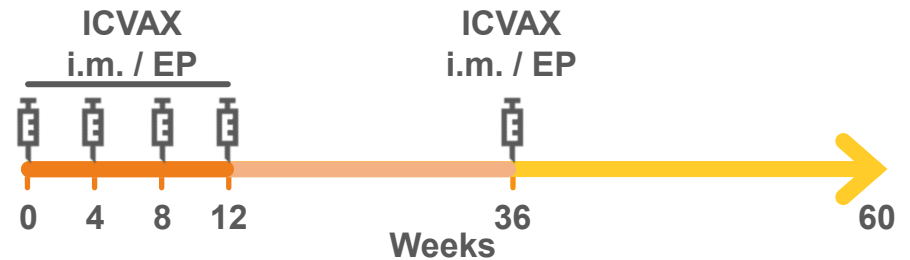


Design:

Double-blind, randomized, placebo-controlled, dose escalation.

Subjects:

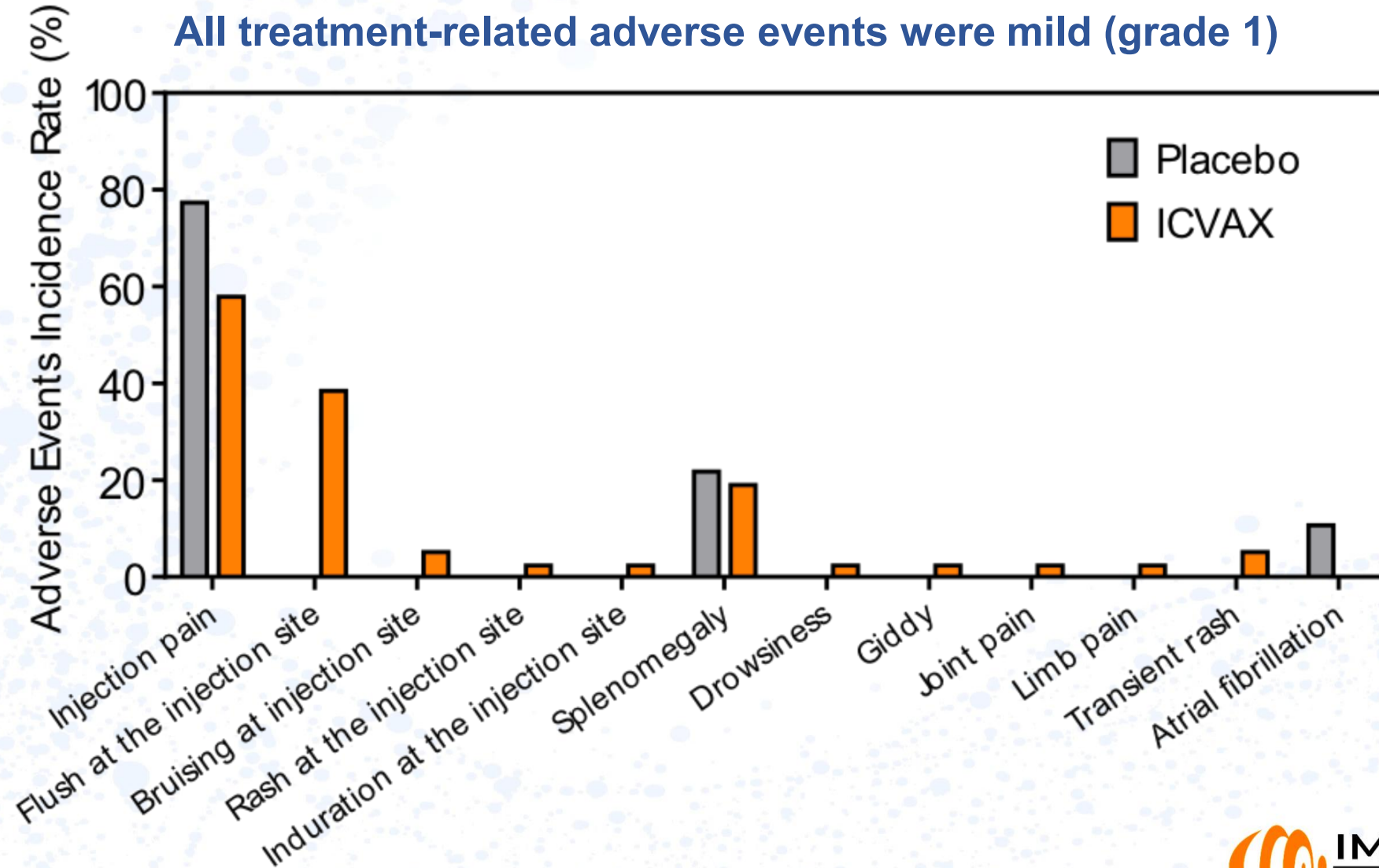
HIV-infected people receiving suppressive antiretroviral therapy



- 100% of subjects completed the entire clinical trial

ICVAX[®] is Safe in HIV-1 Patients

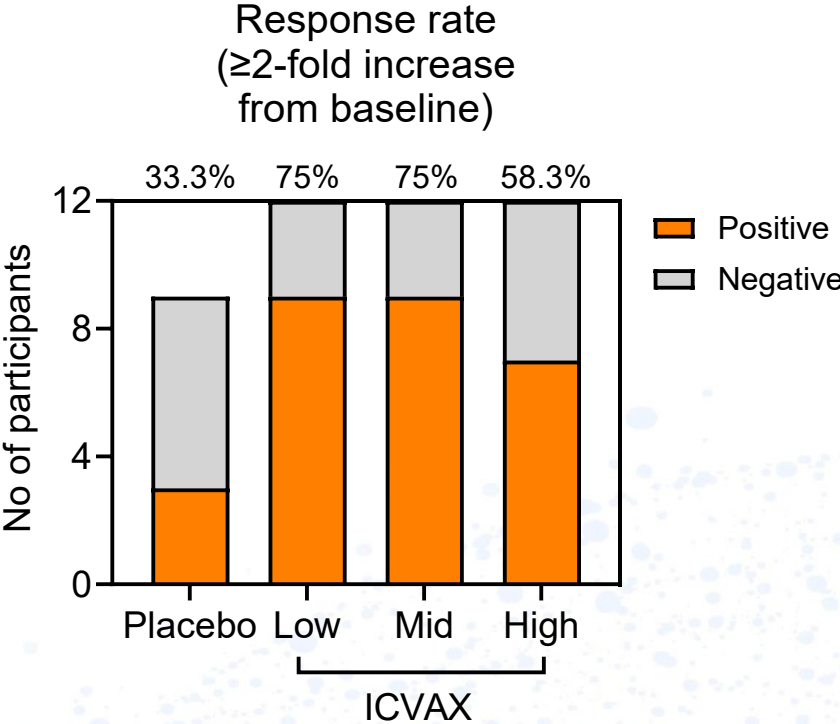
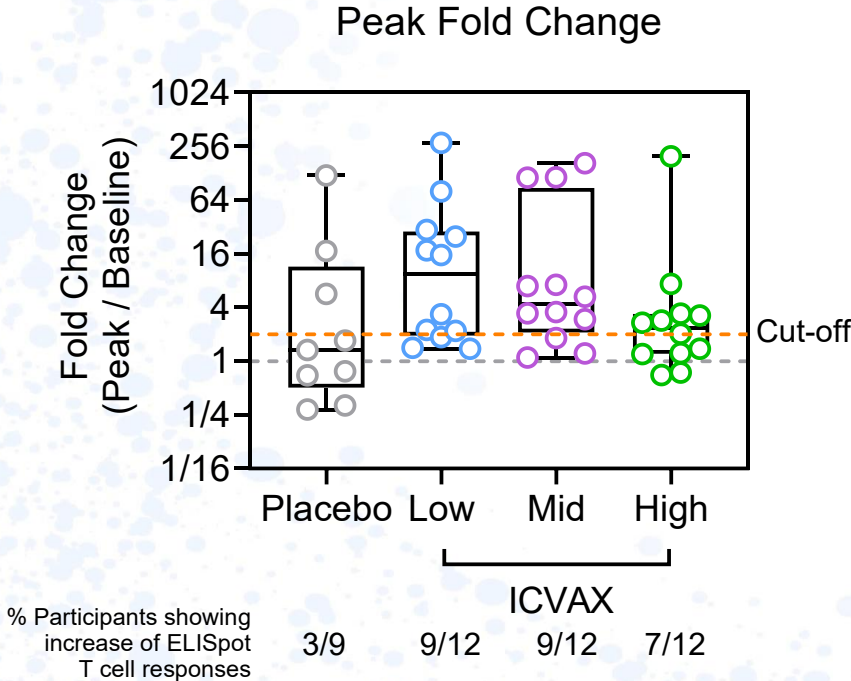
Under Review
Confidential



Optimal ICVAX[®] Dose Boosts Antigen-Specific T Cell Responses in HIV-1 Patients

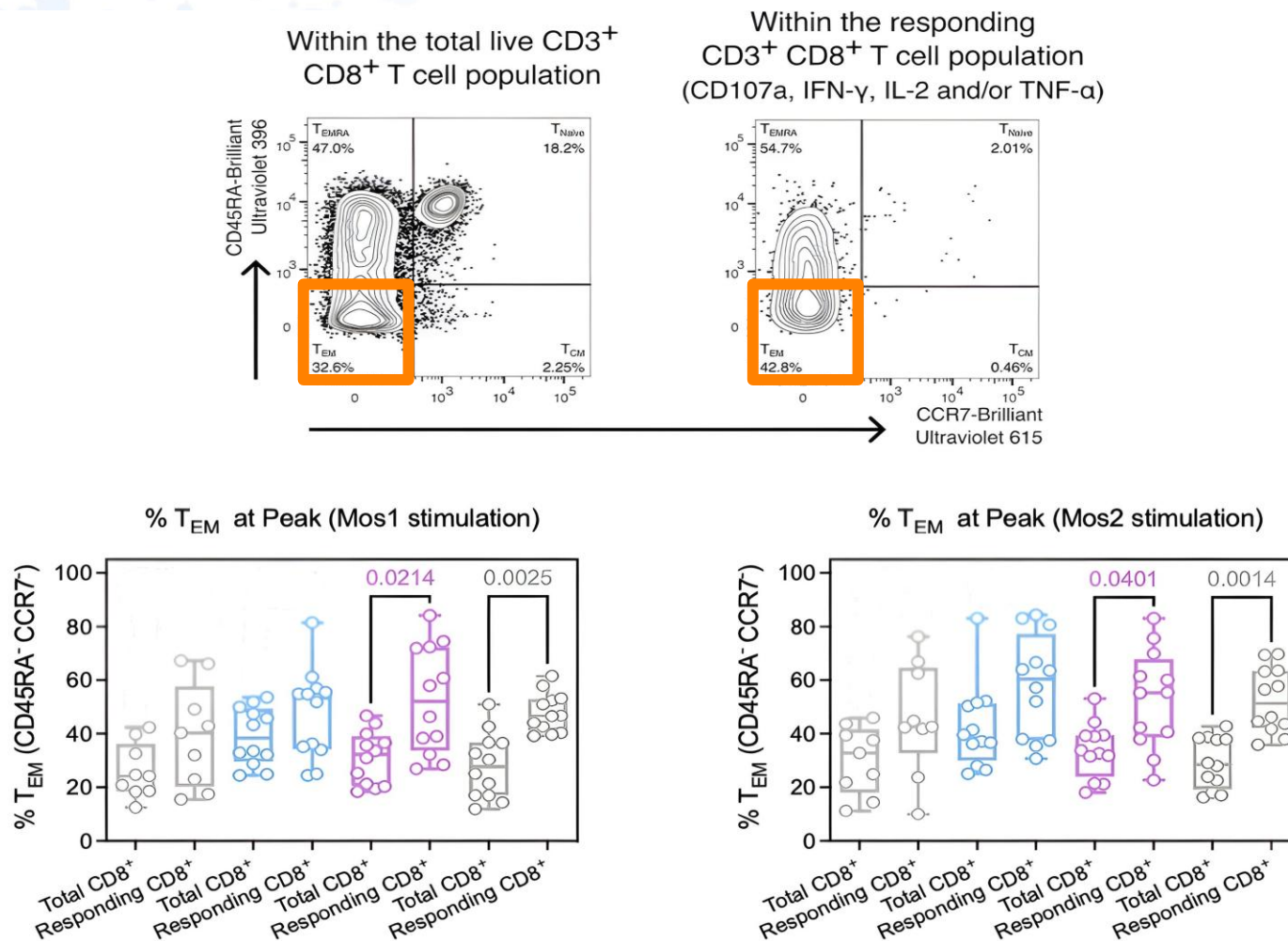
Vaccine significantly boosts T cell responses

High T cell immune response rate



Mid and High doses of ICVAX[®] Induces Effector-Memory CD8⁺ T Cells in HIV-1 Patients

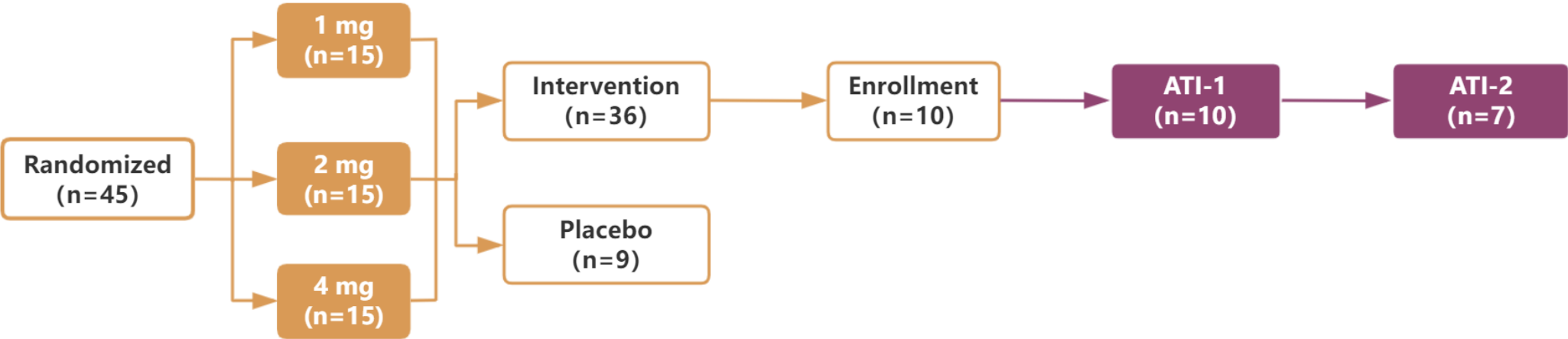
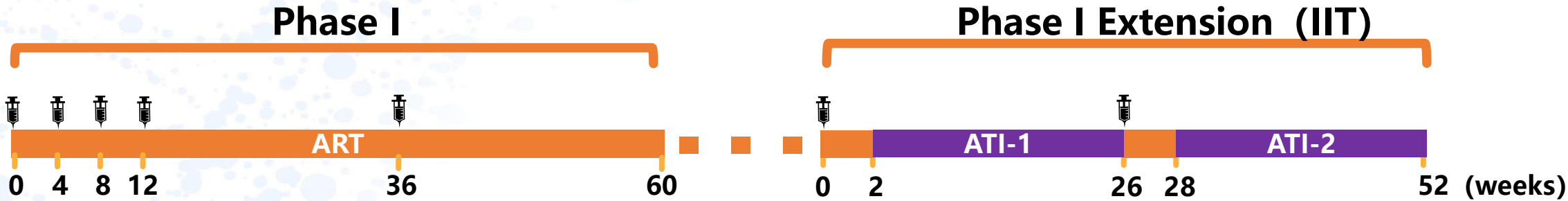
- Effector-memory CD8⁺ T cells are associated with better HIV-1 controls



Conclusion of the NMPA- Approved **ICVAX[®]** Phase I Trial

- **ICVAX is safe**
 - All treatment-related adverse events were mild
 - No treatment-related severe adverse events
- **Robust T cell immunogenicity**
 - At optimal dose: 75% response rate
 - Induction of functionally-specialized effector-memory CD8⁺ T cells
- **Phase I results are supportive for further clinical studies**

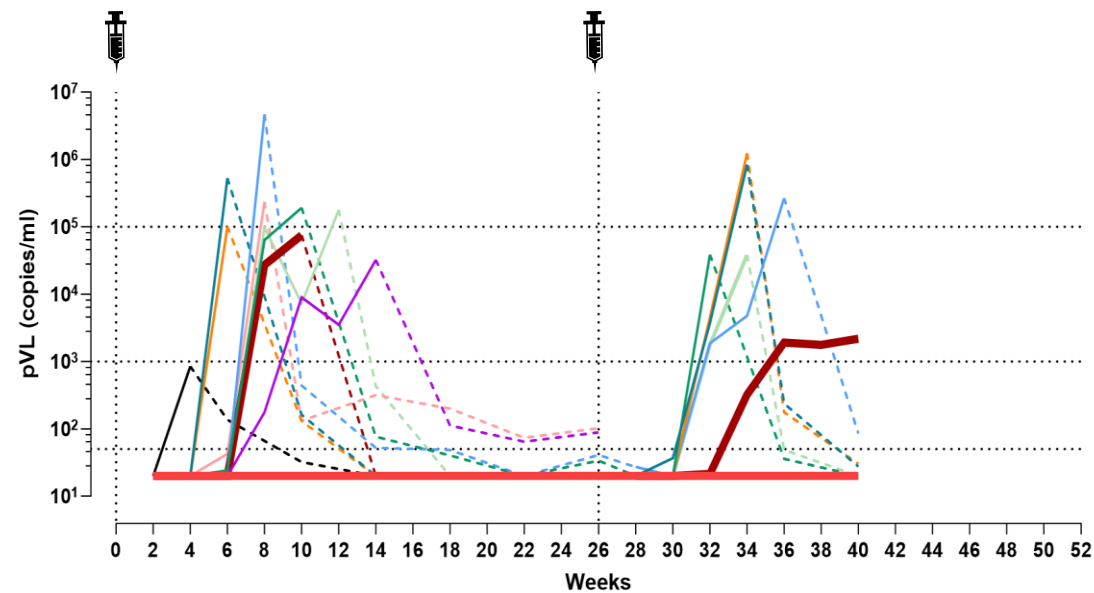
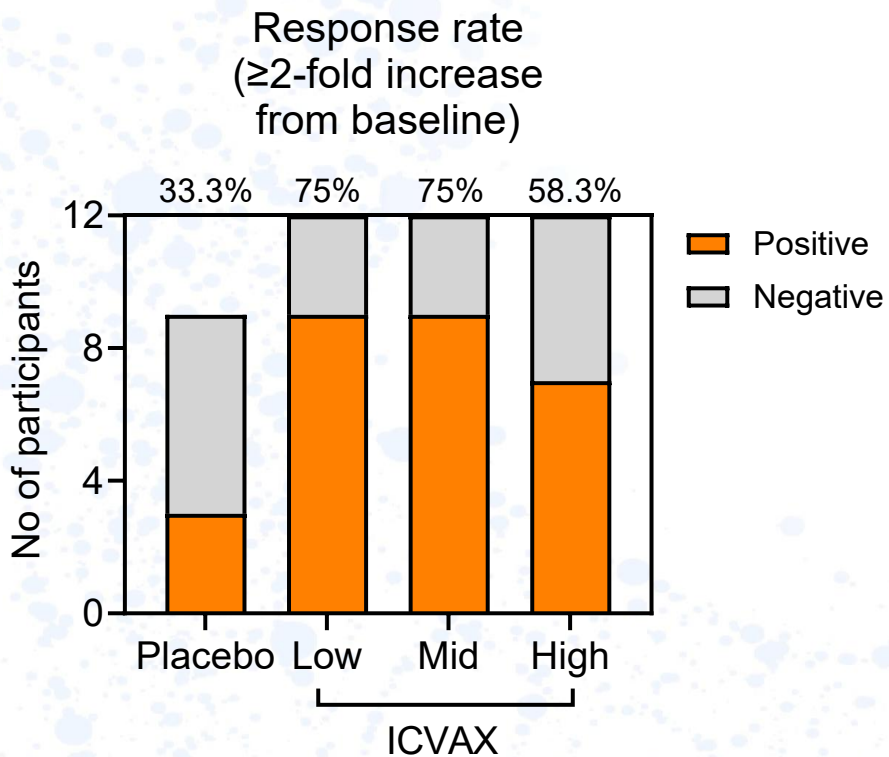
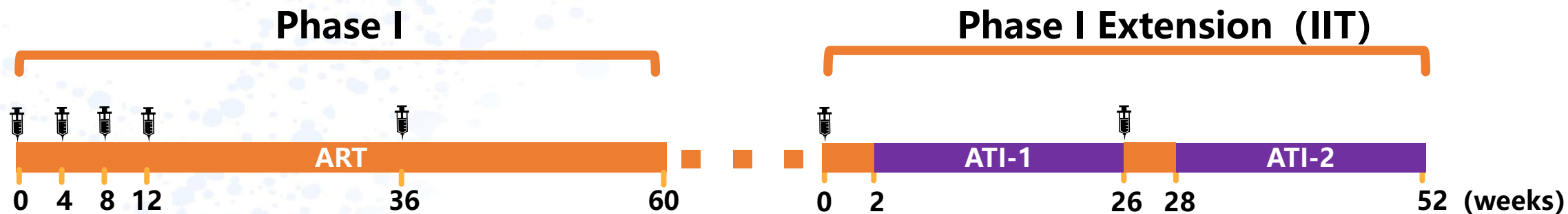
IIT study design



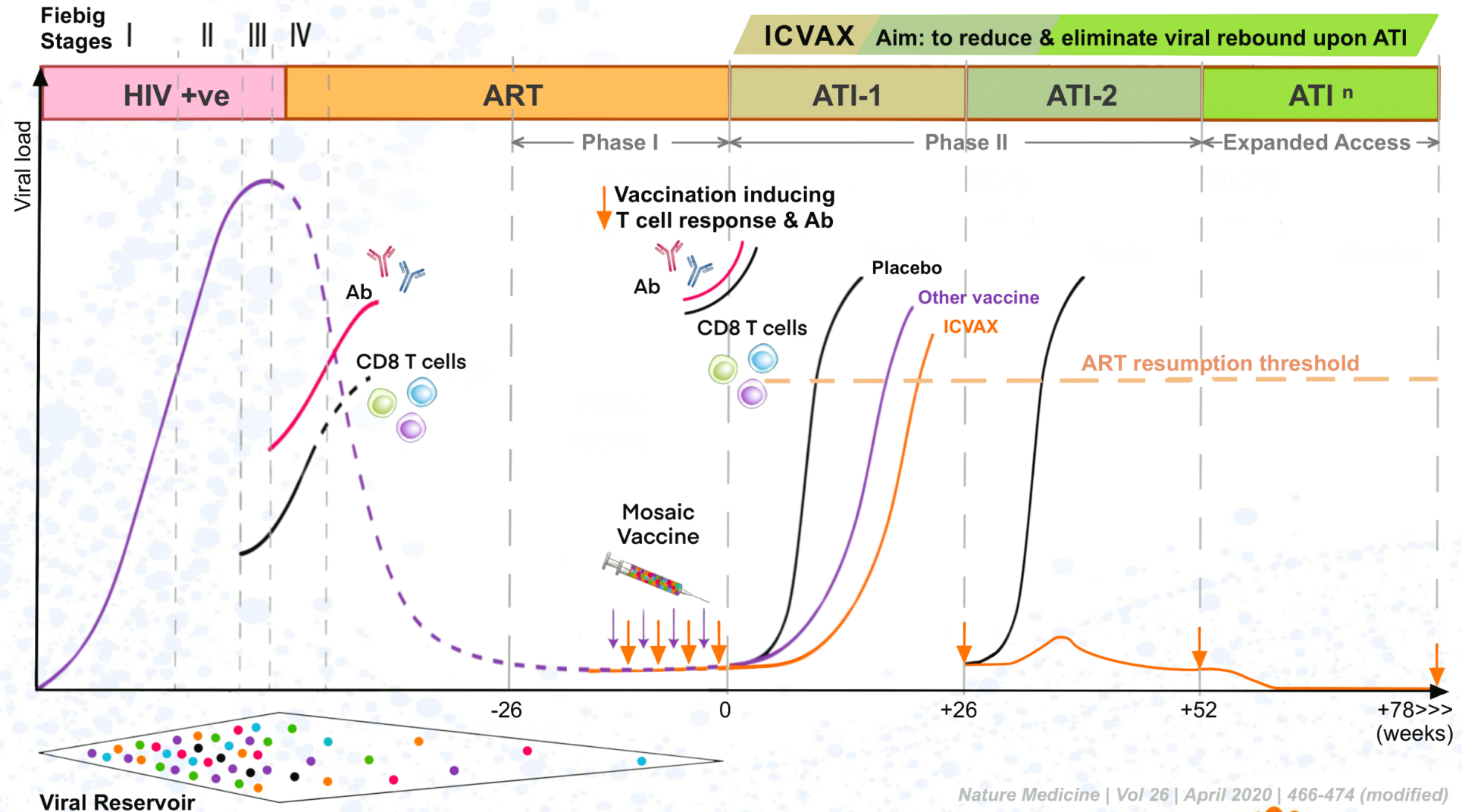
IIT: Investigator-Initiated Trial

ICVAX Immunogenicity & Preliminary Efficacy

Unpublished
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Multi-Centre ICVAX[®] Phase II Clinical Trial



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Acknowledgements



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深圳市第三人民医院
SHENZHEN THIRD PEOPLE'S HOSPITAL



Director And Tenured Chair Professor

Hospital Director,
Chief Physican & Professor



Department of Microbiology
Prof. ZHIWEI CHEN



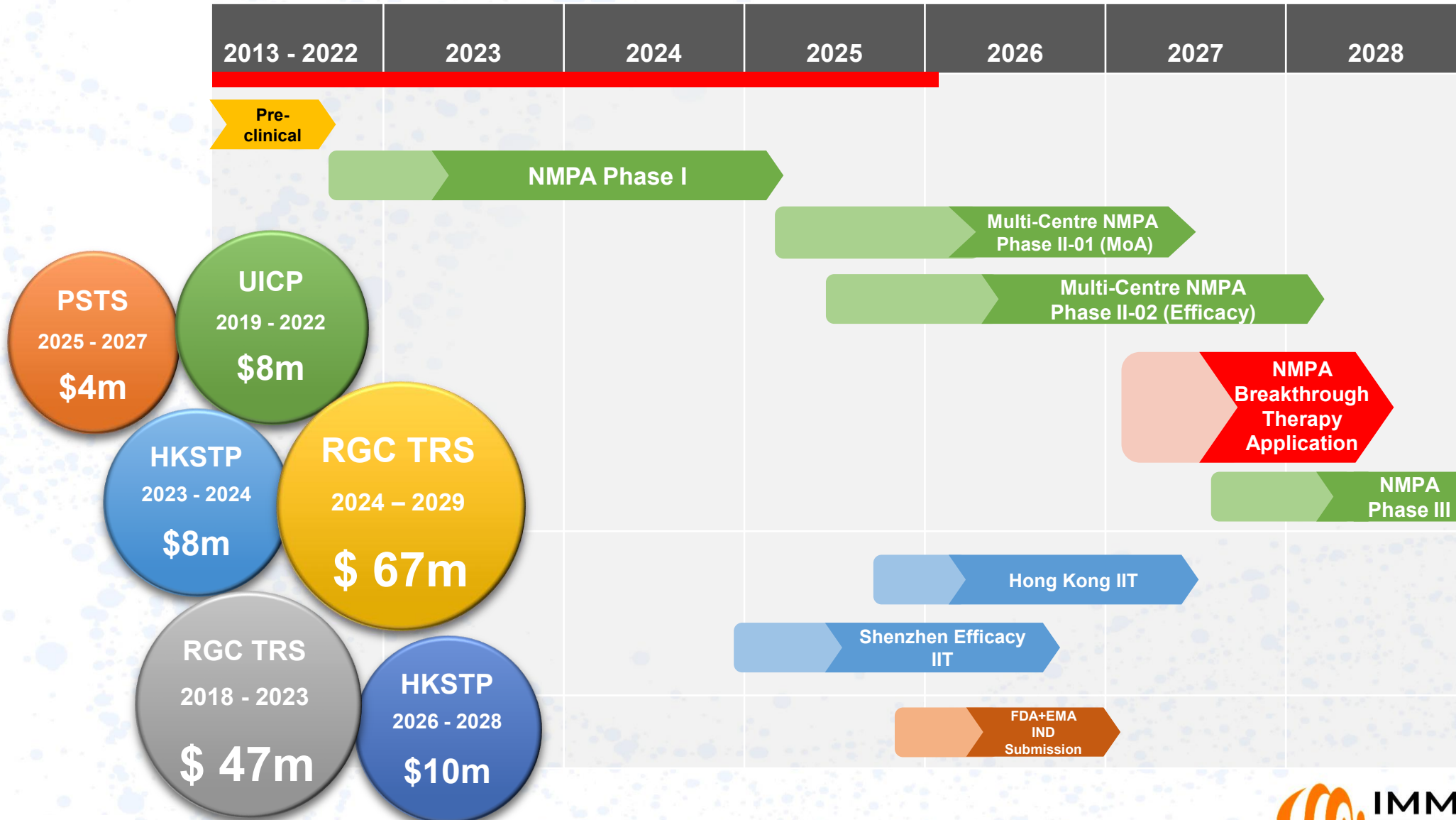
Lu Hongzhou, MD, PhD



Supplementary information

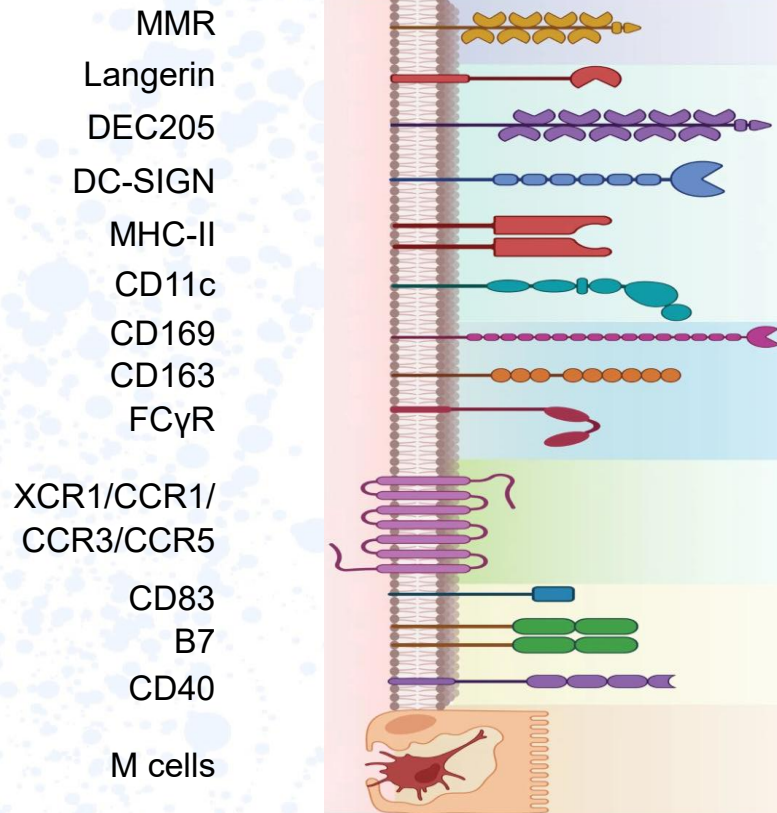


ICVAX[®] Product Development Roadmap



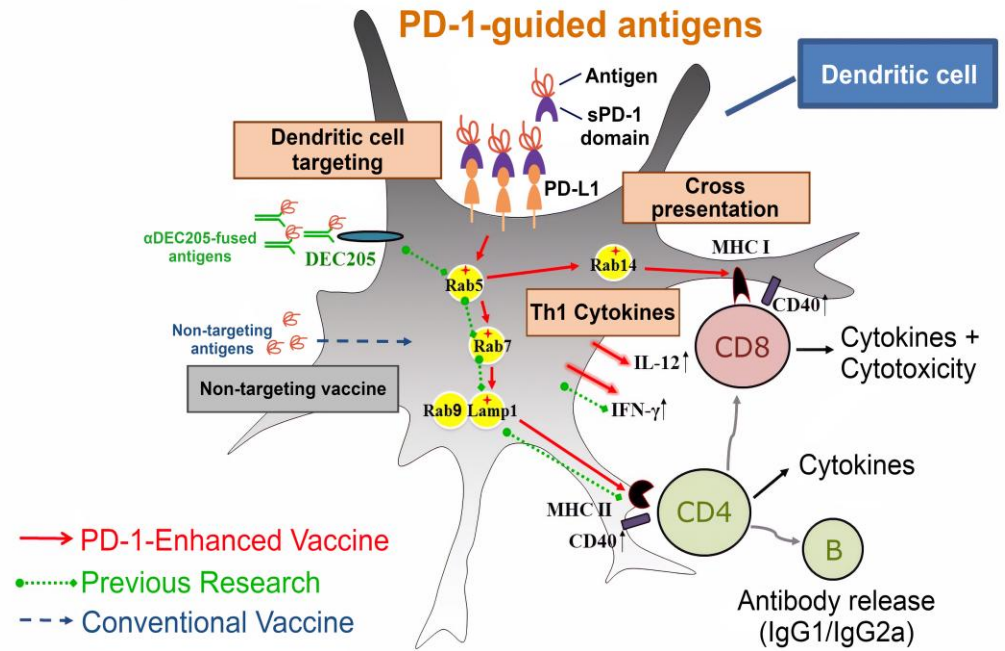
Third Generation: Precision Dendritic Cell Targeting

- Molecules explored for dendritic cell targeting
 - Majority are biased towards CD4⁺ T cell induction



- **PD-1-Enhanced DNA Vaccine Platform**

- PD-1 Guided Delivery
- Significantly enhances both **CD8⁺** and CD4⁺ T cell responses

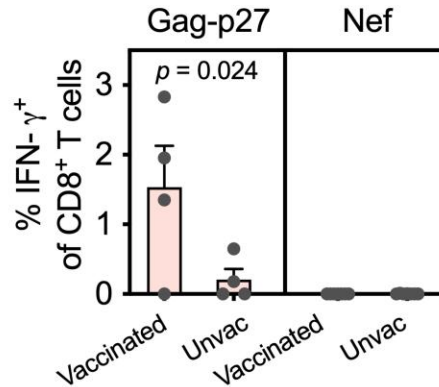


Modified: Zhou, et al. 2013. J Clin Invest.

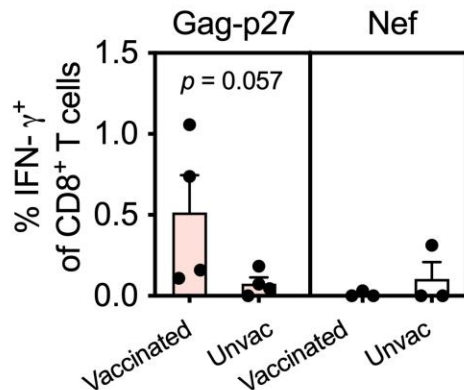
Immunogenicity Booster Remarkably Extends Survival

- Optimal regimen significantly enhanced anti-viral CD8⁺ T cell responses, leading to **sustained viral suppression** and **long-term survival** in macaques

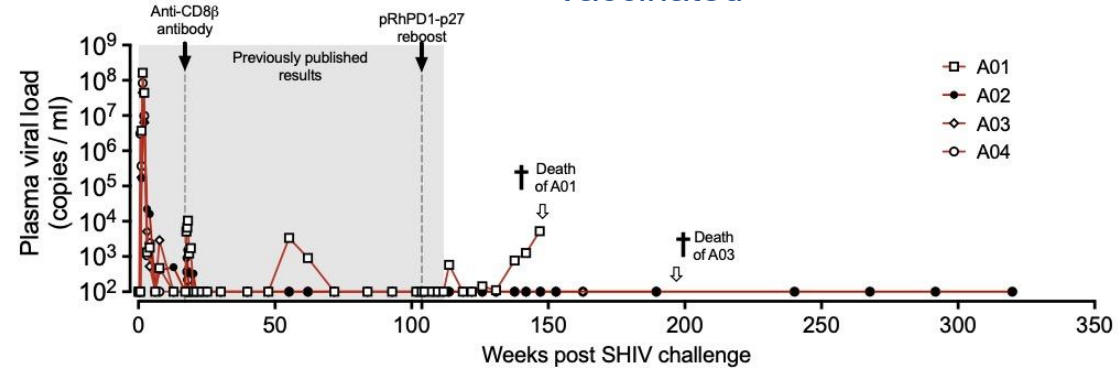
CD8⁺ T cell responses
4 weeks post infection



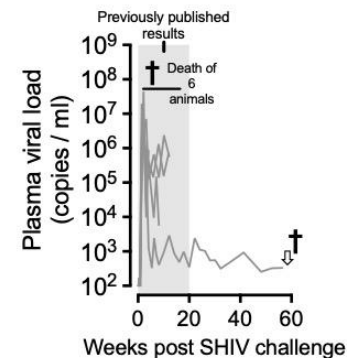
17 weeks post infection



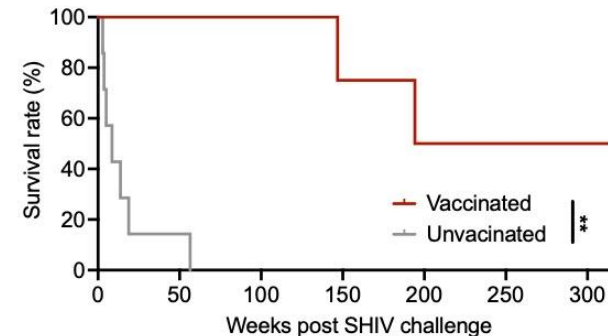
Viral load kinetics
Vaccinated



Viral load kinetics
Unvaccinated

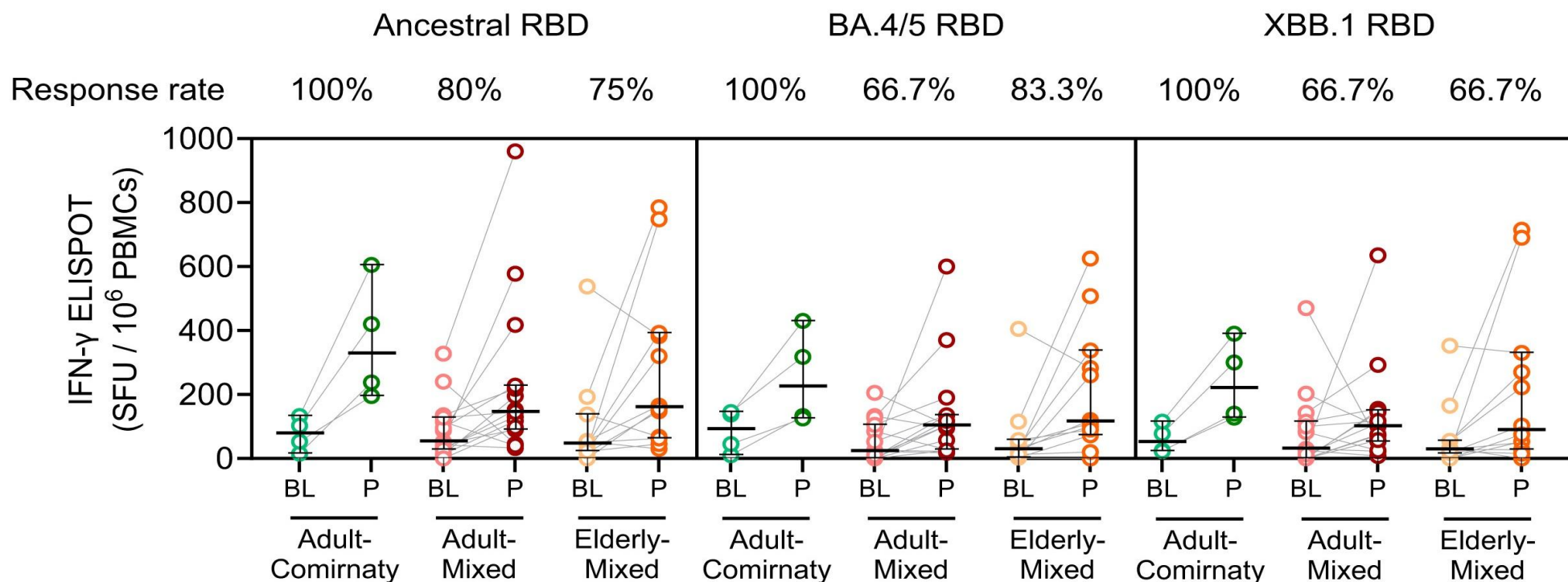


Long Term
Survival



Proof-of-Concept: a PD-1-Enhanced DNA Vaccine Clinical Study

PD-1 enhanced COVID-19 Booster DNA vaccine is safe and induces strong T cell immune responses, especially in elderly.



Wong, et al. 2025. eBioMedicine. 115:105699