Live, Attenuated, Recombinant Poxvirus-Based Vaccine Platform (RPV):

TNX-801: Mpox/ Smallpox Vaccine
TNX-1800: Next Generation Covid-19 Vaccine

NASDAQ: TNXP

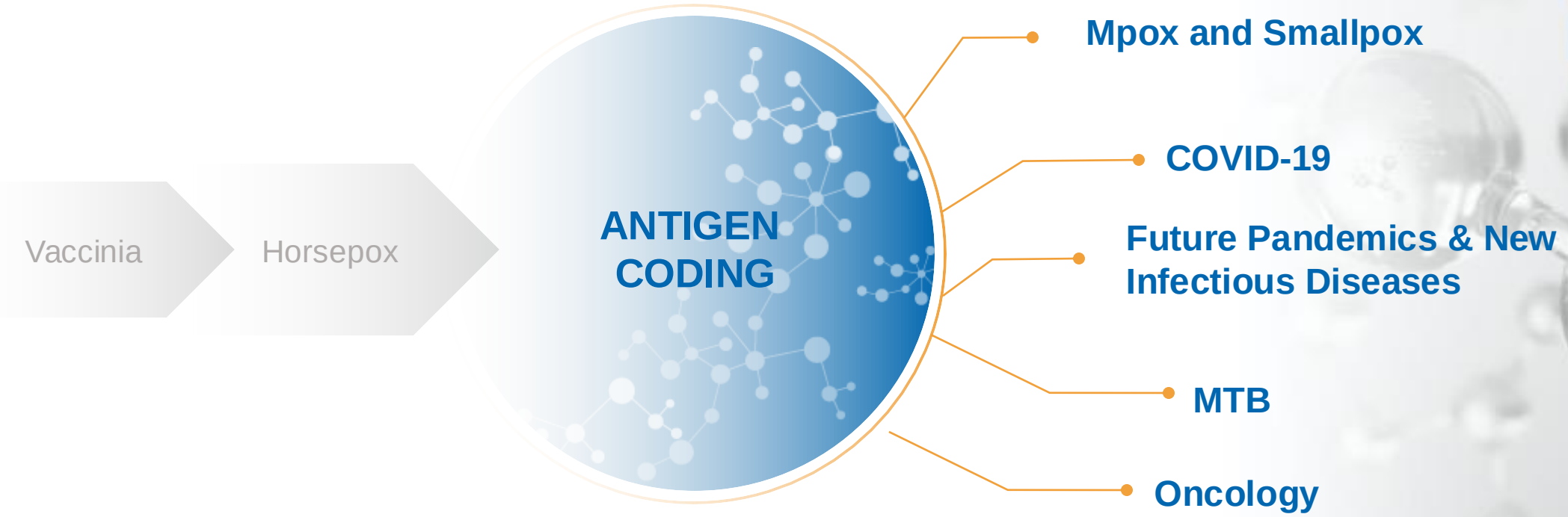
Version P0609 October 7, 2024 (Doc 1521)

Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate” and “intend,” among others. These forward-looking statements are based on Tonix’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the “SEC”) on April 1, 2024, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

TONIX PHARMACEUTICALS

Live Virus Vaccine Platform: Recombinant Pox Vaccine (RPV) Technology for Emerging Infectious Diseases and Oncolytics



RPV VECTOR BELIEVED SIMILAR TO EDWARD JENNER'S VACCINE[1-3]

Using Proven Science To Address Challenging Disease States, We are Developing A Programmable Technology Platform Aimed At Combating Future Threats To Public Health

INFECTIOUS DISEASE PORTFOLIO

[1]Shrick, 2017. *N Engl J Med* 377:1491-1492
[2]Esparza, 2020. *Vaccine*. 38(30): 4773–4779
[3]Brinkmann, 2020. *Genome Biol*. 21: 286

TONIX PHARMACEUTICALS

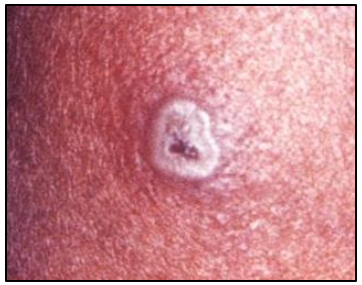
In 1796, Dr. Edward Jenner Introduced Vaccination to Protect Against Smallpox

Jenner observed that "vaccinia" was transmitted from horses to cows by farriers[1]

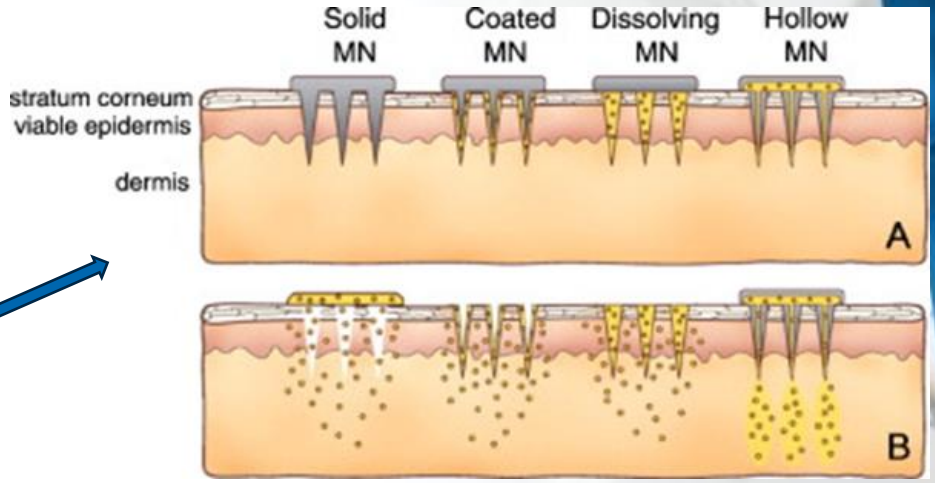
- NextGen Sequencing has shown **horsepox virus** was used as a vaccine during the 19th century[2,3]
- Potential **horsepox vaccine for smallpox** TNX-801 from synthetic biology under development[4]

- **Current administration**
  - Bifurcated needle
  - Percutaneous
  - No sterile injection required

- **Biomarker of protection**
  - Measure of T cell immunity[6]
  - Described by Jenner
  - Used in WHO accelerated eradication program



Take[5]



Microneedle Array Patch (MAP)[7]

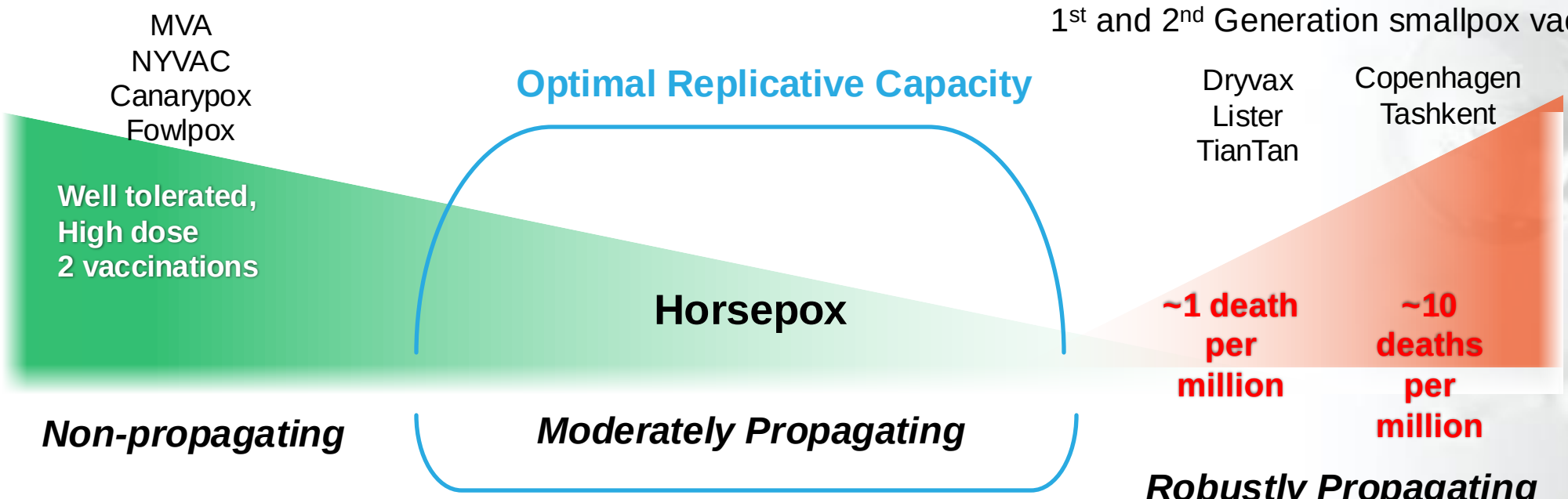
- Feasibility for horsepox under investigation

INFECTIOUS DISEASE PORTFOLIO

[1]Jenner E. "An Inquiry Into the Causes and Effects of the Variole Vaccinae, a Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire and Known by the Name of the cow-pox." London: Sampson Low, 1798.
[2]Schrick L et al. *N Engl J Med. (*2017*)* 377:1491-1492.
[3]Souza ARV, et al. *mBio*. (2023) 14(5):e0188723. doi: 10.1128/mbio.01887-23.
[4]TNX-801 is an investigational new biologic and is not approved for any indication
[5]Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=3276
[6]Fulginiti VA, et al. *Clin Infect Dis.* (2003) 37(2):241-250.
[7]Kim YC et al Advanced Drug Delivery Reviews 2012;64(14)1547-1568

TONIX PHARMACEUTICALS

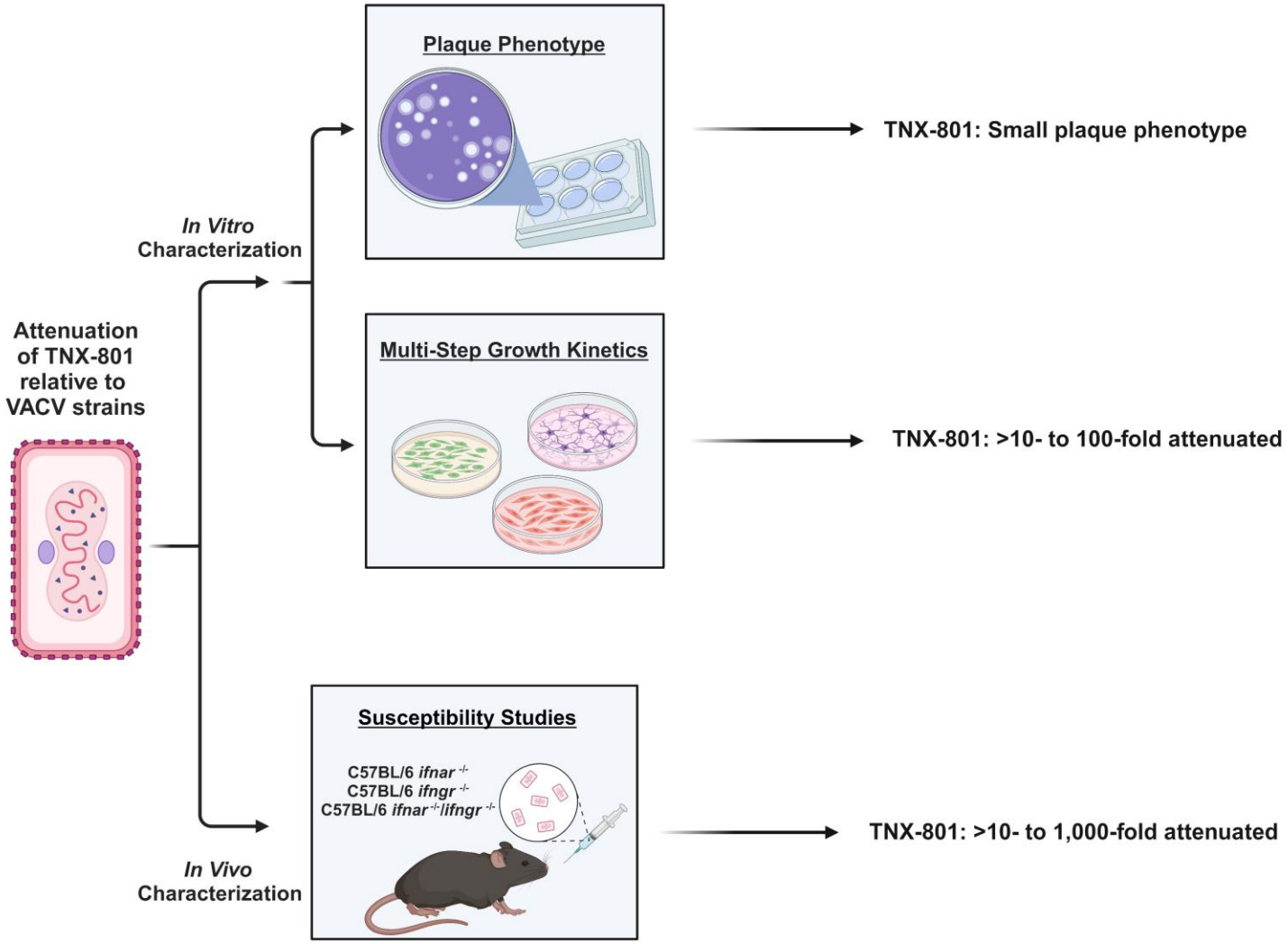
The Balance of Tolerability and Reactogenicity for Pox-based Vaccines



Replicating live-virus vaccines appear to stimulate innate, humoral and T cell immunity

INFECTIOUS DISEASE PORTFOLIO

TNX-801 is Attenuated >10-to-1,000-fold vs. Vaccinia (VACV) in Immunocompromised Mouse Model



Mpox Declared Public Health Emergency of International Concern (PHEIC) by WHO* on August 14, 2024: New Clade 1

- Clade 1 - first wave in Democratic Republic of Congo (DRC),
  - 10% mortality,
  - Affects children
- Additional emerging mutation,
  - ~0.5% mortality,
  - Affects both MSM (men who have sex with men) + heterosexual transmission primarily in adults
- 2024 mpox epidemic out-of-control in DRC has led to >20,000 cases mid-August caught and spread to 12 countries in Africa
- First cases identified in Kenya, Sweden, Thailand, Singapore and India
- Two FDA-approved vaccines:
  - Jynneos® (Bavarian-Nordic) – requires 2 dose regimen, durability of neutralization antibody titers being studied[1,2]; also approved for use in adults by the WHO[3]
  - ACAM 2000 (Emergent) – single-dose, reactogenic, provides durable protection; approved for people at high risk of mpox infection[4]; FDA approved for smallpox

*WHO = World Health Organization

[1]Zaeck LM, *Nat Med.* 2023 29(1):270-278. doi: 10.1038/s41591-022-02090

[2]Berens-Riha N, et al. *Euro Surveill.* 2022 27(48):2200894. doi: 10.2807/1560-7917.ES.2022.27.48.2200894.

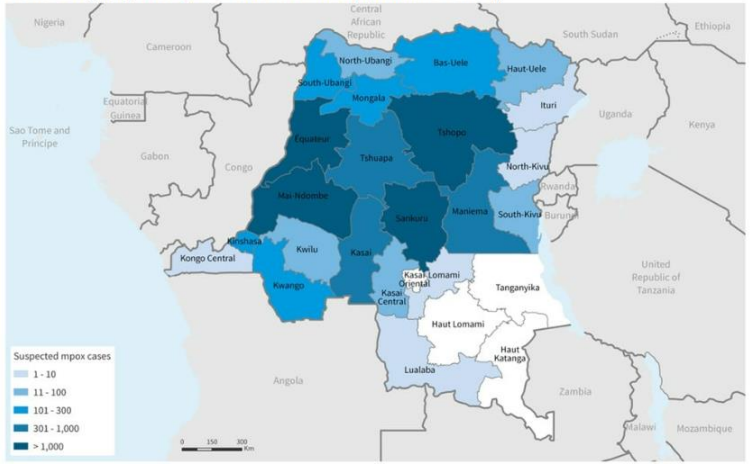
[3]Keaton, J. Sept. 13, 2024. *Associated Press.* "WHO grants first mpox vaccine approval to ramp up response to disease in Africa." URL: https://bit.ly/4e4yyeb

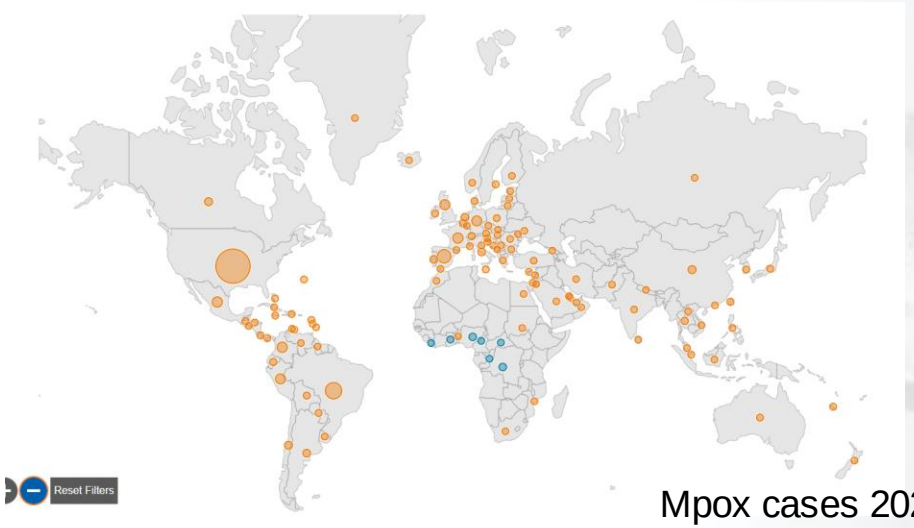
[4]https://www.fda.gov/vaccines-blood-biologics/vaccines/key-facts-about-vaccines-prevent-mpox-disease#:~:text=ACAM2000%20Vaccine,for%20smallpox%20or%20mpox%20infection.

EUA- Emergency Use Authorization

Mpox Remains a Threat in Africa and Worldwide

Figure 1: Geographic distribution of suspected mpox cases by province, Democratic Republic of the Congo, 1 January – 4 November 2023 (Epi weeks 1 to 44)





Mpox cases 2021-2023 (CDC)

REUTERS

WHO 'very worried' about spread of mpox in DRC

Jennifer Rigby

Fri, December 8, 2023 at 7:41 AM EST · 2 min read

CNN Health | Life, But Better | Fitness | Food | Sleep | Mindfulness | Relationships

Mpox cases in the US are on the rise as vaccination rates lag and new threats loom

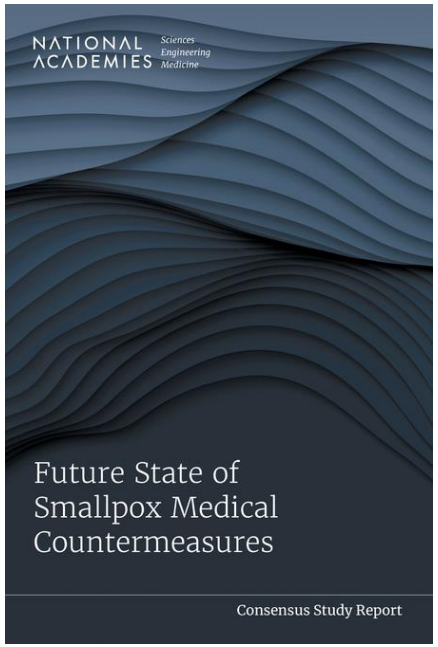
By Deidre McPhillips, CNN

6 minute read · Published 6:30 AM EDT, Thu March 28, 2024

WHO https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON493
Accessed 11/29/2023

Smallpox Preparedness is a Recognized Priority. National Stockpile Expansion is Predicted, Periodic Replenishment Required

Smallpox and other orthopoxviruses pose significant threats to the United States and the world due to their potential for weaponization, accidental release, and vulnerability of populations who stopped routinely vaccinating against smallpox in the 1970s.[1]



March 2024

(2-2) Smallpox vaccines that have improved safety across different population subgroups and are available as a single dose would support faster and more effective response to contain smallpox and other orthopoxvirus outbreaks. The development of novel smallpox vaccines using multi-vaccine platforms (i.e., use common vaccine vectors, manufacturing ingredients, and processes) would improve the capacity for rapid vaccine production in response to a smallpox event and reduce the need for stockpiling in the SNS at current levels.

TONIX PHARMACEUTICALS

TNX-801 Target Product Profile
Indications: Mpox, Smallpox, Other Emerging Orthopoxviruses

Attribute	TNX-801
Doses	1
Durability	>10 years
Breadth of Immunity	Broad- whole organism
Efficacy	>90% (Pan–orthopoxvirus including Mpox Clade 1)
Route	Microneedle patch
Stability	2º-8º C

Attribute	TNX-801
Scalability	Standard Viral Vaccine Mfg
Attenuation	10-1000x more attenuated than VACV
Safety Risk	Low
Intended Population	All
Blacks Forward Transmission	
Affordable	

INFECTIOUS DISEASE PORTFOLIO

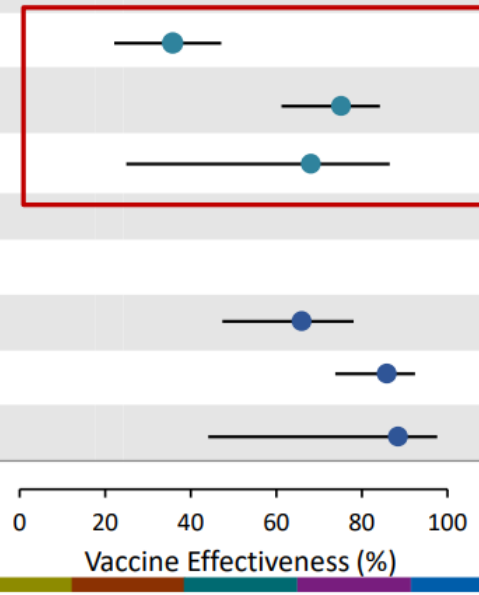
TNX-801 is an investigational biologic in the pre-IND stage of development

TONIX PHARMACEUTICALS

An Effective Single-Dose Mpox Vaccine Could Increase Protection and Improve Coverage Compared to a Two-Dose Regimen

Vaccine effectiveness of JYNNEOS against mpox ranges from 36%–75% for 1-dose vaccination and 66%–89% for 2-dose vaccination

	Cases	Controls	Adjusted* VE (95% CI)
1-dose JYNNEOS			
Epic Cosmos case-control study	146	1000	36% (22–47)
Multi-jurisdictional case-control study	58	237	75% (61–84)
New York State case-control study	10	23	68% (25–86)
2-dose JYNNEOS			
Epic Cosmos case-control study	25	335	66% (47–78)
Multi-jurisdictional case-control study	14	122	86% (74–89)
New York State case-control study	2	19	89% (44–98)



CDC/ ACIP Oct 25, 2023

U.S. Mpox Vaccine Coverage in High- Risk Groups (CDC)

1-dose: 38.8%
2-dose: 24.3%

37% Drop Out

INFECTIOUS DISEASE PORTFOLIO

TONIX PHARMACEUTICALS

TNX-801: Global Vaccine Equity Advantages

Potentially much lower relative price than incumbent

- One dose
- Smaller dose
- High scale manufacturing using existing, standard technologies

Competition in marketplace with second vaccine: Drives affordability

One-dose vaccine

- Allows for ring vaccination strategy
- Eliminates dropout between doses
- Improves on real-world vaccine effectiveness

Microneedle one-dose delivery

- Improves local accessibility
- Improves acceptability and higher coverage rates

Free up vaccine supplies for countries now without access

Enable WHO global stockpile for developing countries

TNX-801: Immunogenicity and Efficacy in Non-Human Primates (NHPs)

viruses

MDPI

Article

Single Dose of Recombinant Chimeric Horsepox Virus (TNX-801) Vaccination Protects Macaques from Lethal Monkeypox Challenge

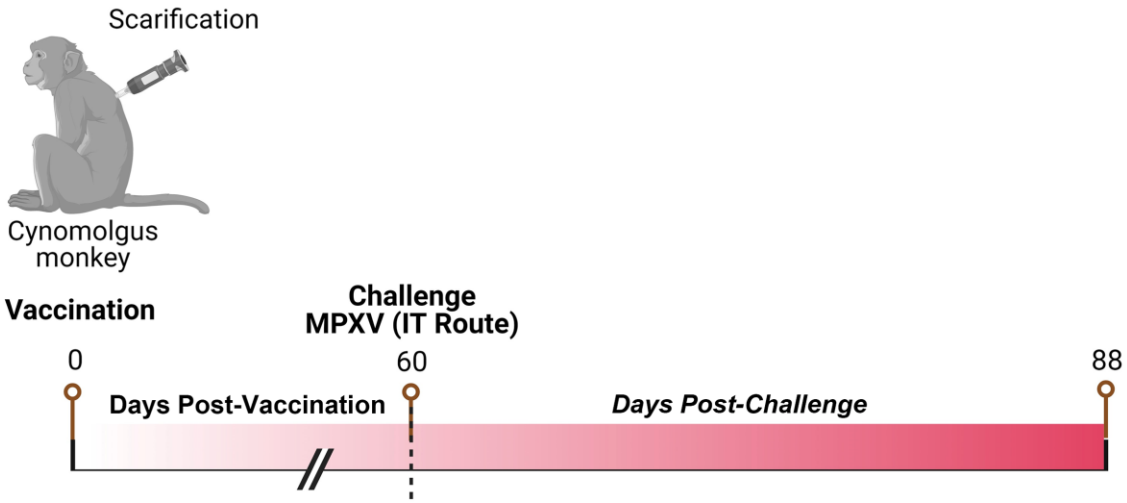
Ryan S. Noyce [1], Landon W. Westfall [2,†], Siobhan Fogarty [3], Karen Gilbert [2], Onesmo Mpanju [4], Helen Stillwell [3,‡], José Esparza [5], Bruce Daugherty [3], Fusataka Koide [2], David H. Evans [1] and Seth Lederman [3,*]

Vaccine administered with bifurcated needle

Immunogenicity and Efficacy in NHPs: Study Design

Vaccination					Challenge		
Group	Vaccine	N	Dose (Log_{10} PFU)	Route	*Virus*	*Dose (Log_{10} PFU)*	*Route*
1	TNX-801 (High)	4	6.6	Scarification	*MPXV (Zaire)*	*5.0*	*IT*
2	TNX-801 (Low)	4	5.7	Scarification	*MPXV (Zaire)*	*5.0*	*IT*
3	rVACV	4	5.0	Scarification	*MPXV (Zaire)*	*5.0*	*IT*
4	Mock	4	-	Scarification	*MPXV (Zaire)*	*5.0*	*IT*

rVACV = Plaque pick from ACAM2000 (Approved Vaccine)

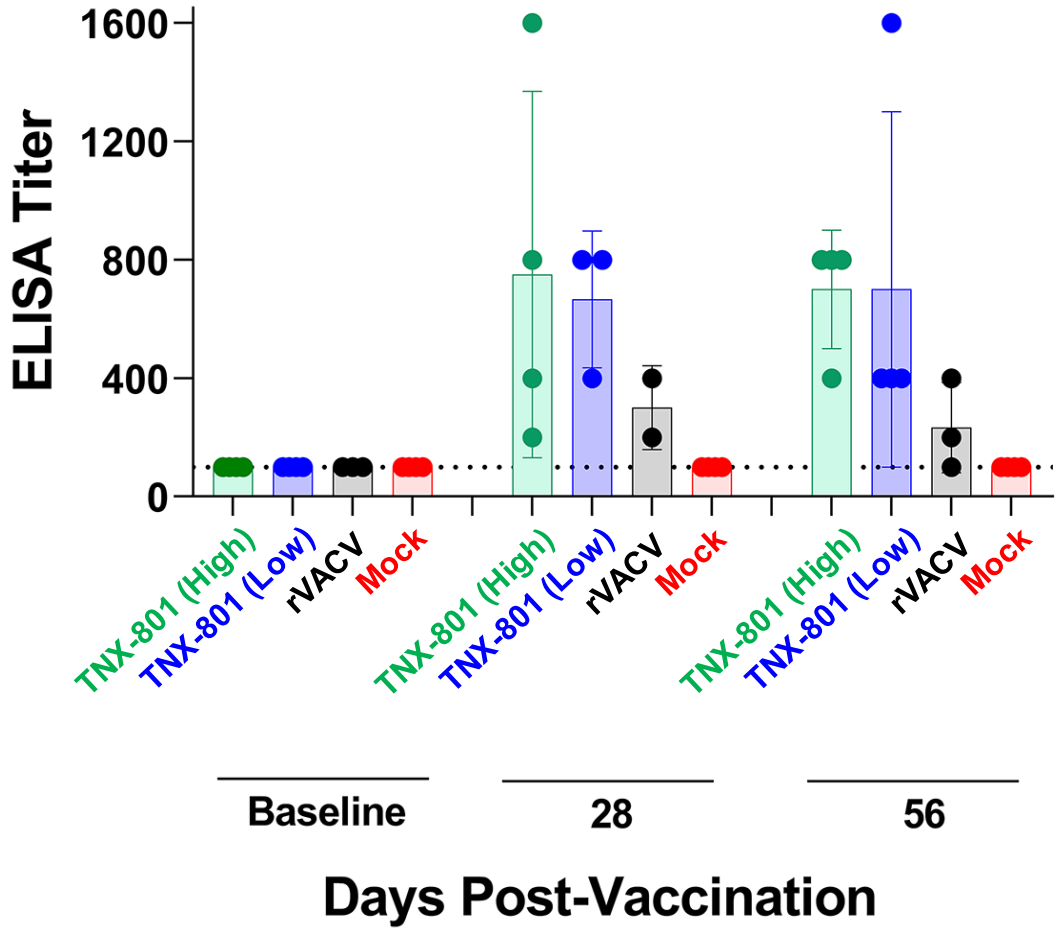


"Take" observed in all TNX-801 vaccinated NHPs except one

Post-vaccination, no NHP showed lesions during first 60 days

Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

TNX-801 Immunogenicity: 100% Seroconversion

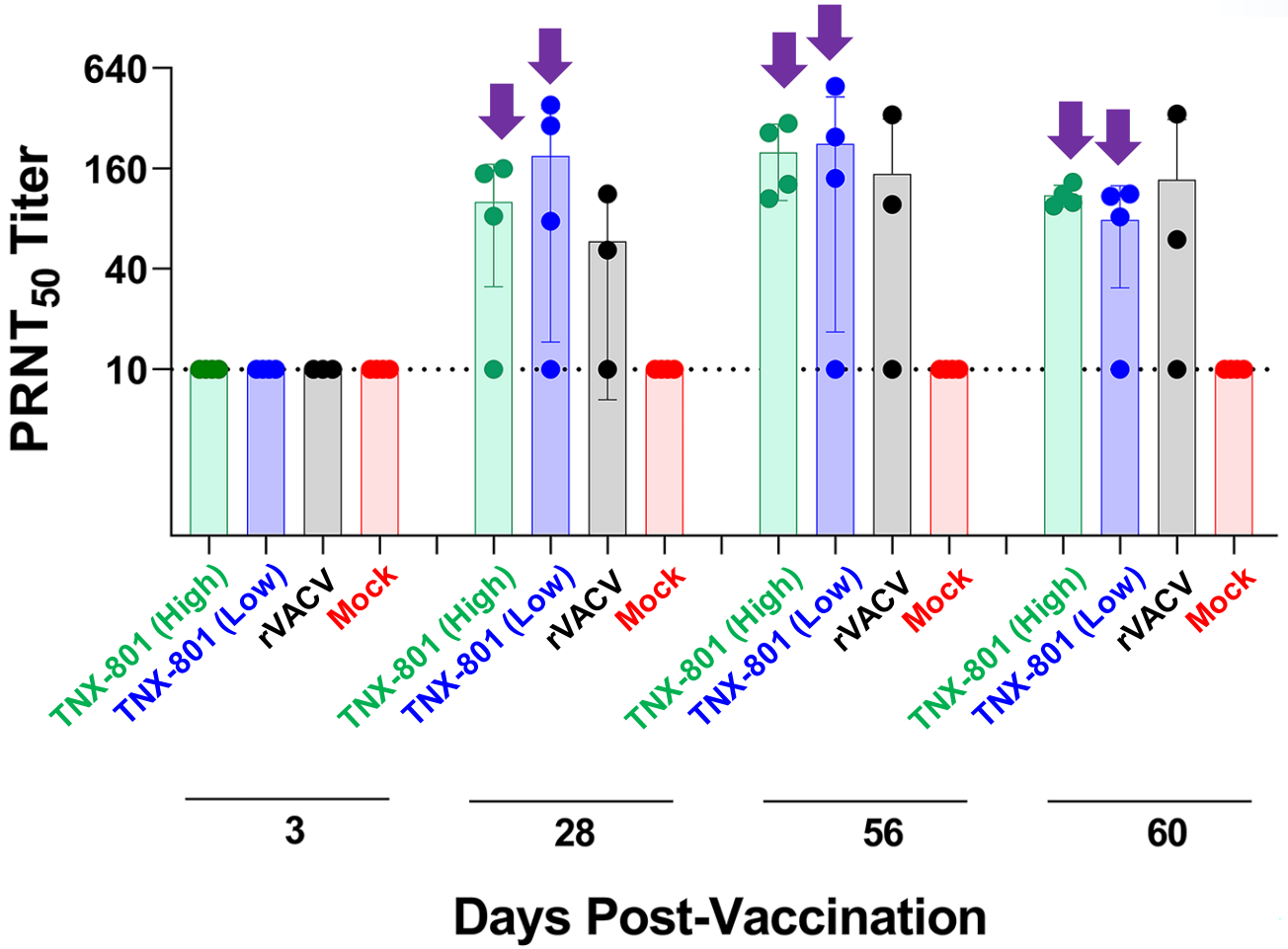


100% seroconversion in Tonix-801 vaccinated groups with antibody titers 2- to 16-fold higher than baseline by day 28 and 4-to 8–fold higher at day 56

Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

TNX-801 Immunogenicity: Neutralizing Antibody

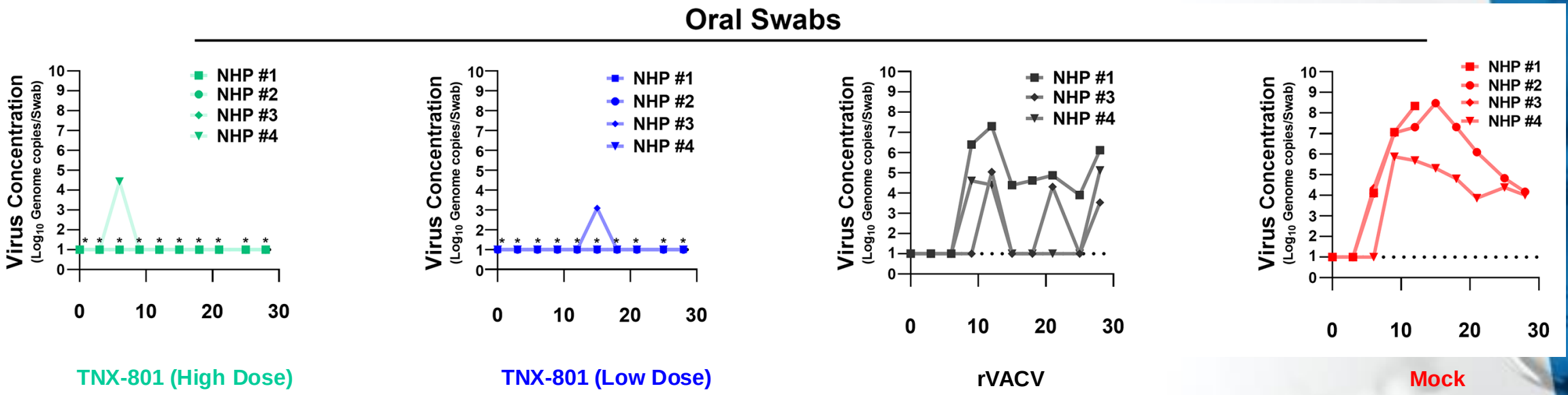
(PRNT$_{50}$ Assay)



88% of TNX-801 vaccinated NHPs had neutralizing antibody responses 8- to 50-fold from baseline

Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

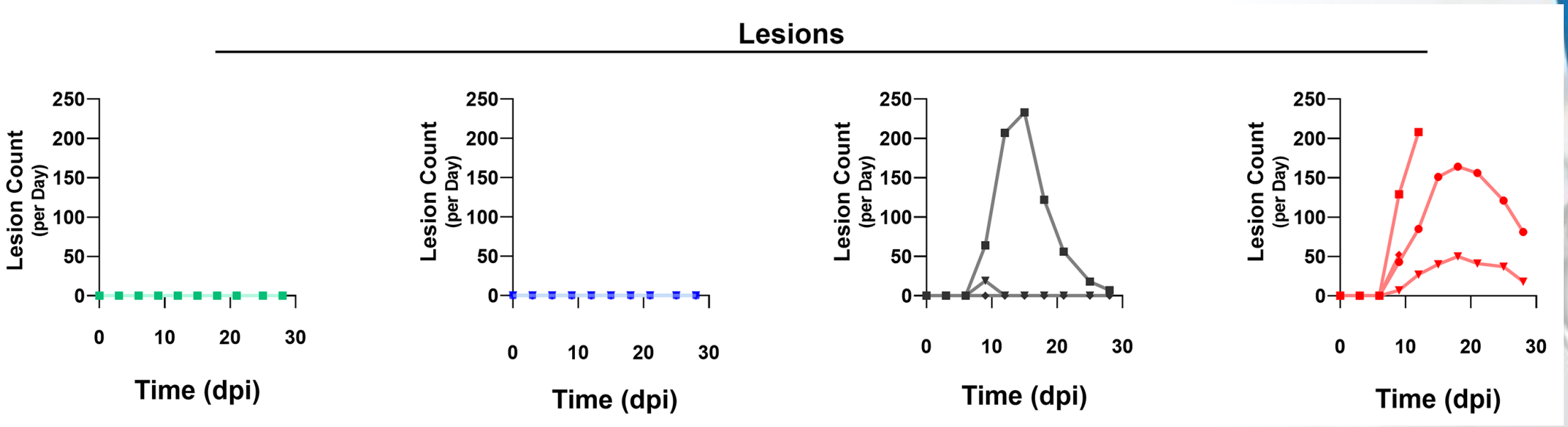
TNX-801 Virus Shedding: Minimal/No Shedding



Potential to Reduce Forward Transmission

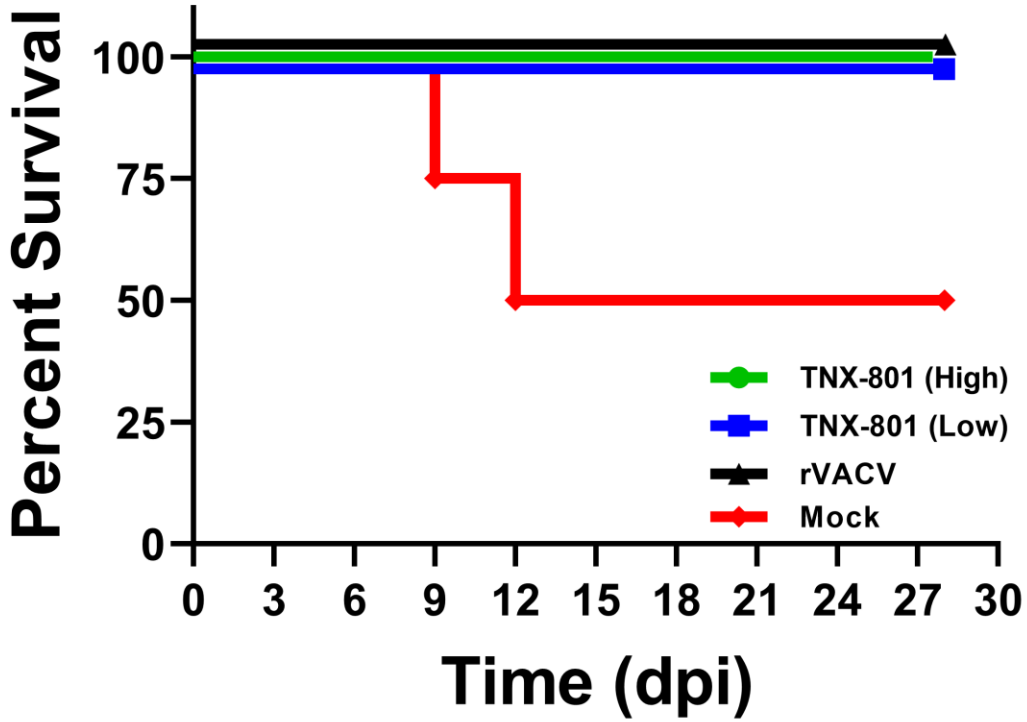
Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

Clinical Disease: No Lesions Were Observed in the TNX-801 Vaccinated Groups



Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

Survival: 100% of TNX-801 Vaccinated NHPs Survived Lethal Challenge

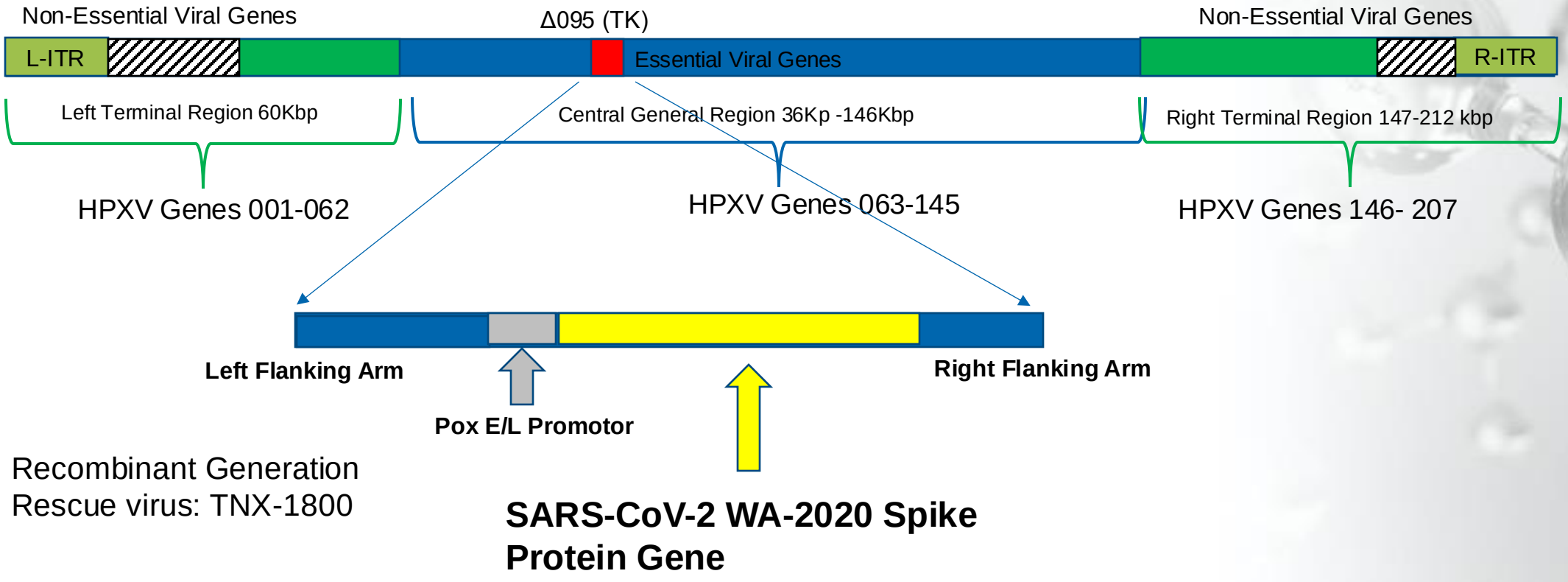


No deaths in Tonix-801 vaccinated groups

Noyce *et al*. Viruses. 2023 Jan 26;15(2):356.

TNX 801 Vaccine Platform Can Carry Multiple Genes Such as Spike Protein: Next Generation SARS-CoV-2 Vaccine (TNX-1800*)

Development of HPXV as a recombinant Delivery Vector Platform

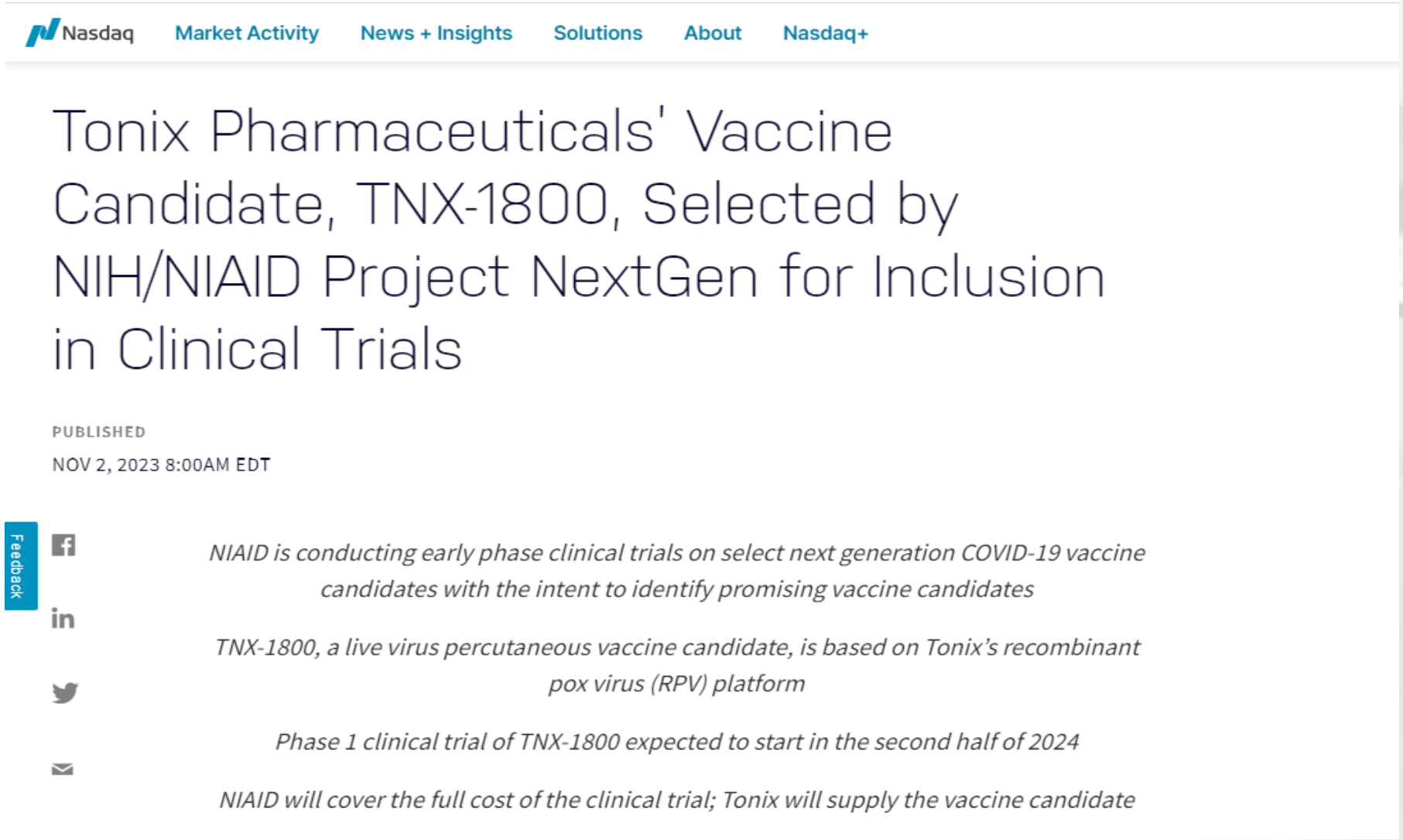


Recombinant Generation
Rescue virus: TNX-1800

SARS-CoV-2 WA-2020 Spike Protein Gene

*TNX-1800 has not been approved for any indication

TNX-1800: The Tonix RPV Platform Selected by NIH/NIAID for Project NextGen COVID-19 Vaccine



Nasdaq Market Activity News + Insights Solutions About Nasdaq+

Tonix Pharmaceuticals' Vaccine Candidate, TNX-1800, Selected by NIH/NIAID Project NextGen for Inclusion in Clinical Trials

PUBLISHED

NOV 2, 2023 8:00AM EDT

Feedback

NIAID is conducting early phase clinical trials on select next generation COVID-19 vaccine candidates with the intent to identify promising vaccine candidates

TNX-1800, a live virus percutaneous vaccine candidate, is based on Tonix's recombinant pox virus (RPV) platform

Phase 1 clinical trial of TNX-1800 expected to start in the second half of 2024

NIAID will cover the full cost of the clinical trial; Tonix will supply the vaccine candidate

THANK YOU