UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): April 6, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On April 6, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") presented data from its live virus vaccine platform development program in two oral presentations at the World Vaccine Congress held April 3-6, 2023 (the "Presentations"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. The Presentations, which may contain nonpublic information, are filed as Exhibits 99.02 and 99.03 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01, 99.02 and 99.03 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On April 6, 2023, the Company presented data from the Presentations entitled "*TNX-801: Live Attenuated Orthopoxvirus (Horsepox) Vaccine for Mpox and Smallpox*" and "*The Development of Horsepox virus as a vaccine platform: Evaluation of TNX-1800 as a SARS-CoV-2 Vaccine*," which describe the history of live virus vaccines and the rationale for the development of the Company's Recombinant Pox Virus platform.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe,"

“estimate,” “potential,” “predict,” “project,” “should,” “would” and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company’s filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, dated April 6, 2023
99.02	TNX-801: Live Attenuated Orthopoxvirus (Horsepox) Vaccine for Mpox and Smallpox
99.03	The Development of Horsepox virus as a vaccine platform: Evaluation of TNX-1800 as a SARS-CoV-2 Vaccine
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: April 6, 2023

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.1

Tonix Pharmaceuticals Presents Data from its Vaccine Development Program at the World Vaccine Congress

Preclinical data demonstrate the efficacy of TNX-801 vaccination against mpox virus challenge in a non-human primate model

Phase 1 trial with TNX-801 for the prevention of mpox and smallpox is expected to start in the second half of 2023

CHATHAM, N.J., April 6, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, presented data from its live virus vaccine platform development program in two oral presentations at the World Vaccine Congress being held in Washington D.C., April 3-6, 2023. Copies of the Company's presentations are available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com.

"Tonix's live virus vaccine technology is designed to help protect against emerging infectious diseases by providing durable protection, and can be widely deployed without the need for sterile injection or ultra-cold shipping and storage," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Our lead vaccine candidate, TNX-801, is a live virus vaccine in development to protect against monkeypox ('mpox') and smallpox. We believe TNX-801 is closer in genetic structure and properties to the smallpox vaccines used in the U.S. and Europe before 1900 than the modern vaccinia smallpox vaccines. Relative to modern vaccinia vaccines, TNX-801 has reduced virulence in animals, and we believe it has the potential for widespread use to protect against mpox and smallpox."

The presentation, titled, "*TNX-801: A Live Attenuated Orthopoxvirus (Horsepox) Vaccine for Mpox and Smallpox*," describes the history of live virus vaccines and the rationale for the development of the Company's Recombinant Pox Virus (RPV) platform. The presentation demonstrates that non-human primates vaccinated with TNX-801 were fully protected with sterilizing immunity from a lethal challenge.

The presentation, titled, "*The Development of Horsepox virus as a vaccine platform: Evaluation of TNX-1800 as a SARS-CoV-2 Vaccine*," describes TNX-1800, a live virus vaccine based on the horsepox viral vector platform, which was developed to protect against COVID-19. The presentation shows that in animal testing, TNX-1800 protected upper and lower airways after challenge with SARS-CoV-2, suggesting an ability to block forward transmission. TNX-1800 is an example of the ability of Tonix's adaptable vaccine platform to protect against emerging threats and future pandemics.

About TNX-801

TNX-801 is a live virus vaccine based on horsepox[2,3]. Tonix is developing TNX-801 for percutaneous administration as a vaccine to protect against mpox and smallpox. Tonix's TNX-801 is based on the sequence of the 1976 natural isolate Mongolian horsepox clone MNR-763. [2] Molecular analysis of DNA sequences suggests that TNX-801 is closer than modern smallpox vaccines to the vaccine discovered and disseminated by Dr. Edward Jenner in 1798[4-6]. For example, recent studies[7,8] have shown approximately 99.7% colinear identity between TNX-801 and the circa 1860 U.S. smallpox vaccine VK05.[9] The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[10]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Dr. Edward Jenner invented vaccination in 1798 and the procedure was called "vaccination" because 'cow' is 'vacca' in Latin and the inoculum material was initially obtained from lesions on the udders of cows affected by a mild disease known as cowpox. However, Dr. Jenner suspected that cowpox originated from horses[6]. Subsequently, Dr. Jenner and others immunized against smallpox using material directly obtained from horses. The use of vaccines from horses was sometimes called 'equination' from the Latin 'equus' which means 'horse'[11]. Equination and vaccination were practiced side-by-side in Europe[11,12].

About the Recombinant Pox Virus (RPV) Platform

Horsepox virus and vaccines based on its use as a vector are live replicating viruses that elicit strong immune responses. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been exploited as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) manufacturable at scale, and (7) ability to provide direct antigen presentation. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials. Tonix's TNX-801 and RPV vaccine candidates are administered percutaneously using a two-pronged, or "bifurcated" needle. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796 and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox, a respiratory-transmitted disease caused by variola.

About Mpox and Smallpox

Mpox[13] and smallpox[14] are diseases in humans caused by the mpox and smallpox (or variola) viruses, respectively. Mpox and variola are closely related orthopox viruses. Vaccination against smallpox with live virus vaccines based on horsepox or vaccinia protects against mpox. After routine smallpox vaccination was stopped in about 1970, mpox has become a growing problem in Africa. Since May of 2022, approximately 30,000 cases have been identified in the United States[15,16]. There are two distinct clades of the mpox virus: the central African (Congo Basin) clade, and the west African clade which is associated with the recent outbreak. Historically, the Congo Basin clade has caused more severe disease than the west African clade. In recent times, the case fatality ratio for the virus is about 3–6%[17]. In November 2022, the WHO began using a new preferred term "mpox" as a synonym for monkeypox[18]. Smallpox is considered eradicated, but there are concerns about malicious reintroduction.

Tonix Pharmaceuticals Holding Corp.[1]

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with interim data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the second quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the second half of 2023. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

This press release and further information about Tonix can be found at www.tonixpharma.com.

[1] *All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

[2] *Noyce RS, et al. (2018) PLoS One. 13(1):e0188453*

[3] *Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536*

[4] *Schrick L et al. (2017) N Engl J Med. 377:1491.*

[5] *Qin et al. (2015) J. Virol. 89:1809.*

[6] *Jenner E. "An Inquiry Into the Causes and Effects of the Variolae 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.*

[7] *Brinkmann A et al, Genome Biology (2020) 21:286 https://doi.org/10.1186/s13059-020-02202-0*

[8] *Duggan A et al. Genome Biology (2020) 21:175 https://doi.org/10.1186/s13059-020-02079-z*

[9] *Tonix press release. Dec 4, 2020 https://ir.tonixpharma.com/news-events/press-releases/detail/1236/vaccine-genome-researchers-report-99-7-colinear-identity*

[10] *Trindale GS et al. (2016) Viruses (12). Pii: E328. PMID:27973399*

[11] *Esparza E, et al (2017) Vaccine. 35(52):7222-7230.*

[12] *Esparza J et al. (2020) Vaccine.; 38(30):4773-4779.*

[13] *www.cdc.gov/poxvirus/monkeypox/about.html*

[14] *www.cdc.gov/smallpox/research/*

[15] *Mandavilli, A. The New York Times. May 26, 2020. "Who is protected against monkeypox"*

[16] www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html - Accessed Feb 8, 2023

[17] https://www.who.int/news-room/fact-sheets/detail/monkeypox#:~:text=There%20are%20two%20distinct%20genetic,thought%20to%20be%20more%20transmissible – Accessed Feb 8, 2023

[18] https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease - Accessed Feb 8, 2023

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of 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," "expect," 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, risks related to the 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, and periodic 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. The information set forth herein speaks only as of the date thereof.

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Exhibit 99.02

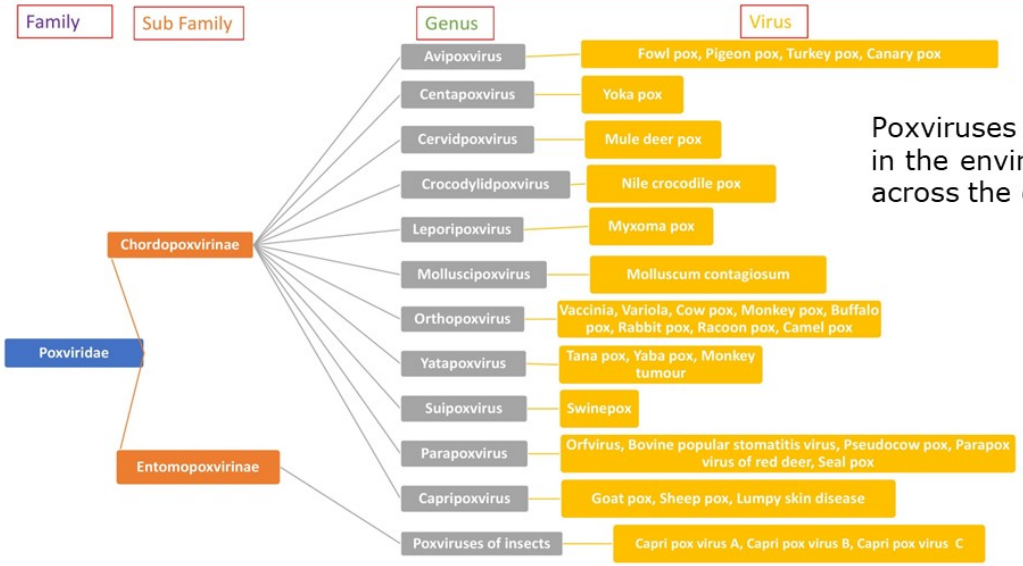
Cautionary Note on Forward-Looking Statements

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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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.

Poxviruses

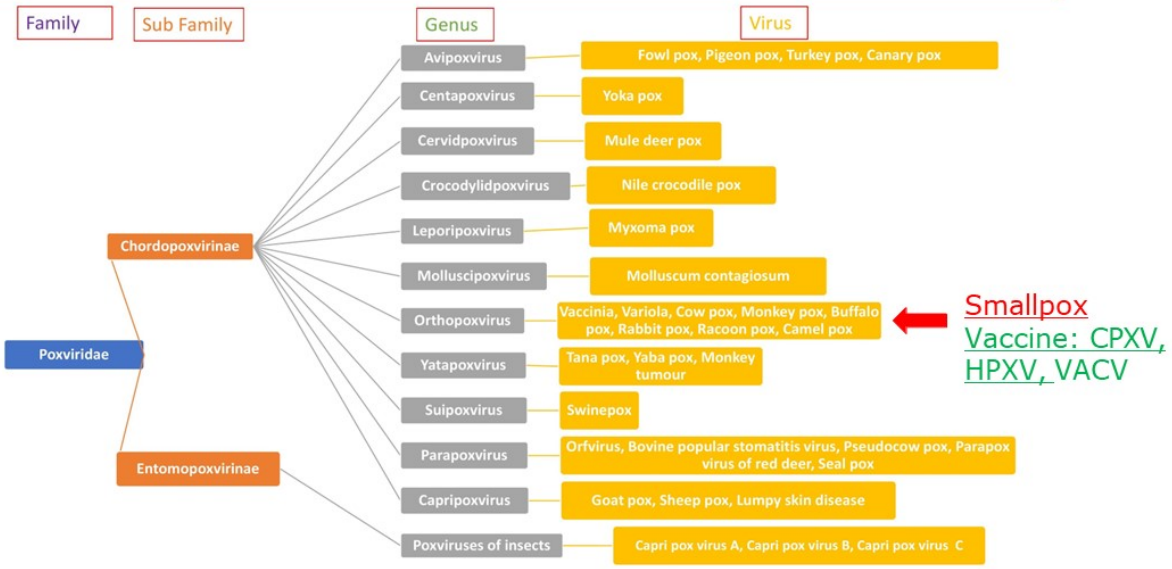
- Family: ***Poxviridae***
- Two subfamilies:
  1) *Chordopoxvirinae*
  2) *Entomopoxvirinae*
- 22 Genera
- Double stranded DNA, enveloped, ~128-380kb
- Virions: brick-shaped, ~250 x 350 nm
- Infect vertebrate and invertebrate hosts

Poxviruses



Poxviruses are ubiquitous in the environment across the globe

Orthopox Viruses

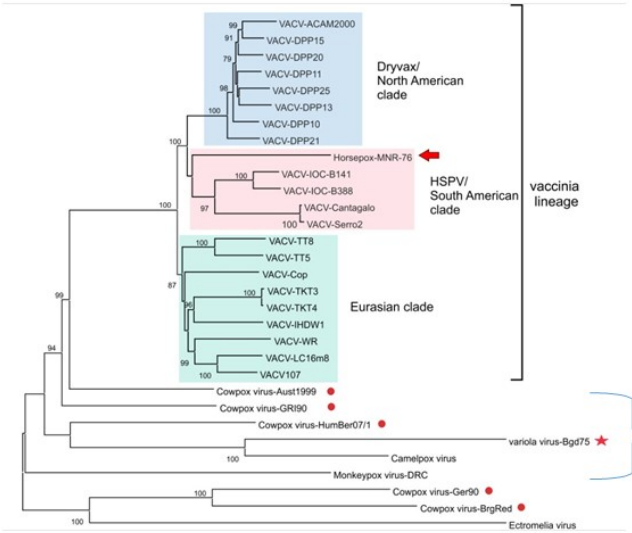


In 1796, Edward Jenner Successfully Used Vaccination to Protect Against Smallpox

- Jenner observed milkmaids were protected from smallpox, reasoned that infection with an illness similar to smallpox but less deadly could protect one against smallpox
  - "Cowpox" was the name of a disease in cows that could transfer to humans and cause sores
  - Jenner "vaccinated" (from *vacca*, Latin for "cow") a patient with pustule matter from "cowpox" sores on a milkmaid's hands; that patient remained healthy when challenged with smallpox virus
- Jenner suspected that the agent causing cowpox, which he called **vaccinia**, actually originated in horses and had been transferred from horses to cows' udders by dirty hands

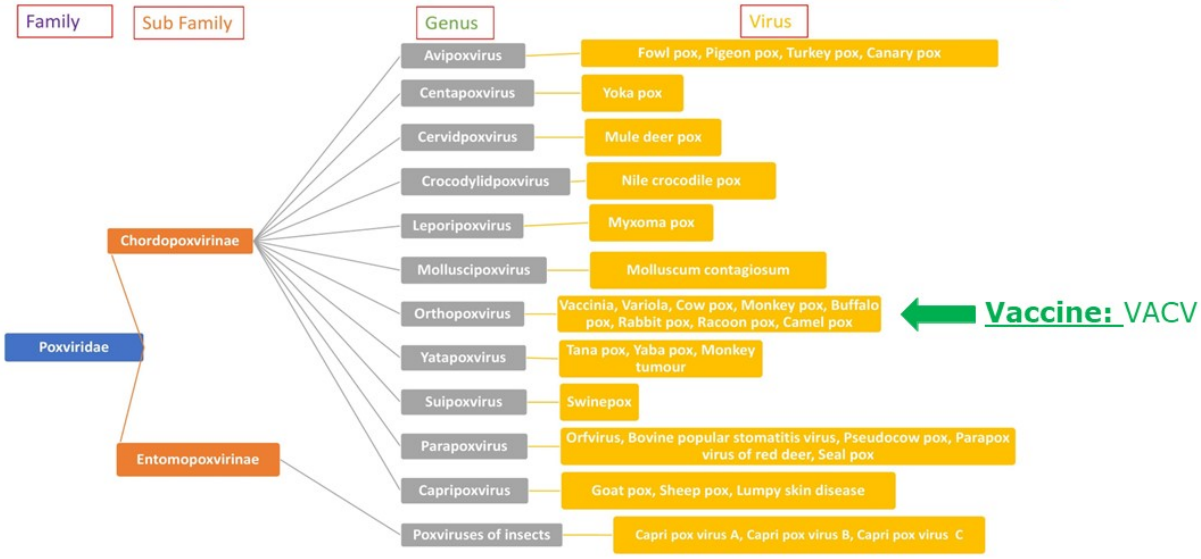
The College of Physicians of Philadelphia. Accessed July 15, 2021. https://www.historyofvaccines.org

Phylogenetic Tree of Genus *Orthopox*



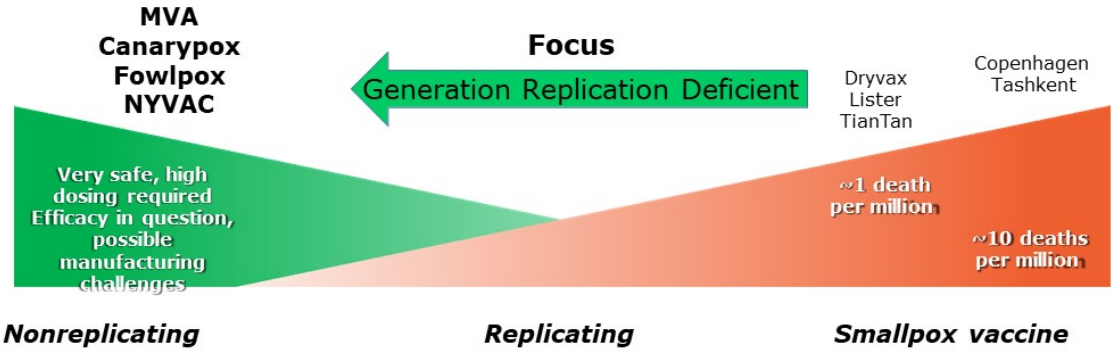
Cowpox close orthopox relative to smallpox (Variola)
Conferred protection against Variola

Orthopox Viruses; Poxvirus-based Vaccines



Recombinant Pox-based Vector Development Addressing "Safety" minimization of Adverse Events

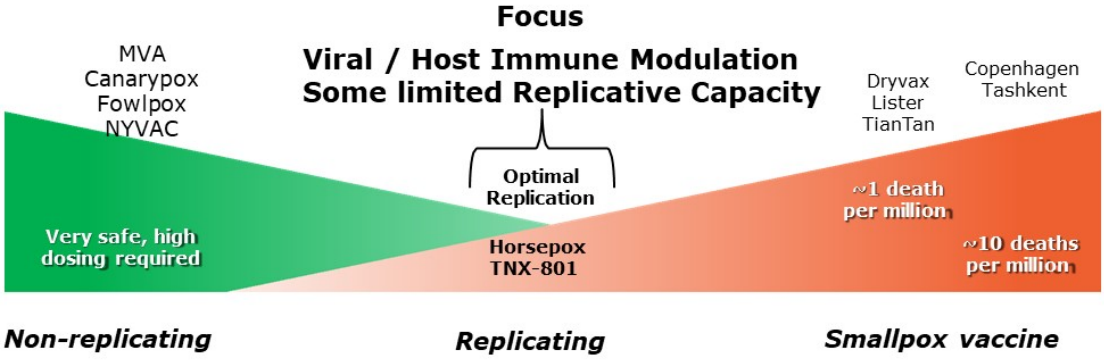
- Three decades pox-vector modifications and engineering focused on the generation of *replication deficient (RD) vectors*



Recombinant Pox-based Vector Development Addressing "Safety" minimization of Adverse Events

Considering the overall body of data from RD pox-based vectors
Have we gone to far in vector engineering requiring *RD*?

- Safety data is great but immunological responses are typically weak or suboptimal immune responses
- *Some Replicative Capacity is essential, Horsepox TNX-801**



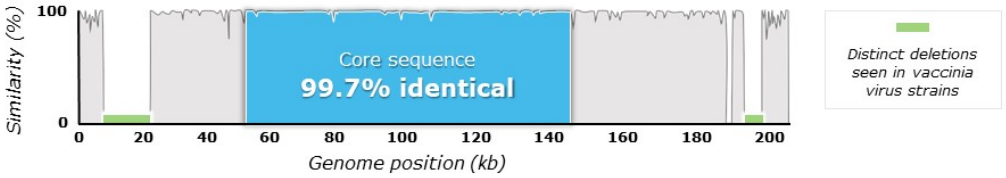
*TNX-801 has not been approved for any indication.

Equination, Use of Vaccines From Horses, Was Also Effective Against Smallpox

- Equination, the use of vaccines from horses (*equus* in Latin), was successfully used in parallel with vaccination in Europe[1]
- Vaccine producers may have propagated stocks by periodically supplementing or refreshing them with horsepox[2]

A 1902 smallpox vaccine (**Mulford**) was found to be **99.7% identical to HPVX** in core viral sequence, implicating a HPXV-like virus as a progenitor to modern vaccinia[3]

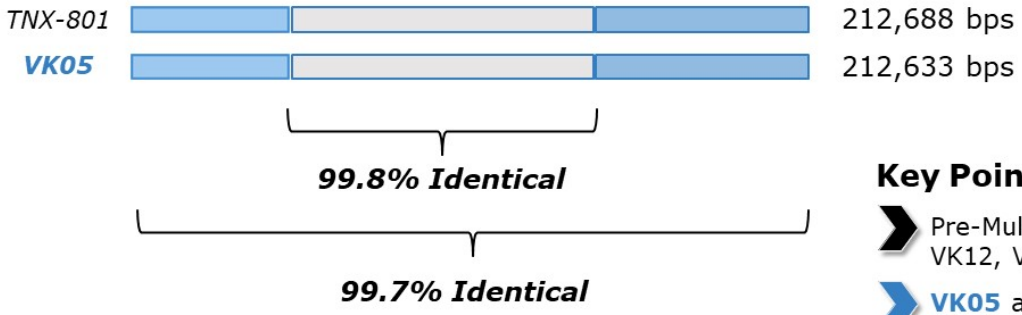
Sequence Identity for the 1902 Mulford Vaccine Compared to HPVX[3]



1. Esparza J, et al. *Vaccine*. 2017;35(52):7222-7230.
2. Esparza J, et al. *Vaccine*. 2020;38(30):4773-4779.
3. Schrick L, et al. *N Engl J Med*. 2017;377(15):1491-1492.

HPXV and HPXV-Like Viruses Were Used as Civil War-Era (1860s-1870s) Vaccines

VK05 has the highest identity to HPXV across the whole genome and represents a true HSPV strain



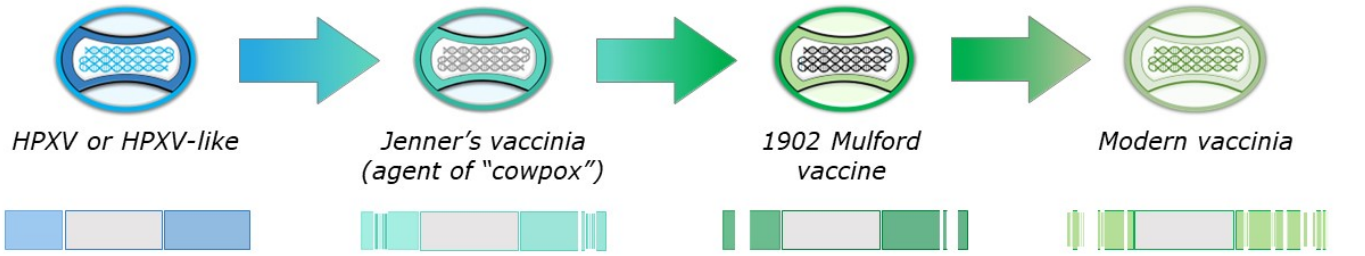
Key Points

- Pre-Mulford vaccines: VK05, VK12, VK02, VK08, and VK01
- **VK05** and **TNX-801** (HPXV) have colinear structural identity across their whole genome

Brinkmann A, et al. *Genome Biol*. 2020;21(1):286.

Evolution of the Vaccinia Genome

- Recent studies demonstrate that HPXV and HPXV-like viruses were used as smallpox vaccines in the 1800s[1,2]



HPXV or HPXV-like

Jenner's vaccinia (agent of "cowpox")

1902 Mulford vaccine

Modern vaccinia

Civil War-era vaccines are genetically diverse, with some strains having 1 or both ITRs intact

One recently identified strain, VK05, was found to be **99.7% identical to HPXV** across the whole genome

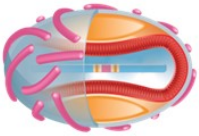
The 1902 Mulford vaccine is similar to both horsepox (99.7% identical core sequence) and vaccinia (**similar ITR deletions**)

Selected for WHO Eradication Intensification Program (1967)

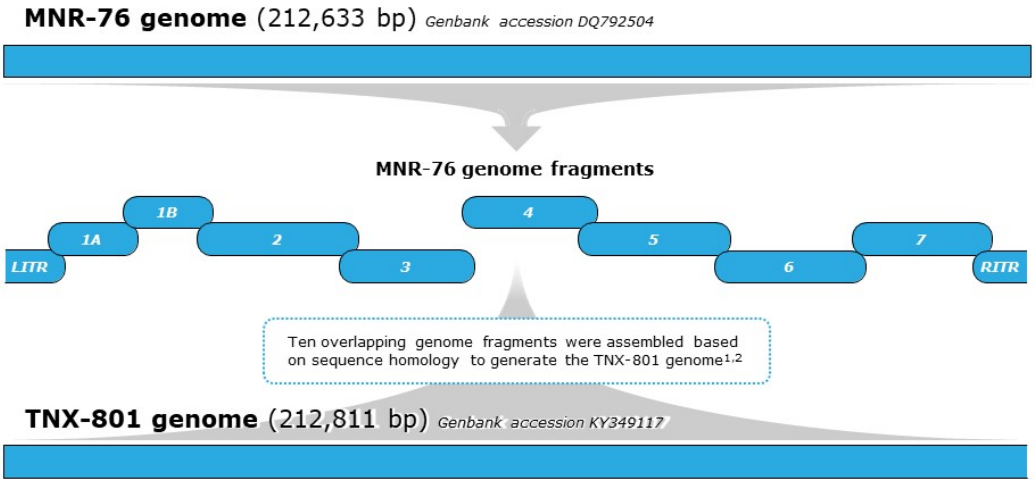
1. Duggan AT, et al. *Genome Biol.* 2020;21(1):175.
2. Brinkmann A, et al. *Genome Biol.* 2020;21(1):286.

TNX-801 Core Genome Is Identical to the Published HPXV Strain MNR-76

The core genome of TNX-801 is identical to MNR-76[1]



TNX-801
scHPXV (Horsepox)
212,811 bp

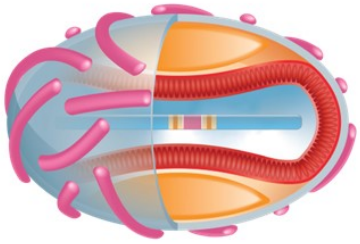


1. Noyce RS, et al. *PLoS One.* 2018;13(1):e0188453.
2. Schrick L, et al. *N Engl J Med.* 2017;377(15):1491-1492.

Properties of TNX-801 Live HPXV Vaccine

- TNX-801 is a vaccine based on sequence of isolated HPXV clone MNR-76[1,2]
  - The core genome of TNX-801 is identical to MNR-76, with ~70 bp terminal hairpin sequences from vaccinia added due to incomplete sequencing of MNR-76[1,2]
  - Small plaque size in culture (suggesting lower virulence) that appears similar to the CDC publication of the 1976 horsepox isolate MNR-76[3]
  - Substantially decreased virulence in mice relative to a vaccinia-based vaccine strain[2]
  - Protects macaques from monkeypox with no overt sign of clinical symptoms and no lesions in 8/8 animals at 2 doses of TNX-801[4]

TNX-801



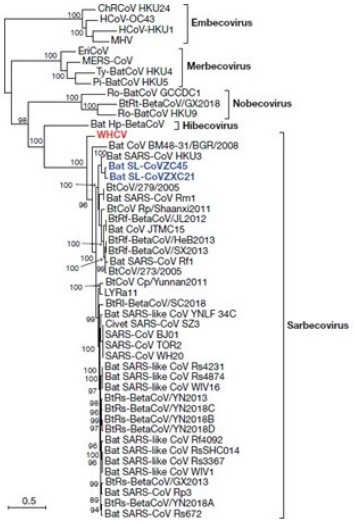
Horsepox Virus

scHPXV *(212 kb)*

1. Tulman ER, et al. *J Virol.* 2006;80(18):9244-58.
2. Noyce RS, et al. *PLoS One.* 2018;13(1):e0188453.
3. Trindade GS, et al. *Viruses.* 2016;8(12):328.
4. Noyce, RS, et al. Poster presented at: American Society of Microbiology BioThreats Conference; January 29, 2020; Arlington, VA. 114.

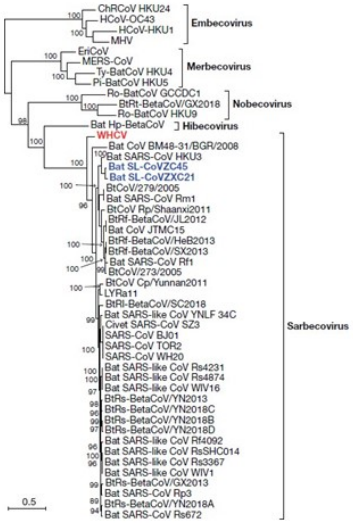
SARS-CoV-2

- SARS-CoV-2 emerged from Wuhan, China in 2019/2020
- Family: *Coronaviridae*
  - Genus: *Betacoronavirus*
  - Positive sense, single stranded, RNA virus
  - Genome: ~30kb



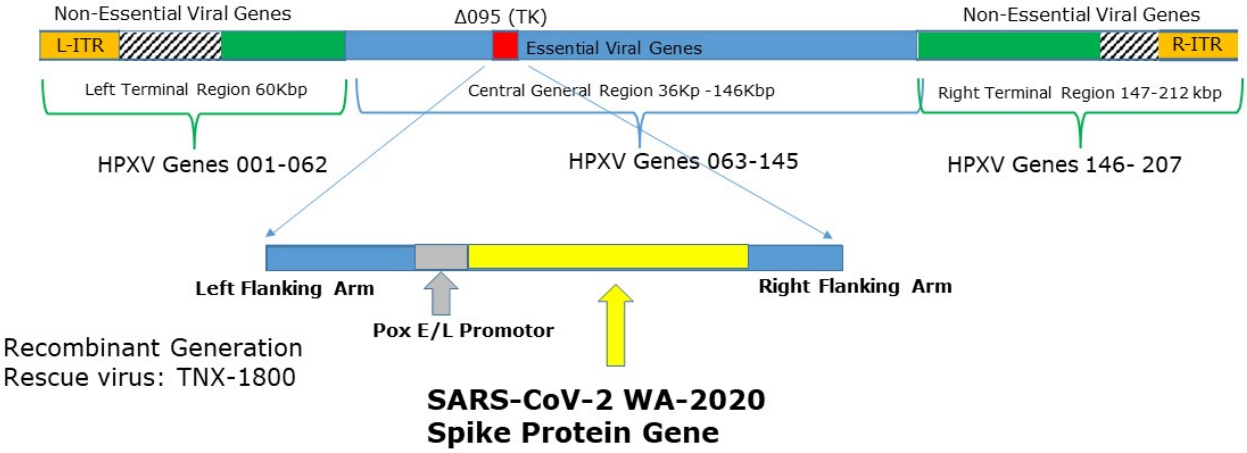
SARS-CoV-2

- SARS-CoV-2 emerged from Wuhan, China in 2019/2020
- Family: *Coronaviridae*
  - Genus: *Betacoronavirus*
  - Positive sense, single stranded, RNA virus
  - Genome: ~30kb
- ***Develop HPXV vaccine platform***
  - Model system: SARS CoV-2
  - "Proof of concept"
  - Encoding Spike protein (WA-2020)
  - ***TNX-1800***



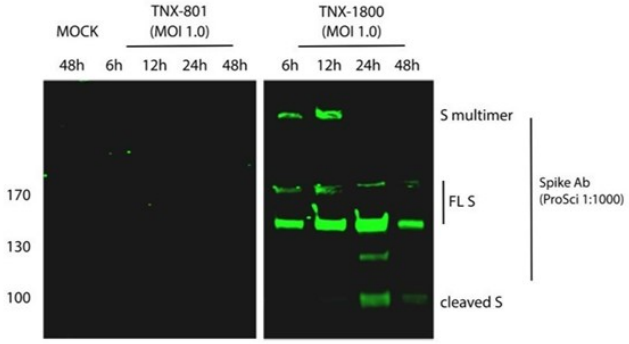
Recombinant SARS-CoV-2 Vaccine Generation (TNX-1800*)

Development of HPXV as a recombinant Delivery Vector Platform



*TNX-1800 has not been approved for any indication.

Recombinant Vaccine Expressing Heterologous Antigen (TNX-1800): Spike Protein Expression



TNX-1800 rapidly expresses SARS-CoV-2 spike protein

Preliminary Immunogenicity Studies

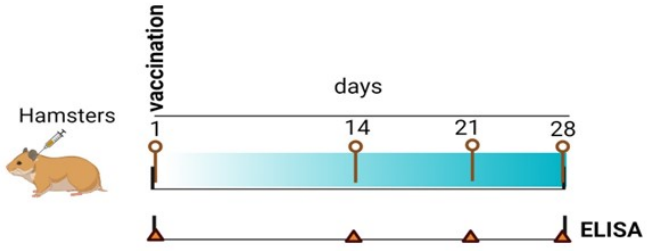
- Goal: *Investigate immunogenicity and tolerability following administration of a single dose of TNX-1800*

- Two animal models:

  1) Syrian Hamsters

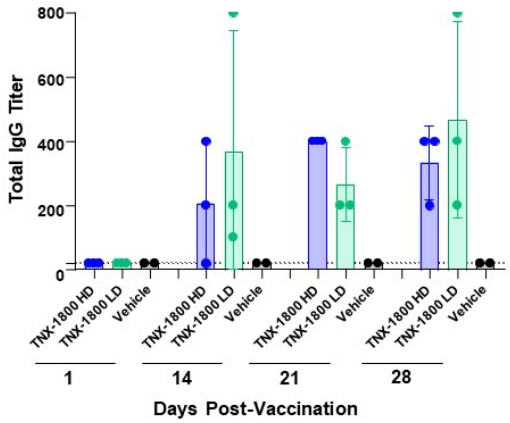
  2) New Zealand Rabbits

Preliminary Immunogenicity: Hamster Study Design



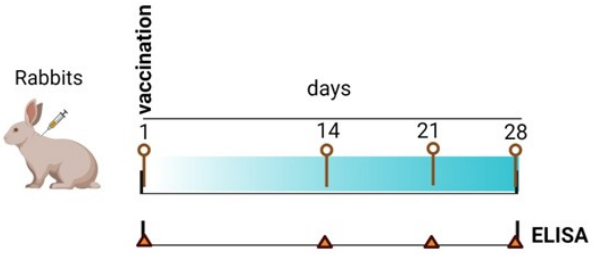
Vaccination in Hamsters				
Group	Vaccine	Number	Dose (log_{10} PFU/animal)	Route
1	TNX-1800 (HD)	2M/1F	6.5	Percutaneous
2	TNX-1800 (LD)	2M/1F	5.5	Percutaneous
3	Vehicle	1M/1F	-	Percutaneous

Preliminary Immunogenicity: SARS CoV-2 Spike Protein Specific ELISA Titers



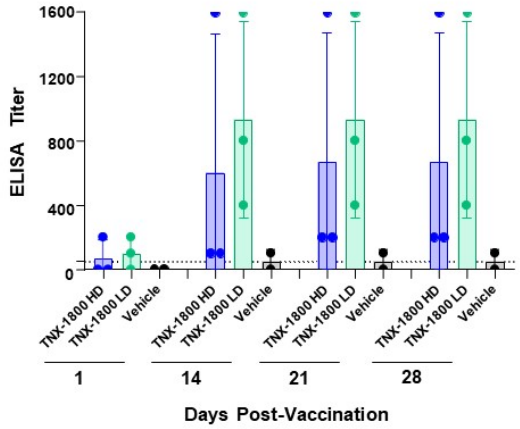
100% Hamsters in TNX-1800 vaccinated group had IgG antibody response

Preliminary Immunogenicity: Rabbit Study Design



Vaccination in Rabbits				
Group	Vaccine	Number	Dose (log_{10} PFU/animal)	Route
1	TNX-1800 (HD)	2M/1F	6.5	Percutaneous
2	TNX-1800 (LD)	2M/1F	5.5	Percutaneous
3	Vehicle	1M/1F	-	Percutaneous

Preliminary Immunogenicity: SARS CoV-2 Spike Protein Specific ELISA Titers



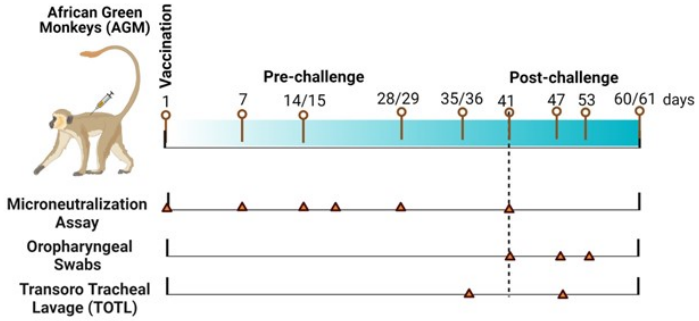
100% Rabbits in TNX-1800 vaccinated group had IgG antibody response

Preliminary Immunogenicity Studies: Conclusion

1) 100% of animals generate an antibody response
2) Vaccine was well-tolerated
   - No adverse events
   - No disseminated horsepox virus infection

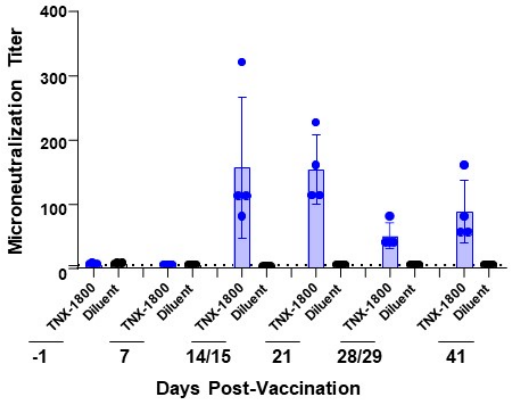
➢ *Proceeded to efficacy studies in NHPs*

Preliminary Efficacy Study Design: African Green Macaques



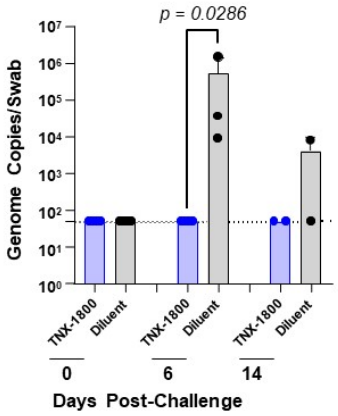
Vaccination					Challenge		
Group	Vaccine	N	Dose (Log_{10} PFU)	Route	*SARS-CoV-2 Challenge strain*	*Dose (Log_{10} PFU)*	*Route*
1	Diluent	4	Sham	Percutaneous	*USA-WA1/2020*	*6.3*	*IT/IN*
2	TNX-1800	4	6.5	Percutaneous	*USA-WA1/2020*	*6.3*	*IT/IN*

Immunogenicity: Neutralization Titers



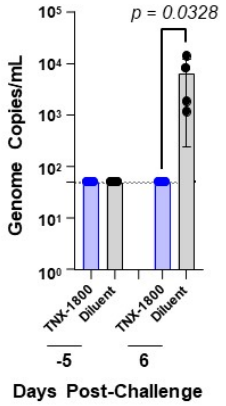
100% NHPs in TNX-1800 vaccinated group had neutralizing antibody response

Virus Replication/Shedding: Oropharyngeal (OP) swabs



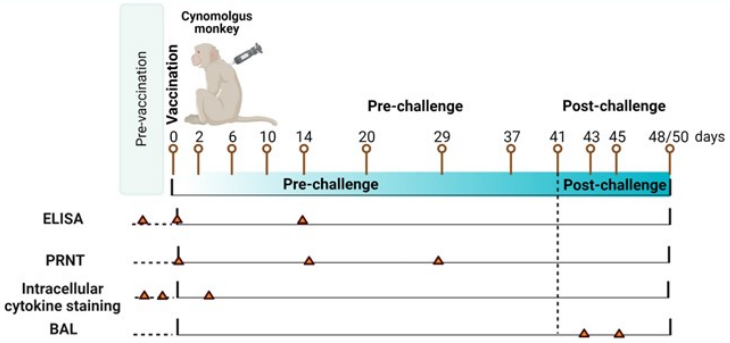
100% NHPs in TNX-1800 vaccinated group had no detectable SARS-CoV-2 genome

Virus Replication/Shedding: Tracheal Lavage



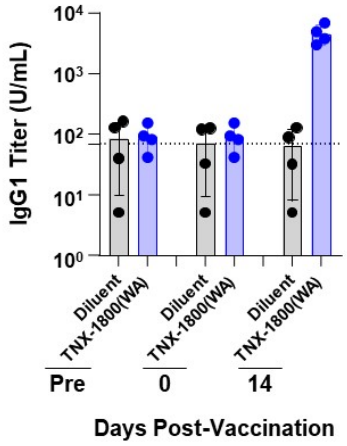
100% NHPs in TNX-1800 vaccinated group had no detectable SARS-CoV-2 genome

Preliminary Efficacy Study Design: Cynomolgus Macaques



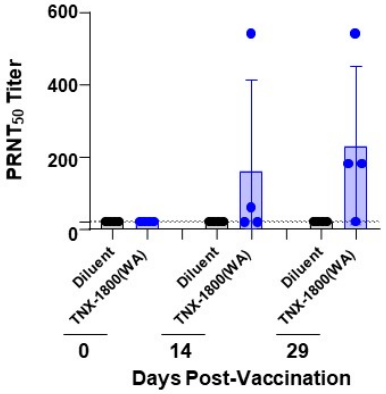
Vaccination					Challenge		
Group	Vaccine	N	Dose (Log_{10} PFU)	Route	*SARS-CoV-2 Challenge strain*	*Dose (Log_{10} PFU)*	*Route*
1	Diluent	4	Sham	Percutaneous	*USA-WA1/2020*	*5.0*	*IT/IN*
2	TNX-1800	4	6.1	Percutaneous	*USA-WA1/2020*	*5.0*	*IT/IN*

Immunogenicity: Total Anti-SARS-CoV-2 Spike Protein IgG1 Titer (ELISA)



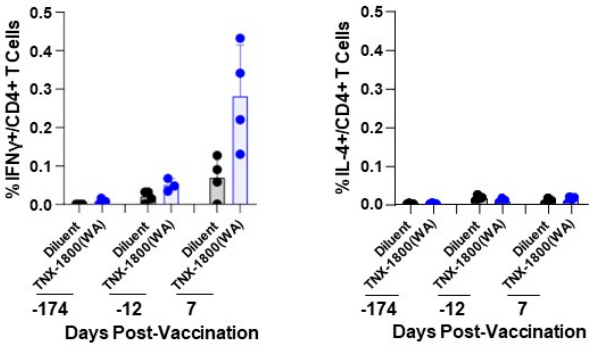
100% NHPs in TNX-1800 vaccinated group had IgG1 antibody response

Immunogenicity: Neutralizing Antibody ($PRNT_{50}$ Assay)



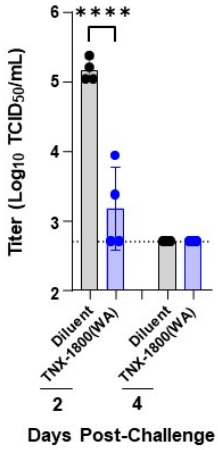
100% NHPs in TNX-1800 vaccinated group had neutralizing antibody response

Immunogenicity: Cell Mediated Response



100% NHPs in TNX-1800 vaccinated group had CD4⁺ T-cell/IFNγ (T_H1) response

Virus Replication/Shedding: Bronchoalveolar lavage (BAL) ($TCID_{50}$)



Infectious virus declined rapidly by ~100-fold in TNX-1800 vaccinated group

Conclusions

- TNX-1800 engineered to expressed heterologous antigen
  - "Proof of concept"
  - SARS-CoV-2 WA-2020 Spike protein
- 2 preliminary immunogenicity and 2 efficacy studies
  - Animal models: Hamsters, Rabbits, Cynomolgus and African green macaques
- A single dose of TNX-1800 vaccination was well tolerated
  - No severe adverse events following vaccination
  - Did not produce disseminated infection in any animal model

Conclusions

- TNX-1800 vaccination via route percutaneous was immunogenic
  - 100% response in all 4 animal models
  - Rapid generation of antibody response (Total IgG and/or neutralizing antibody)
  - Induced $CD4^+$ T-cell response
    - Responses were skewed to T_H1
- Efficacy studies in cynomolgus and African green macaques
  - Challenged with SARS-CoV-2 WA-2020
  - Virus shedding/replication was reduced by ~10 to 1,000-fold

Conclusions

- No longer continuing with clinical development of SARS-CoV-2 vaccine program
  1) New variants (e.g., XBB) appear to be boosting pre-existing immunity resulting in "herd immunity"
  2) Challenging regulatory hurdles for clinical evidence
- Additional vector development for heterologous genes from other pathogens underway:
  1) Additional insertion sites for stable expression
  2) Multivalency for additional heterologous antigens
  3) Additional routes of vaccination

Acknowledgements

- Tonix Pharmaceuticals
  - Siobhan Fogarty
  - Helen Stillwell
  - Bruce Daugherty
  - Seth Lederman
- University of Alberta
  - Ryan Noyce
  - David Evans
- Southern Research
- BIOQUAL

Exhibit 99.03

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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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.

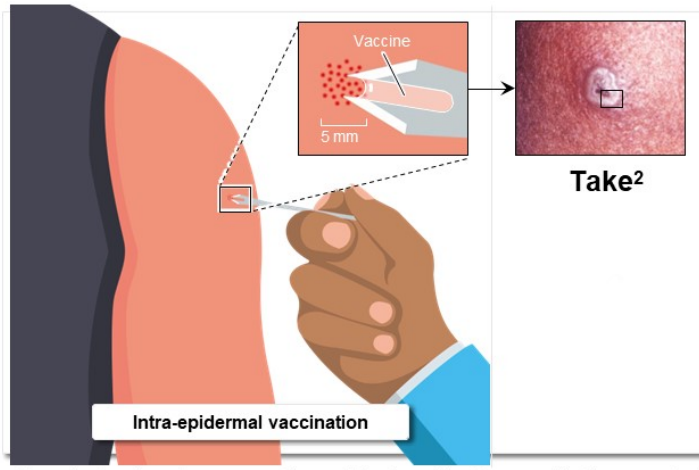
In 1796 Edward Jenner Successfully Used Vaccination to Protect Against Smallpox

- Jenner reasoned infection with illness similar to smallpox, but less deadly, could protect against smallpox
  - "Jenner "vaccinated" (*vacca*, Latin for "cow") a patient with pustule matter from "cowpox" sores on a milkmaid's hands;
  - Patient remained healthy when challenged with smallpox virus

- Jenner wrote he suspected that the agent causing cowpox, which he called **vaccinia**, *actually originated in horses* and was transferred from horses to cows' udders by contaminated farm workers' hands.

The College of Physicians of Philadelphia. Accessed July 15, 2021. https://www.historyofvaccines.org

Vaccinia Induces a Skin Reaction Called "Take" Described by Dr. Edward Jenner



Take[2]

- **Biomarker of protection**
  - Smallpox was eradicated using this marker
  - Revaccination indicated for recipients without "take"
- **Measure of T cell immunity**
  - No need for blood draws or complex laboratory studies
  - No other functional T cell assay is approved or in clinical use for vaccination

*Example of major cutaneous reaction, or "take," resulting from a replication-competent live-virus vaccine with intradermal delivery, indicating successful vaccination[1,2]

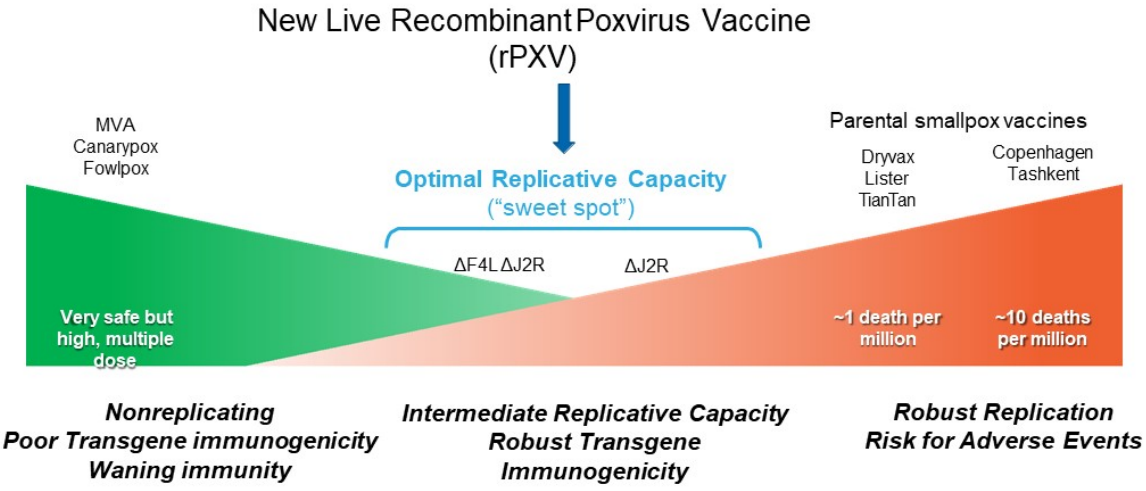
[1]Fulginiti VA, et al. *Clin Infect Dis*. 2003;37(2):241-250.
[2]Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=32 76

TNX-801 Development

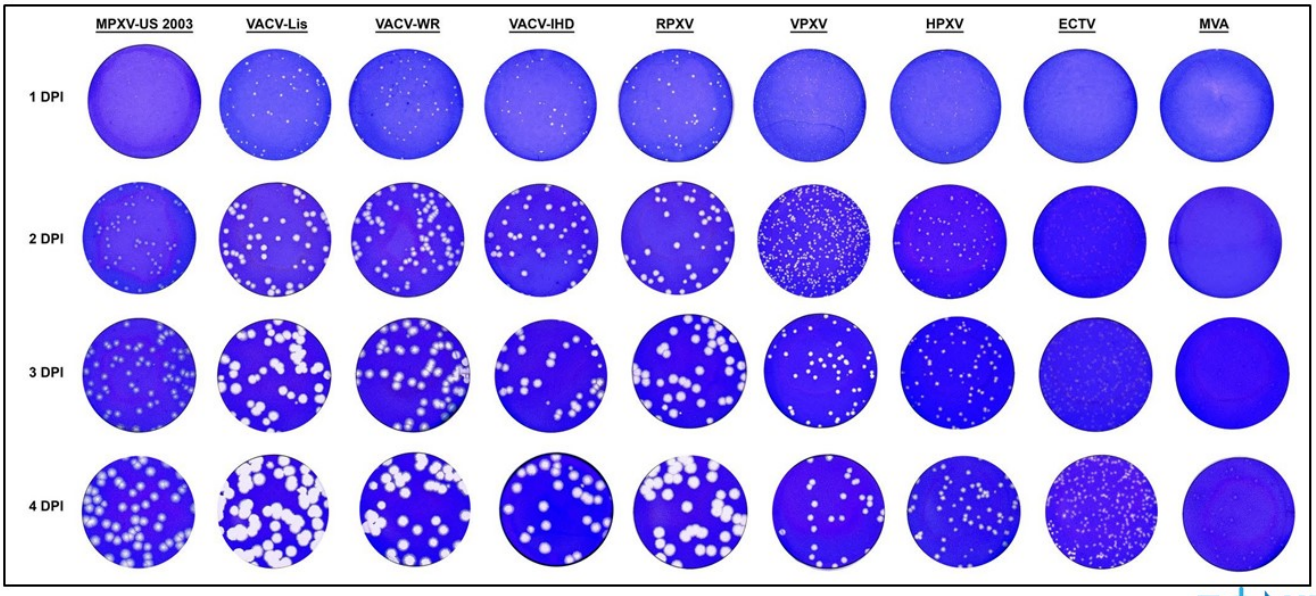
- **U.S. smallpox vaccine manufactured in 1902 (H.K. Mulford)**
  - **99.7% similar to horsepox in core viral sequence[1,2]**
- **Tonix-801 is based on a sequence of an isolated horsepox (HPXV) clone[3]**
  - Synthesized[4] in 2018 (isolate was unavailable outside of CDC)
  - No new gene elements introduced
- **Sequencing showed Tonix-801 identical to CDC publication of a 1976 horsepox isolate[5]**

[1]Tulman ER, et al. Genome of horsepox virus. *J Virol*. 2006 80(18):9244-58.PMID:16940 536
2 Schrick, L. et al An Early American Smallpox Vaccine Based on Horsepox *NEngl J Med* 2017; 377:149
3Noyce RS, et al.. Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. *PLoS One*. 2018 Jan 19;13(1):e0188453
4Trindade GS, et al. Serro 2 Virus Highlights the Fundamental Genomic and Biological Features of a Natural Vaccinia Virus Infecting Humans. *Viruses* 2016 Dec 10;8(12). pii: E328. PMID:27 9733 99
PMCID: PMC5192389 DOI: 10.3390/v8120328
5Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

Illustrative Safety Spectrum Of Pox-based Vaccine Vectors
Optimizing Live Virus Vaccines



Orthopoxvirus Virulence as Visualized by Plaque Assay



viruses

MDPI

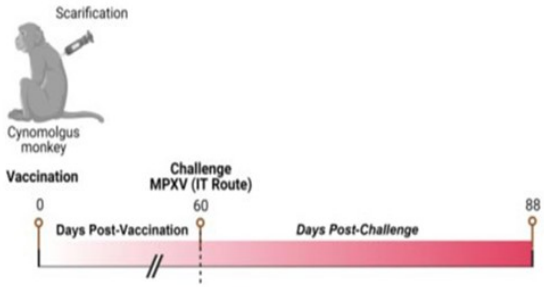
Article

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,*]

TNX-801 Vaccination and Lethal Challenge in Macaques

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

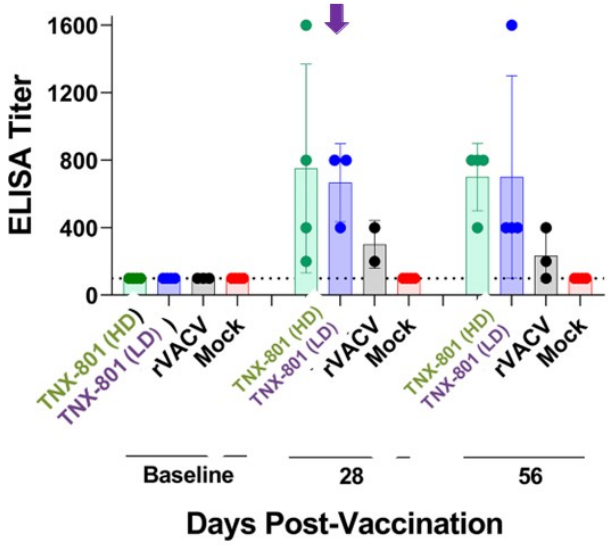


"Take" observed in all TNX-801 vaccinated NHPs except one.

- If no take by day 7 were revaccinated on day 14.

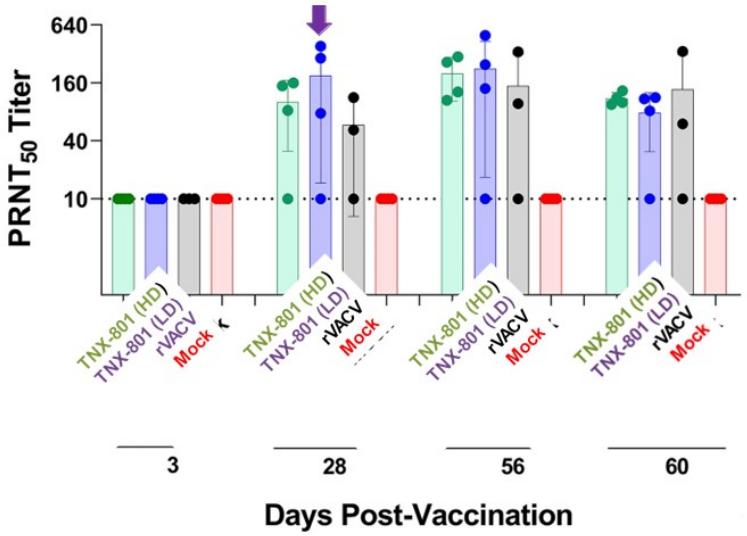
Post-vaccination, no NHP showed lesions during first 60 days

Immunogenicity: Total IgG (ELISA)



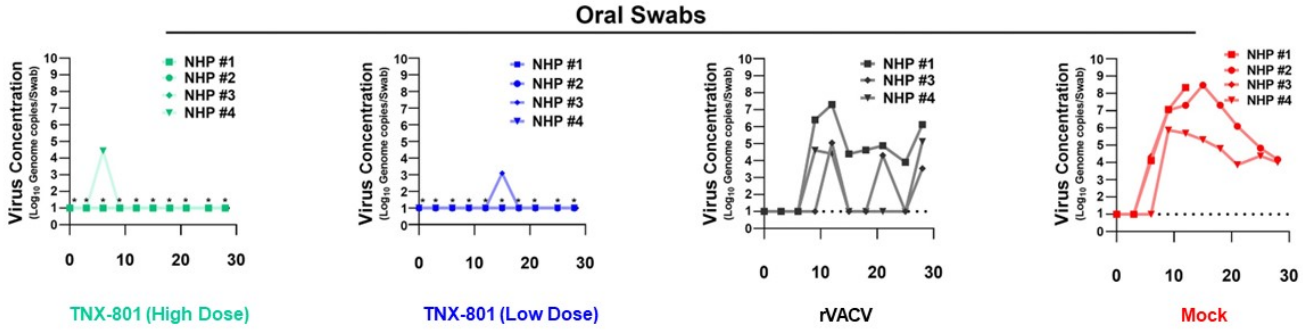
100% seroconversion in Tonix-801 vaccinated groups with antibody titers 2- to 16-fold higher than baseline by day 28 and 4-to 8–fold higher at day 56.

Immunogenicity: Neutralizing Antibody ($PRNT_{50}$ Assay)



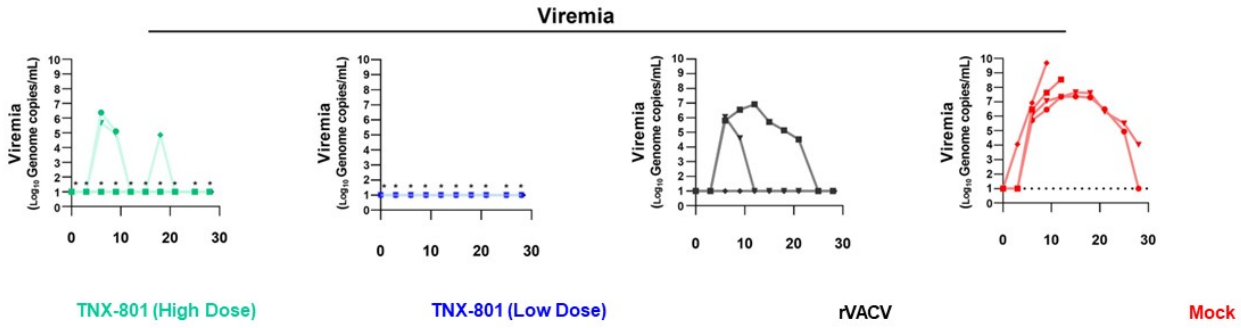
88% of TNX-801 vaccinated NHPs had neutralizing antibody responses 8- to 50-fold from baseline

Measured Virus Shedding: Oral Swabs



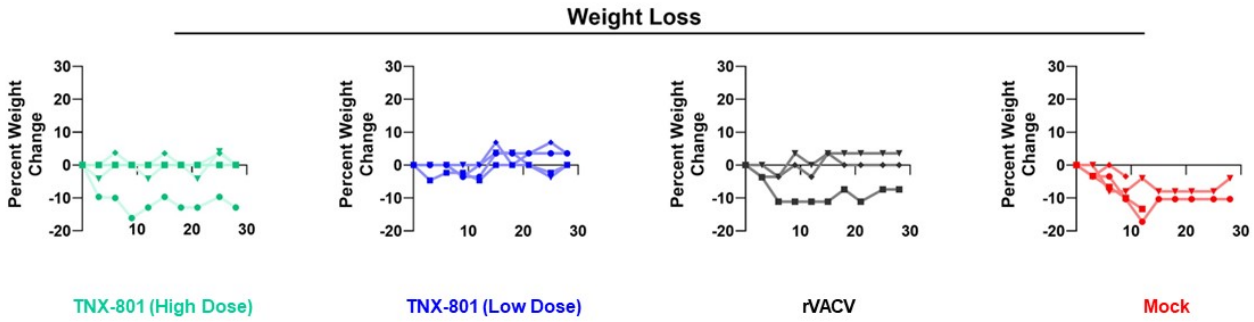
Minimal or no virus shedding in Tonix-801 vaccinated groups

Measured Viremia



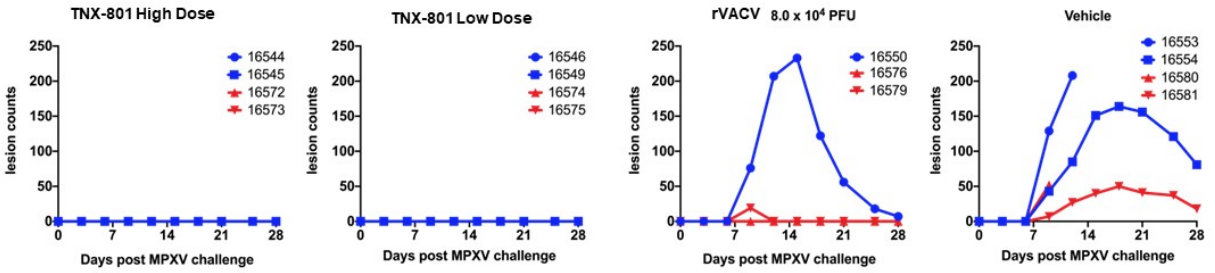
Minimal sporadic or no viremia in Tonix-801 vaccinated groups

Clinical Disease: Weight Loss



Minimal or no weight loss in Tonix-801 vaccinated groups

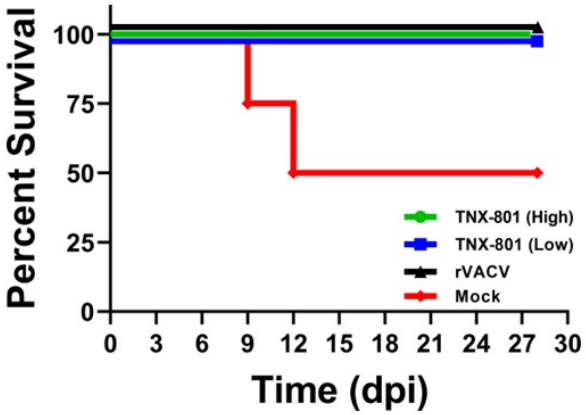
Clinical Signs After MPXV Challenge



NHPs vaccinated with Tonix-801:
No lesions observed after MPXV challenge in any of the eight animals

[1]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

Clinical Disease: Lethality



No deaths in Tonix-801 vaccinated groups

Study Conclusions for TNX-801 Non-Human Primate Challenge

- A single dose vaccination was well tolerated
  - No severe adverse events
- Vaccination was immunogenic
- Mpox disease (lesions) was not observed following MPXV (Zaire) challenge
- All vaccinated NHPs survived lethal challenge

Live Recombinant Poxvirus (rPXV) Vaccine Platform Profile

POTENTIALLY LONGER DURABILITY DUE TO POX-ENGINEERED ARCHITECTURE

- Live virus vaccines present unique "danger signals" (PAMPs)
- Results in strong immune response

PROGRAMMABLE VECTOR DESIGN FOR USE IN DIFFERENT DISEASES

- Large capacity for expressing inserted genes
- Wide range of clinical applications: pandemic, biodefense, infectious disease, smallpox, oncology

LIVE VIRUS-BASED SCIENCE IS WELL ESTABLISHED

- Streamlined development
- Ability to vertically integrate development and manufacturing
- Standard cold-chain requirements

Approved Recombinant Poxvirus-Based Commercial Products[1-3]

Product	Application / disease	Location	Poxvirus vector	Host restricted?	Doses released to environment
TROVAC-AIV H5N1 *Boehringer Ingelheim*	Agriculture/avian influenza	Mexico, Central America	TROVAC-AIV H5N1	**No** ***Replication competent***	**2 billion** (as of 2006)
Purevax FeLV *Boehringer Ingelheim*	Companion animals (cats)/FeLV	US, others	ALVAC-FeLV Gag/Pol	Yes *Replication incompetent*	Unknown
Purevax Rabies *Boehringer Ingelheim*	Companion animals (cats)/rabies	US, others	ALVAC-RG	Yes *Replication incompetent*	Unknown
Recombitek *Boehringer Ingelheim*	Companion animals (dogs)/canine distemper	US, others	ALVAC-HA, F	Yes *Replication incompetent*	Unknown
Raboral V-RG Rabisin *Boehringer Ingelheim*	Wildlife control of rabies	US, Europe, Israel	Vaccinia Copenhagen RG	**No** ***Replication competent***	**250 million doses** *5 million doses/year*

[1]Boehringer Ingelheim. Accessed July 15, 2021. https://www.boehringer-ingelheim.com/animal-health/ products
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[3]Maki J, Guiot AL, Aubert M, et al. Oral vaccination of wildlife using a vaccinia-rabies-glycoprotein recombinant virus vaccine (RABORAL V-RG®): a global review. *Vet Res*. 2017;48(1):57.

TONIX PHARMACEUTICALS

Emerging Infectious Disease R&D and Manufacturing Capability

R&D Center –Frederick, MD

Advanced Development, MA

Commercial Manufacturing, MT(Planned)

TONIX PHARMACEUTICALS

American Pandemic Preparedness Plan (AP3) White House OSTP

AP3 Plan Element	Tonix rPXV Vaccine Platform Potential
Rapid Design, Testing Review <100 days	4-6 mo. Design-to-FIH trial
Rapid Production Scale Up	Large scale production <130 days possible
Distribution	Stable Traditional cold-chain
Administration	Intraepidermal : BFN or skin patch Non-Sterile No syringes
Adaptation	rPXV platform can express large inserts
Public Health Strategy	Potential to reduce onward transmission 1 dose only Ideal for Ring Vaccination Strategy

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THANK YOU
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