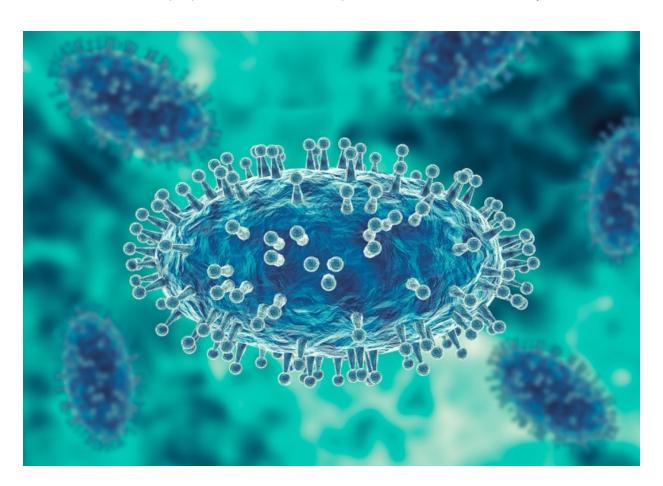


Modern Twist to Centuries-Old Smallpox Vaccine Poised to Combat Deadly Mpox Strain as WHO Declares Global Emergency

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CHATHAM, NJ / ACCESSWIRE / August 23, 2024 /Following an upsurge of cases in the Democratic Republic of the Congo and several other countries in Africa, the World Health Organization (WHO) declared mpox a public health emergency of international concern on Aug. 14 - the second such declaration in two years. The WHO has called on vaccine manufacturers to step up efforts to curb the spread of a new, more deadly strain of the virus.



The WHO also is asking companies and organizations to bring in their vaccines, inviting developers of mpox vaccines to submit an Expression of Interest for Emergency Use Listing (EUL).

Amid this backdrop, **Tonix Pharmaceuticals** (NASDAQ:TNXP) is developing a vaccine candidate, called TNX-801, that could play a role in combating this escalating global health crisis. Tonix has successfully completed non-human primate studies showing protection from challenge with lethal doses of the Clade 1 monkeypox virus that is driving the new epidemic.

Clearly more testing is ahead for TNX-801, but the technology behind it is rooted in the science of Edward Jenner's smallpox vaccine of the late 1700s, the only vaccine to successfully eradicate a contagious viral pathogen.

These credentials have earned the vaccine technology platform upon which TNX-801 is based a competitive spot in the NIH's NextGen program for a more effective, single-dose COVID-19 vaccine to potentially provide durable protection instead of the every-six month booster strategy of mRNA vaccines.

Last month, another of Tonix's technologies was awarded a contract for up to \$34 million by the U.S. Department of Defense to develop a single broad spectrum antiviral that would work against multiple potential biowarfare agents.

An Historical Approach to Modern Challenges

The current mpox crisis can be traced back to a decision made in the 1970s to discontinue routine smallpox vaccinations after smallpox was successfully eradicated. Research shows that the smallpox vaccine also provided immunity against mpox. In retrospect, smallpox vaccination kept mpox out of the human population in Africa. So an unintended consequence of stopping vaccinations for smallpox meant that mpox, then known as monkeypox (which is still the name of the virus), was able to reemerge in the human population.

Tonix's mpox vaccine is believed to be closely related to the original smallpox vaccine invented by British physician Edward Jenner in 1796. Jenner's vaccine is credited with being the first and only vaccine to successfully eradicate a viral pathogen. This triumph depended on several important attributes of the vaccine, including that it was generally well-tolerated, provided long-term immunity with a single dose, prevented forward transmission and provided a simple biomarker confirmation of protective immunity known as a "take".

TNX-801 is designed to have these same attributes; it is delivered in a single dose that provides protective immunity to animals that is marked by a "take". It is believed to have a high likelihood of providing durable immunity and preventing forward transmission. Furthermore, unlike many other vaccines, TNX-801 does not require complex ultra cold-chain storage, making it a strong candidate for global distribution.

The Science Behind TNX-801

Unlike mRNA vaccines, which primarily elicit an antibody response that requires frequent booster shots, TNX-801 is designed to trigger a robust T-cell response. T-cells have the ability to recognize and remember internal parts of viral proteins, not just those on the surface. T-cell memory lasts for years - even decades - providing long-term immunity and potentially eliminating the need for repeated boosters.

In preclinical trials, Tonix says TNX-801 demonstrated the ability to prevent death, clinical disease and lesions caused by a lethal challenge of monkeypox virus in non-human primates. Similar to Jenner's smallpox vaccine, TNX-801 also significantly reduced viral shedding, suggesting that it can block forward transmission,. Tonix is rushing to manufacture vaccine suitable for Phase 1 human trials.

Beyond Mpox: A Platform for Future Pandemics

The vaccine platform on which TNX-801 is based has potential applications beyond mpox. The company says the TNX-1800 version of the platform, for example, is designed to protect against COVID-19 and has shown promise in preclinical studies. The U.S. National Institute of Health has recognized the potential of Tonix's platform by selecting it for Project NextGen, aimed at developing next-generation COVID-19 vaccines and pandemic platform technologies.

As the world faces the growing threat of mpox and other infectious diseases, Tonix Pharmaceuticals is not only attempting to address the current crisis with TNX-801, but also potentially contributing to a future where pandemics can be more predictably contained.

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