# COMMERCIAL SCALE VACCINE MANUFACTURING FACILITY ADVANCES IN THE BITTERROOT

### Hamilton to Welcome Tonix Pharmaceuticals to the Valley's Biotech Corridor

(HAMILTON, Mont.) June 24, 2021 — Dr. Seth Lederman, CEO of Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, said today that plans are advancing to construct a commercial-scale manufacturing facility to develop and manufacture vaccines in the Bitterroot Valley.

During a roundtable discussion today in Hamilton hosted by the Ravalli County Economic Development Authority (RCEDA), Lederman and community leaders announced a new public/private sector collaboration between Ravalli County and Tonix Pharmaceuticals that will bring more high-tech bioscience jobs to the Bitterroot Valley. Lederman said he was pleased that the Hamilton City Council voted in April to ensure that critical infrastructure will be available to Tonix once the construction phase is complete. Tonix's new manufacturing site will be constructed on 44 acres of land designated by Ravalli County as a Target Economic Development District (TEDD), which allows for tax money generated at the site to be used for building infrastructure inside the district.

Attendees included Lederman, Rocky Mountain Lab Associate Director Dr. Marshall Bloom, Hamilton Mayor Dominic Farrenkopf, Ravalli County Commissioner Greg Chilcott, and RCEDA board chair Ryan Oster. The panel met to discuss recent developments in a longstanding effort to turn southwest Montana into a renowned biotech corridor. Tonix joins the U.S. National Institutes of Health's Rocky Mountain Laboratories (RML) in Hamilton, which is an internationally recognized leader in vaccine development and virology research. GlaxoSmithKline (GSK) also has a vaccine manufacturing facility in Hamilton.

Lederman has said that once the facility is completed, Tonix expects to create many high-tech bioscience jobs. The new Montana facility is intended to develop and produce Tonix's vaccine candidates, including TNX-1800, a potential COVID-19 vaccine.

"One of the things that the COVID-19 pandemic exposed was major shortcomings in U.S. domestic vaccine development and manufacturing capabilities," said **Seth Lederman**, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "Tonix is striving to be a pioneer in American made vaccine development and production. We believe it is vital to bring these skills and high-tech jobs back to the U.S. both in the fight against the COVID-19 pandemic and it's long lasting effects, and to prepare for prospective future pandemics. Building our new Montana facility demonstrates our dedication to the development of our vaccines and creating good American jobs. We are excited to be at the forefront of this exciting time in domestic manufacturing and biotech in Montana, and we look forward to continued collaboration with the community partners here in the Bitterroot valley."

"This is an unprecedented opportunity for economic development in Montana, and Ravalli county in particular," said **Julie Foster**, the Executive Director of the Ravalli County Economic Development

Authority (RCEDA). "We're excited that we were able to work in collaboration with the city, county and the folks at Tonix to move this project forward and bring more good jobs to the Bitterroot Valley."

In addition to a COVID-19 vaccine, Tonix is also developing a diagnostic test for T cell immunity to COVID-19, as well as an antiviral therapeutic for COVID-19. Tonix also announced earlier this week that it plans to develop TNX-102 SL, currently in phase 3 development for fibromyalgia, as a potential treatment for Long COVID Syndrome. The disease's symptoms include pain, sleep disturbance, fatigue, and brain fog, which are also seen in fibromyalgia. Tonix plans to meet with the U.S. Food and Drug Administration (FDA) in the third quarter of 2021 to determine the design of a pivotal phase 2 study. Some studies have indicated that Long COVID Syndrome, officially called Post-Acute Sequelae of COVID-19 (PASC), can occur in more than 30% of COVID-19 patients that have recovered.

### About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL¹, is in mid-Phase 3 development for the management of fibromyalgia, with positive data from the Phase 3 RELIEF study reported in December 2020. The Company expects interim data from the second Phase 3 study, RALLY, in the third quarter of 2021 and topline data in the first quarter of 2022. Tonix's immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800², is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801², live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

## **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 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

<sup>&</sup>lt;sup>1</sup> TNX-102 SL is an investigational new drug and has not been approved for any indication.

<sup>&</sup>lt;sup>2</sup> TNX-1800 and TNX-801 are investigational new biologics and have not been approved for any indication.

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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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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