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Tonix Pharmaceuticals Holding Corp. (NASDAQ/TNXP/$4.36/Not rated)

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1st HONOR Trial Patient Enrolled, Catalyst for PIPE Funding

This last week proved to be a very busy week for Tonix. The Company announced that the first participant in its 550-patient HONOR Phase III trial has been officially enrolled, thus starting the clock on the Company's lead product Phase III timeline. Later in the week, Tonix announced it had placed 1,800,000 million shares, priced at $4.45 per share in a PIPE transaction, netting approximately $8 million in new funds, and this morning, the Company received notification by NASDAQ that the stock has now regained closing bid compliance with NASDAQ's Bid Price Rule, following the 1-for-10 reverse stock split that took place on March 17th. Last week's PIPE transaction is expected to close tomorrow, April 4th. Proceeds will be used to support the HONOR trial, continue the development of TNX-102 SL and other pipeline products and for general corporate purposes, including potentially for possible acquisitions of other companies, products or technologies, although, as noted in SEC filings, no such acquisitions are currently contemplated.

Clinical Status

With the HONOR trial now underway, investors will be measuring the trial's progress by patient enrollment. As of Friday, March 31st, the trial had 11 US sites enrolling out of the 33 sites expected to participate in the trial. Most of currently enrolling sites are located near areas with a significant military personnel presence such as Oakland and Oceanside, California, Colorado Springs, Colorado, San Antonio, Texas and Tampa, Florida.

In addition to the clinical benchmark of patient enrollment, Tonix has been active in other areas that support an eventual NDA filing. In March, 2017, the Company had an Initial Comprehensive Multidisciplinary Breakthrough Therapy Type B meeting with the FDA to review the possibility of accelerating the development and submission of the TNX-102 SL NDA. The outcome of this meeting will be provided when the official meeting minutes become available 30 days after the meeting.

Bridging Studies Underway

Tonix is completing several bioequivalence, pharmacokinetic (PK) and manufacturing studies to support the eventual TNX-102 SL NDA filing. The Company has completed a Phase 1 bioequivalence study that compared the PK profiles of the single-dose of TNX-102 SL 2.8 mg tablets manufactured at the facility used to produce tablets for the Phase II AtEase study to the TNX-102 SL 2.8.mg tablets produced for the current clinical studies and the eventual to be-marketed product, assuming TNX-102 SL receives FDA approval, by a different manufacturer. This study demonstrated that the TNX-102 SL 2.8 mg tablets manufactured at the two different facilities were bioequivalent and thus allows the use of the AtEase study data to be part of the TNX-102 SL NDA filing package.

Please find Important Disclosures beginning on Page 3.

Since Tonix will be seeking FDA marketing approval for TNX-102 SL under a 505(b)(2) filing, the Company must also complete bridging PK studies with the reference listed drug (RLD), in this case, **AMRIX ®** extended-release capsules (30 mg). In study design pre-approved by the FDA, Tonix will run a comparative study of TNX-102 SL 5.6 mg (two 2.8 mg tablets) to **AMRIX** 30 mg extended-release capsules in a multiple dose bridging PK study to provide systemic exposure bridge data between the two formulations. If the exposures of TNX-102 SL (2 x 2.8 mg tablets) are less than the RLD maximum approved dose (30 mg) for the initial dose and at steady state, the results of this study will provide the necessary systemic exposure bridge of TNX-102 SL 5.6.mg to AMRIX 30 mg extended-release capsules and the approval of TNX-102 SL for PTSD will be able rely on the clinical and nonclinical safety findings of the currently approved cyclobenzaprine drug products.

Finally, Tonix must also complete Food Effect and Dose-proportionality Studies as part of the NDA filing package supporting TNX-102 SL product registration. First, a randomized, open-label, 2-way crossover, food-effect, comparative bioavailability study of TNX-102 SL will be conducted. Data will be collected following the administration of a single dose in healthy subjects under both fasting and fed conditions. A second randomized, open label, 2-way crossover, dose-proportionality, comparative bioavailability study of TNX-102 SL will assess exposure in healthy subjects following a single dose under fasting conditions only.

A note here about 505(b)(2) filings. With taking the 505(b)(2) filing regulatory path, Tonix is relying upon NDA submission data for TNX-102 SL that may be related to products already approved by the FDA, as is the case with **AMRIX**. **AMRIX** extended-release tablets are currently marketed by Teva Pharmaceuticals for muscle relaxation. If there are any third-party patents still in force related to **AMRIX** or similar products, there is a risk Tonix may be required to certify or to defend that its TNX-102 SL formulation does not infringe on any valid patents or that those patents are invalid or unenforceable. If such an issue arose, it could delay potential FDA approval for TNX-102 SL regardless of Phase III trial outcomes.

Increasing Visibility Around TNX-801

Tonix management has been bringing TNX-801 forward in communications with investors. TNX-801 is a novel potential smallpox-preventing vaccine based on a live synthetic version of an equine pox virus, HPXV, grown in cell culture. TNX-801 was synthesized by Professor David Evans and Dr. Ryan Noyce at the University of Alberta, Canada in collaboration with Tonix. TNX-801 is being developed as a potential smallpox-prevention vaccine for widespread immunization and for the U.S. strategic national stockpile. TNX-801 has unique virulence properties that may suggest lower toxicity and potential safety advantages over existing vaccinia-based vaccines that have been associated with adverse side effects such as myopericarditis. Vaccine manufacturing activities have been initiated to support further nonclinical testing of TNX-801. Tonix recently filed a patent application on the novel virus vaccine.

With the recent passage of the 21st Century Cures Act, Congress reauthorized the rare pediatric Priority Review Voucher (PRV) program and created a new PRV program for medical countermeasures that will sunset on October 1, 2023. Tonix management believes TNX-801 may qualify as a medical countermeasure, and therefore may be eligible for a Priority Review Voucher for FDA approval. If TNX-801 succeeds in qualifying for priority review in an indication that does not have any commercially approved products, seeking such a priority voucher for TNX-801 may provide a potential path to monetizing the technology as the Federal government's BioShield Special Reserve Fund (SRF) is the sole market for medical countermeasure products. In February 2017, Sarpeta Therapeutics sold its (pediatric) priority review voucher (PRV) to Gilead for $125 million, speeding up the US Food and Drug Administration (FDA) approval process for any future drug or biologic of Gilead's choosing from 10 months to six months.
(http://www.raps.org/Regulatory-Focus/News/2017/02/21/26898/Sarepta-Sells-Priority-Review-Voucher-for-125M-to-Gilead/#sthash.T967FrDW.dpuf)

Comment

In reviewing the clinical landscape for new treatments in PTSD, it would appear that Tonix may have found a window of opportunity, both in terms of a lack of competition for patients and having a window to complete potential registration trials in a timeframe that holds few competitors. With the exception of one medical device company, Brainsway (pivotal/Phase III for the HAC-Coil, a deep transcranial magnetic stimulation device) who is currently recruiting patients, our review of clinicaltrials.gov shows virtually no other ongoing US Phase III trials employing novel therapeutics for the treatment of PTSD. A small number of companies are in Phase II trials and many of those trials will not be completed until 2018. NeoSync, the only other device company in trials for PTSD, is in early stage proof-of-concept trials also using transcranial magnetic stimulation. The Brainsway trial is expected to be completed by June 2017 and read out in the fall 2017.

We expect investors will be highly focused on any news related to the HONOR trial progress and on execution regarding the supportive trials that will be part of an eventual NDA filing for TNX-102 SL, assuming the HONOR trial produces favorable results. However, with only a single interim analysis planned at approximately a year from now, and virtually no other therapeutics in advanced clinical trials, it will be difficult to assess the probability of TNX-102 SL's clinical success much before the interim analysis. News related to the Brainsway Phase III trial could trigger volatility in TNXP shares in the absence of other trial-related news. *SG*

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