Pliant Therapeutics Announces Accelerated Bexotegrast Development Plan for the Treatment of Idiopathic Pulmonary Fibrosis

03-12-2024 at 7:30 AM EDT

Acceptance by European Union and other global health authorities of the pivotal, adaptive Phase 2b/3 trial will significantly shorten bexotegrast's time to Phase 3 data

Upsized Oxford Finance debt facility extends cash runway and funds accelerated development through 2026

SOUTH SAN FRANCISCO, Calif., March 12, 2024 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical-stage biotechnology company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases, today announced the implementation of BEACON-IPF as a pivotal, adaptive Phase 2b/3 trial in patients with idiopathic pulmonary fibrosis (IPF). The adaptive design implementation, based on acceptance by the European Union (EU) and other global health authorities, will significantly shorten bexotegrast's late-stage development compared to a traditional Phase 3 trial. Bexotegrast is an oral, small molecule, dual-selective inhibitor of αvβ6 and αvβ1 integrins in clinical development for the treatment of IPF and primary sclerosing cholangitis (PSC).

"The implementation of BEACON-IPF as an accelerated pivotal, adaptive Phase 2b/3 trial design is another example of our efficient approach to drug development," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "With this trial design, we could shorten the time to Phase 3 data meaningfully."

Following acceptance by the EU and various other global health authorities, the Company is implementing BEACON-IPF as a Phase 2b/3 operationally seamless, adaptive design which includes the ongoing BEACON-IPF Phase 2b trial. Patients will begin enrolling in the Phase 3 component immediately after completion of enrollment of the Phase 2b component of the trial. Because of the seamless design, the power of the Phase 2b will be increased by augmenting the sample size by 90 patients, allowing both components to support potential registration. This increase is expected to have minimal impact on timelines.

The Company also announced an amendment to its May 2022 $100 million loan facility with Oxford Finance LLC, upsizing the facility to a total size of $150 million of available non-dilutive capital. This facility, along with the Company's December 31, 2023 cash and cash equivalents of $495.7 million are expected to fund Pliant through 2026.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-stage biopharmaceutical company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases. Pliant's lead product candidate, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant is conducting BEACON-IPF, a Phase 2b/3 trial of bexotegrast in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of αvß1 integrin for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant has initiated a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 integrins, that is being developed for the treatment of solid tumors. In addition to clinical-stage programs, Pliant currently has a preclinical program targeting muscular dystrophies. For additional information, please visit: www.PliantRx.com. Follow us on social media: X, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding our expectation that the expansion of BEACON-IPF Phase 2b Trial into a pivotal, adaptive Phase 2b/3 Trial has the potential to significantly accelerate bexotegrast's late-stage development compared to a traditional Phase 3 trial and potentially shorten the time to Phase 3 data; our plans to begin enrolling Phase 3 patients immediately upon the completion of enrollment of Phase 2b; the anticipated impact of augmenting the sample size of our Phase 2b trial in IPF; our access to future capital under the Oxford debt facility and the sufficiency of our cash runway to fund operations through the end of 2026. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the impact of current macroeconomic and marketplace conditions on our business, operations, clinical supply and plans, our interactions with health authorities, our reliance on third parties for critical aspects of our development operations, the risks inherent in the drug development process, competition with other drugs and drug candidates, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, including the availability of additional term loans under our loan facility, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the

period ended December 31, 2023 which is on file with the SEC and available on the SEC's website at www.sec.gov. Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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