February 16, 2021

Citius Pharmaceuticals Issues Shareholder Letter with Corporate Update on Recent Achievements and Anticipated Milestones for 2021

-2021 Expected to be a Banner Year for Advancing Three Product Platforms in the Clinic:

-Mino-Lok® Interim Efficacy Analysis

-Halo-Lido filing IND and in Phase 2b trial

-Mino-Wrap™ in Pre-Clinical Development, targeting IND by end of year

-NoveCite subsidiary progressing with: continued data collection from an ongoing proof-of-concept sheep ARDS model; initiating the manufacture of clinical-grade induced-mesenchymal stem cells (i-MSCs); and implementation of FDA-required animal GLP toxicology studies

CRANFORD, N.J., Feb. 16, 2021 /PRNewswire/ -- Citius Pharmaceuticals, Inc. ("Citius" or the "Company") (Nasdaq: CTXR), a specialty pharmaceutical company developing and commercializing critical care drug products, today issued a shareholder letter providing a corporate update on the Company's recent achievements and anticipated milestones for 2021.

Highlights from the letter include:

- Mino-Lok® pivotal trial interim analysis and review by the Data Monitoring Committee (DMC) expected in the second quarter
- Halo-Lido IND (second quarter) and Phase 2b protocol to be filed afterwards
- Mino-Wrap™ in pre-clinical development with plans to submit IND to the FDA by the end of the year
- NoveCite *i*-MSCs development is progressing with: ongoing data generation from our proof-of-concept sheep acute respiratory distress syndrome (ARDS) model demonstrating impressive interim results (studies to be completed in second quarter); FDA-required GLP animal toxicology studies have been implemented; and development of an *i*-MSC master cell bank (MCB) followed by cGMP manufacturing is underway
- Private placement for gross proceeds of $20.0 million and investors' exercise of

warrants generating $4.5 million in gross proceeds completed in January 2021 and February 2021, respectively

"Our important achievements against the COVID headwinds last year give us great confidence that 2021 will be a banner year for advancing our three product platforms in the clinic, and our corporate decision to commence the development of NoveCite next-generation cellular therapies further expands our goal as a specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products for significant unmet medical needs" said Myron Holubiak, President and CEO of Citius Pharmaceuticals. "Our advanced clinical program for Mino-Lok is moving forward with expected full enrollment for the Phase 3 pivotal trial this year. For Halo-Lido, we expect to file an Investigational New Drug Application (IND) for the combination by the second quarter and initiate our Phase 2b trial by year-end. We also plan to start pre-clinical pharmacology and toxicology studies for Mino-Wrap within the next few months along with chemistry, manufacturing and controls (CMC) development, and we target filing an IND by the end of 2021. In addition to the plans described above for our NoveCite *i*-MSCs Program, we plan to submit an IND to the FDA and initiate our Phase 1 first-in-human clinical trial in COVID-19 ARDS by the end of the second quarter of 2022. Our recent $20 million private round of financing and investors' exercise of warrants for net proceeds of approximately $4.5 million provides significant financial runway to move forward with our three programs in the clinic, as well as manufacturing development for our unique induced-mesenchymal stem cell therapy for ARDS associated with COVID-19. We are excited about the road ahead and thankful as always for the ongoing support of our shareholders."

To read the Shareholder Letter in its entirety, please visit the Company's Investor Info website at ir.citiuspharma.com.

About Citius Pharmaceuticals, Inc.
Citius is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products, with a focus on anti-infectives and cancer care. For more information, please visit www.citiuspharma.com.

Safe Harbor
This press release may contain "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. Such statements are made based on our expectations and beliefs concerning future events impacting Citius. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "plan," "expect," "should," and "may" and other words and terms of similar meaning or use of future dates. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated are: risks associated with conducting clinical trials and drug development, including anticipated development timelines and study results; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; the early stage of products under development; our dependence on third-party suppliers; our need for substantial additional funds; patent and intellectual property matters; market and other conditions; our ability to attract, integrate, and retain key personnel; the estimated markets for our product candidates and the acceptance thereof by any market; risks related to our

growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; government regulation; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

Contact:
Andrew Scott
Vice President, Corporate Development
(O) 908-967-6677 x105
(M) 646-522-8410
ascott@citiuspharma.com

View original content:http://www.prnewswire.com/news-releases/citius-pharmaceuticals-issues-shareholder-letter-with-corporate-update-on-recent-achievements-and-anticipated-milestones-for-2021-301228425.html

SOURCE Citius Pharmaceuticals, Inc.