Global Cancer Immunotherapy MKT led by Astra Zeneca: AZN; Celgene: CELG & Newcomer; Citius Pharmaceuticals NASDAQ: CTXR

Global Cancer immunotherapy MKT to reach 152B by 2024 led by Astra Zeneca: AZN; Celgene: CELG Including Late Stage Newcomer; Citius Pharmaceuticals NASDAQ: CTXR

CTXR Logo

CRANFORD, NEW JERSEY, UNITED STATES, May 4, 2022 / EINPresswire.com/ -- The Global Cancer immunotherapy market is expected to reach 152 Billion by 2024 led by Astra Zeneca Nasdaq: AZN; Celgene Corp. (NASDAQ: CELG) Including Late Stage Newcomer; Citius Pharmaceuticals, Inc. (NASDAQ: CTXR)

Pharmaceutical Advancements for Oncology, Anti-Infectives in Adjunct Cancer Care, Unique Prescription Products and Stem Cell Therapies: Citius Pharmaceuticals, Inc. (NASDAQ: CTXR)

> 2022 is a year of important catalysts for Citius as we continue to make progress on multiple fronts. We recently released topline results for I/ONTAK which were consistent with the prior FDA-approved"
>
> *Leonard Mazur, CTXR Chairman and CEO*

- Two Late-Stage Product Candidates Progressing to Phase 3 Clinical Trials.
- Mino-Lok(R) Granted Fast Track Designation by the U.S. FDA.
- I/ONTAK Received Orphan Drug Designation by the U.S. FDA.
- Developing a Novel Proprietary Mesenchymal Stem Cell

Treatment for Acute Respiratory Conditions with Near-Term Focus on Acute Respiratory Distress Syndrome Associated with COVID-19.

- First Patient Enrolled in Phase 2b Study of Halo-Lido for Prescription Treatment of Hemorrhoids.

- Bio-Pharma Industry Veteran Management Realignment to Support Commercialization of Late-Stage Product Candidates.

Citius Pharmaceuticals, Inc. (NASDAQ: CTXR) Recent Highlights and Upcoming Milestones

- Citius anticipates filing a biologics license application (BLA) for I/ONTAK® with the U.S. Food and Drug Administration (FDA) in the second half of 2022;

- Topline data from the Phase 3 study of cancer immunotherapy I/ONTAK are consistent with the previously-approved formulation of denileukin diftitox (ONTAK), and there are no new safety signals;

- Halo-Lido Phase 2b trial initiated in April 2022 with last patient enrollment anticipated by the end of 2022;

- Phase 3 Mino-Lok ® trial proceeding without modification as recommended by the independent data monitoring committee (DMC) following all three DMC reviews;

- Mino-Lok Phase 3 trial completion anticipated by end of 2022; and,

- Pre-clinical development ongoing for Citius' Mino-Wrap and induced mesenchymal stem cell

CTXR Mino-Lok

CTXR Antibiotic

CTXR NASDAQ

programs.

CTXR Mission

"2022 is a year of important catalysts for Citius as we continue to make progress on multiple fronts. We recently released topline results for I/ONTAK which were consistent with the prior FDA-approved and marketed formulation of denileukin diftitox (ONTAK). In preparation for a planned BLA submission in the second half of 2022, we are marshalling the necessary manufacturing and commercial resources to support the application, and ultimately a successful launch," stated Leonard Mazur, Chairman and CEO of Citius.

"Our Mino-Lok program continues to advance in accordance with the recommendations of the independent data monitoring committee, which advised us to continue with the trial as planned, following each of its three data reviews. We remain encouraged by the positive signal conveyed by the DMC guidance to proceed. Coupled with the recent ramp up in patient recruitment following an easing of COVID-related hospital restrictions, we believe our efforts to increase engagement with existing trial sites and to onboard additional sites will continue to drive trial enrollment and enable us to achieve the necessary trial events to support statistically significant results," added Mazur.

"In April, we initiated our Phase 2b Halo-Lido trial for the treatment of hemorrhoids. By the end of 2022, we expect to complete trial enrollment. A data readout will follow upon validation and analysis of the information provided in the electronic patient reported outcome tool (ePRO) designed with guidance from the FDA. The results will be used to design the Phase 3 trial. As this product would ultimately be marketed directly to consumers, rather than to targeted physician and hospital groups like our other pipeline candidates, we will evaluate alternatives to optimize the value of this asset as we advance the program. Citius considers all strategic alternatives to maximize the value of our portfolio, individually and collectively, on an ongoing basis. We believe we remain well capitalized to advance our programs through multiple catalysts this year, and we plan to continue building long-term value in the business by focusing on execution," concluded Mr. Mazur.

2022 Achieved and Anticipated Catalysts

- Report Topline results of I/ONTAK Phase 3 trial (April 2022)

- Initiate Halo-Lido Phase 2b trial (April 2022)

Submit I/ONTAK BLA application (2H 2022)

Complete enrollment in Mino-Lok Phase 3 trial (end of 2022)

Complete enrollment in Halo-Lido Phase 2b trial (end of 2022)

Citius Pharmaceuticals, Inc. (NASDAQ: CTXR) is a late-stage biopharmaceutical company dedicated to the development and commercialization of first-in-class critical care products, with a focus on oncology, anti-infectives in adjunct cancer care, unique prescription products, and stem cell therapies. CTXR has two late-stage product candidates, Mino-Lok(R), an antibiotic lock solution for the treatment of patients with catheter-related bloodstream infections (CRBSIs), which is currently enrolling patients in a Phase 3 Pivotal superiority trial, and I/ONTAK (E7777), a novel IL-2R immunotherapy for an initial indication in cutaneous T-cell lymphoma (CTCL), which has completed enrollment in its Pivotal Phase 3 trial. Mino-Lok(R) was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). I/ONTAK has received orphan drug designation by the FDA for the treatment of CTCL and peripheral T-cell lymphoma (PTCL).

Through its subsidiary, NoveCite, Inc., CTXR is developing a novel proprietary mesenchymal stem cell treatment derived from induced pluripotent stem cells (iPSCs) for acute respiratory conditions, with a near-term focus on acute respiratory distress syndrome (ARDS) associated with COVID-19.

CTXR Enrolls First Patient in Phase 2b Study of Halo-Lido for the Prescription Treatment of Hemorrhoids

On April 26th CTXR announced that the first patient has been enrolled in the Company's Phase 2b clinical study of Halo-Lido for the treatment of hemorrhoids. If approved, Halo-Lido would be the first FDA-approved prescription product indicated for the treatment of hemorrhoids.

The CTXR Phase 2b study is a multi-center, randomized, dose-ranging, double-blind, parallel group comparison clinical trial. Five cohorts of adults with a clinical diagnosis of symptomatic Goligher's classification Grade II or Grade III hemorrhoids will be dosed. Approximately 60 patients per cohort are expected to be enrolled, for a total of 300 patients.

The key objective of the CTXR study is to evaluate the ability of the formulations used in each cohort to provide relief for patients with acute flare ups. The study will evaluate reduction in hemorrhoidal symptoms (including: pain, burning, itching, and swelling) following treatment and is expected to provide the foundation for development of the Phase 3 study. The FDA has guided CTXR in developing a Patient Reported Outcome (ePRO) instrument which patients will use to record and report important safety and efficacy data in real time. The instrument has been adapted for use on an electronic platform and will be loaded on patients' hand-held smart devices. The CTXR study will also be used to validate the ePRO. Results of this trial are expected in the second half of 2023.

"We are pleased to have initiated the Halo-Lido study and expect to complete enrollment later this year. Currently, there are no FDA-approved prescription-strength treatments available to the millions of adults who suffer from hemorrhoid discomfort each year. If approved, Halo-Lido would be the first prescription product indicated for the treatment of hemorrhoids. As such, we believe there is a substantial worldwide market opportunity for this drug candidate. Assuming study results are positive, and in order to realize the full potential of Halo-Lido, we intend to seek strategic or financial partners for this asset at the appropriate time," stated Leonard Mazur, Executive Chairman of CTXR.

Halo-Lido is a proprietary CTXR topical formulation of halobetasol and lidocaine that is intended to provide symptomatic relief to individuals suffering from hemorrhoids. Hemorrhoids are a gastrointestinal disorder characterized by pain, swelling, itching, tenderness, and bleeding. Although hemorrhoids are not life-threatening, individual patients often suffer painful symptoms that can limit social activities and have a negative impact on the quality of life. More than half of the U.S. population will experience hemorrhoidal disease at least once in their life. Each year, nearly 10 million patients in the U.S. report symptoms.

Key Management Realignment to Support Commercialization of Two Late-Stage Product Candidates

Leonard Mazur named Chairman of the Board of Directors and CEO of CTXR.

Co-founder, Myron Holubiak to transition from President & CEO to Executive Vice Chairman of the Board of Directors to build commercial capabilities.
Jaime Bartushak, Chief Financial Officer, to assume additional responsibilities as Chief Business Officer.

Commercial capabilities strengthened with addition of Michael McGuire as VP, Program Leader for Anti-Infectives.

On April 13th CTXR announced that the Board of Directors has approved key management changes to strengthen the Company's commercial capabilities as its two late Phase 3 programs for I/ONTAK (E7777) and Mino-Lok(R) near completion. The organizational alignment will enable CTXR to focus its resources on advancing both of these near-term opportunities and will be effective as of May 1, 2022.

The Board of Directors has appointed Mr. Holubiak to the newly created position of Executive Vice Chairman with responsibility for building the CTXR commercial team and guiding the anticipated product launches of the Company's first commercial products. The near-term focus will be on the successful launch of I/ONTAK for the systemic treatment of cutaneous T-cell lymphoma (CTCL), which recently released topline results from its Phase 3 trial, and Mino-Lok(R) which is expected to complete Phase 3 trial enrollment later this year. Leonard Mazur, CTXR co-

founder and Executive Chairman has been named as CEO and Chairman by the Board of Directors. Additionally, in recognition of the incremental needs of a growing CTXR team, Chief Financial Officer Jaime Bartushak will assume additional responsibilities as Chief Business Officer.

Mr. Holubiak is uniquely experienced to drive the commercialization strategy for CTXR. While President of Roche Laboratories, he led the organization in successfully launching important oncology and antibiotic products including Xeloda(R) for the treatment of breast and colorectal cancer, and Rocephin(R), the most successful injectable cephalosporin antibiotic at the time.

Jamie Bartushak, CTXR Chief Financial Officer, will assume additional operational responsibilities in his expanded role as Chief Business Officer. He will oversee all aspects of finance, business development and operations at the Company.

In order to efficiently bring the CTXR products to market, Michael McGuire will join as VP, Program Leader for Anti-Infectives. Mr. McGuire will work closely with Mr. Holubiak and the rest of the CTXR team to leverage his broad pharmaceutical experience and network.

Michael McGuire has extensive business leadership experience within the pharmaceutical industry, including P&L management, strategic planning, marketing, and new product development. While at Roche Laboratories, Michael led the Tamiflu(R) franchise to become the first billion-dollar product for Roche in the United States and designed an award-winning direct-to-consumer (DTC) Tamiflu educational campaign that raised consumer awareness by 65%.

Most recently, Mr. McGuire was Senior Vice President Commercial, Government Affairs, and Customer Engagement at Melinta Therapeutics. In this role, he called on members of the House and Senate and met with representatives from the Centers for Medicare and Medicaid Services (CMS) and the Biomedical Advanced Research and Development Authority (BARDA) to develop support for the DISARM Act that would change the reimbursement landscape for anti-infectives. Additionally, he integrated three commercial organizations (Melinta, Cempra, and The Medicines Company) while launching two new anti-infective drugs.

Prior to joining Melinta, Michael served as Senior Vice President, Global Infectious Disease at The Medicines Company, a developer of hospital products in the anti-infective and cardiovascular therapeutic areas. He managed global commercial operations for an anti-infective portfolio of products, and successfully launched the drug Orbactiv(TM) in a highly competitive generic and branded marketplace. As a seasoned executive, Mr. McGuire has successfully launched multiple anti-infective products, including a blockbuster drug, built alliances with government agencies, launched consumer awareness programs, and effectively managed commercial organization costs.

For more information on Citius Pharmaceuticals, Inc. (NASDAQ: CTXR) visit
http://www.citiuspharma.com

DISCLAIMER: CAP/FrontPageStocks/CorporateAds.com (CA) is a third-party publisher and news dissemination service provider. CAP/FPS/CA is NOT affiliated in any manner with any company mentioned herein. CAP/FPS/CA is a news dissemination solutions provider and is NOT a registered broker/dealer/analyst/adviser, holds no investment licenses and may NOT sell, offer to sell or offer to buy any security. CAP/FPS/CA's market updates, news alerts and corporate profiles are NOT a solicitation or recommendation to buy, sell or hold securities. The material in this release is intended to be strictly informational and is NEVER to be construed or interpreted as research material. All readers are strongly urged to perform research and due diligence on their own and consult a licensed financial professional before considering any level of investing in stocks. All material included herein is republished content and details which were previously disseminated by the companies mentioned in this release or opinion of the writer. CAP/FPS/ CA is not liable for any investment decisions by its readers or subscribers. Investors are cautioned that they may lose all or a portion of their investment when investing in stocks. CAP/FPS/CA has been compensated $500 by a third party for dissemination of this article.

Disclaimer/Safe Harbor:

These news releases and postings may contain forward-looking statements within the meaning of the Securities Litigation Reform Act. The statements reflect the Company's current views with respect to future events that involve risks and uncertainties. Among others, these risks include the expectation that any of the companies mentioned herein will achieve significant sales, the failure to meet schedule or performance requirements of the companies' contracts, the companies' liquidity position, the companies' ability to obtain new contracts, the emergence of competitors with greater financial resources and the impact of competitive pricing. In the light of these uncertainties, the forward-looking events referred to in this release might not occur.
SOURCE: CorporateAds.com

Leonard Mazur, CTXR Chairman and CEO
Citius Pharmaceuticals Inc.
+1 908-967-6677
email us here
Visit us on social media:
LinkedIn