Chimerix Receives FDA Clearance for Rolling Submission of New Drug Application for Brincidofovir as a Medical Countermeasure for Smallpox

April 28, 2020

DURHAM, N.C., April 28, 2020 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, today announced that the Company has received clearance from the U.S. Food and Drug Administration (FDA) for a rolling submission of its New Drug Application (NDA) for the approval of brincidofovir (BCV) as a medical countermeasure for smallpox. The Company intends to begin the rolling NDA submission for BCV in May 2020 with completion targeted for mid-2020. Chimerix is developing BCV as a potential medical countermeasure for smallpox under an ongoing collaboration and funding provided by the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, under ongoing USG Contract No HHSO10201100013C.

“The value of being prepared for viral outbreaks has never been clearer. The potential for engineered or naturally occurring resistance to the currently approved therapy has made the development of BCV imperative,” stated Mike Sherman, Chief Executive Officer of Chimerix. “The clearance to begin the rolling submission of the NDA for BCV is an important milestone for both the company and BARDA as it brings us one step closer to realizing the mandate of Project Bioshield. Our NDA preparation is already in process and we look forward to working with BARDA on a potential procurement contract in advance of FDA approval.”

In a lethal model, BCV when administered at varying times post-infection demonstrated a statistically significant survival advantage relative to placebo. This observation was consistent throughout all time points.

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Its two clinical-stage development programs are dociparstat sodium (DSTAT) and brincidofovir (BCV).

Dociparstat sodium is a potential first-in-class glycosaminoglycan compound derived from porcine heparin that has low anticoagulant activity but retains the ability to inhibit activities of several key proteins implicated in the viability of AML blasts and leukemic stem cells in the bone marrow during chemotherapy (e.g., CXCL12, selectins, HMGB1, elastase). Randomized Phase 2 data suggest that DSTAT may also accelerate platelet recovery post-chemotherapy via inhibition of platelet factor 4, a negative regulator of platelet production that impairs platelet recovery following chemotherapy. BCV is an antiviral drug candidate in development as a medical countermeasure for smallpox. For further information, please visit the Chimerix website, www.chimerix.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things, Chimerix’s ability to submit and/or obtain regulatory approvals for BCV; and Chimerix’s ability to enter into a procurement contract for BCV as a medical countermeasure. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that BCV may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that Chimerix may not receive a procurement contract for BCV for smallpox in a timely manner or at all; Chimerix’s reliance on a sole source third-party manufacturer for drug supply; risks that ongoing or future trials may not be successful or replicate previous trial results, or may not be predictive of real-world results or of results in subsequent trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

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