Chimerix Announces FDA Acceptance of New Drug Application for Brincidofovir as a Medical Countermeasure for Smallpox

December 7, 2020

FDA Grants Priority Review and Sets PDUFA Date for April 7, 2021

DURHAM, N.C., Dec. 07, 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 U.S. Food and Drug Administration (FDA) has accepted the filing of a New Drug Application (NDA) for brincidofovir (BCV) as a medical countermeasure for smallpox. The FDA granted Priority Review and set an action date of April 7, 2021 under the Prescription Drug User Fee Act (PDUFA).

Brincidofovir, an investigational therapy, is a nucleotide analog lipid-conjugate that has demonstrated antiviral activity as a medical countermeasure against smallpox under the FDA's Animal Efficacy Rule, which allows for testing of investigational drugs in animal models to support effectiveness in diseases which are not ethical or feasible to study in humans.

Chimerix has developed 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 contract number HHSO100201100013C.

The FDA's acceptance of the NDA indicates the application is sufficiently complete to permit a substantive review. A Priority Review designation accelerates the FDA's review time from 10 months to a goal of six months and is granted to drugs that may offer a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition. At this time, the FDA is not planning to hold an advisory committee meeting to discuss this application.

“Our team has continued to execute extremely well in collaboration with BARDA to advance this program,” said Mike Sherman, Chief Executive Officer of Chimerix. “As we’ve observed in recent months, the threat of serious viral infections requires robust pandemic plans to protect the population and our economy. With BCV, we hope to provide that protection from smallpox, and look forward to working with BARDA on next steps in making this countermeasure available to patients in advance of an outbreak.”

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).

DSTAT is a potential first-in-class glycosaminoglycan compound derived from porcine heparin that, compared to commercially available forms of heparin, may be dosed at higher levels without associated bleeding-related complications. DSTAT is being studied in a Phase 2/3 trial to assess safety and efficacy in adults with acute lung injury with underlying COVID-19. A Phase 3 trial protocol to study DSTAT in acute myeloid leukemia has been developed in alignment with the US Food and Drug Administration (FDA) and the first patient visit is expected in early 2021. BCV is an antiviral drug candidate developed as a potential medical countermeasure for smallpox and is currently under review for regulatory approval in the United States. 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 obtain regulatory approval for BCV; and the timing and receipt of a potential procurement contract for BCV in smallpox. 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 will not obtain a procurement contract for BCV in 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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