Chimerix Receives Orphan Drug Designation from the FDA for Brincidofovir for the Treatment of Smallpox

June 7, 2018

DURHAM, N.C., June 07, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for brincidofovir for the treatment of smallpox.

Chimerix has been working with the Biomedical Advanced Research and Development Authority (BARDA) since 2011 to develop brincidofovir as a medical countermeasure for smallpox, demonstrating improved survival rates following confirmed orthopoxvirus infections in multiple animal models.

“We are very pleased to have received Orphan Drug Designation from the FDA for brincidofovir as a treatment for smallpox,” said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix. “Though declared eradicated in the late 1970s, smallpox, whether natural or synthetic, continues to be a potential global threat in today’s interconnected world. We are committed to completing the development program for brincidofovir as a much-needed treatment option for smallpox, in close collaboration with BARDA and FDA.”

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the United States. Orphan Drug Designation provides manufacturers with many benefits, including a waiver of the FDA Prescription Drug User Fee Act.

About Brincidofovir
Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has antiviral activity against all five families of DNA viruses that affect humans, including adenoviruses and variola virus, the virus that causes smallpox. Brincidofovir has a high barrier to resistance, no myelosuppression and a low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA for adenovirus, CMV and smallpox. Brincidofovir has also received Orphan Medicinal Product Designation from the European Commission for the treatment of adenovirus, for the prevention of CMV disease, and for the treatment of smallpox.

About Chimerix
Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. Chimerix's proprietary lipid conjugate technology and compound library have produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and a new clinical candidate, CMX521, the first clinical stage direct-acting antiviral for the treatment and prevention of norovirus. For further information, please visit Chimerix's website, www.chimerix.com.

Forward-Looking Statements
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility that there may not be a viable continued development path for brincidofovir, that FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, brincidofovir may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for brincidofovir with other regulatory authorities. These risks, uncertainties and other factors could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Annual Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Source: Chimerix, Inc.