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Chimerix Presents Positive Results From Brincidofovir Pivotal Study in Animal Model for Smallpox

100 Percent Survival Demonstrated in Animals Treated Immediately With Brincidofovir at Time of Confirmed Infection

DURHAM, N.C., Feb. 08, 2016 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today presented positive results from a pivotal study of its antiviral, brincidofovir, in an animal model for smallpox at the ASM Biodefense and Emerging Diseases Research Meeting in Arlington, Virginia.

The study met its primary endpoint of clinically and statistically significant ($p < 0.05$) reduction in mortality for brincidofovir-treated animals compared with animals that received placebo. At the time of detection of fever, a clinical indication of confirmed infection, animals were randomized to receive placebo or brincidofovir administered immediately or after a 24, 48, or 72 hour delay. Animals that received brincidofovir immediately had 100 percent survival, and animals that received brincidofovir after a 24 or 48 hour delay had a 93 percent survival, statistically significant improvements compared with less than 50 percent survival in animals that received placebo. Treatment with brincidofovir begun immediately or following a 24 or 48 hour delay resulted in an immune response and a reduction in the amount of virus in the blood. These effects in the brincidofovir-treated animals may decrease the spread of infection between animals, and if confirmed in humans, brincidofovir may decrease person-to-person transmission of smallpox in a bioterror event.

"Data from this pivotal animal model study support the potential to advance brincidofovir as a medical countermeasure for smallpox. There is currently no antiviral approved to treat smallpox, considered a Category A Priority Pathogen by the National Institute of Allergy and Infectious Diseases (NIAID). We look forward to working closely with the FDA and BARDA to contribute to the U.S. national security and public health preparedness," said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix.

The pivotal smallpox study was conducted under the Food and Drug Administration's (FDA) 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. In this well-characterized model of smallpox, animals were administered a lethal inoculum of rabbitpox virus and monitored for clinical signs of disease. Following the onset of the first clinical sign of disease, animals were randomized to receive placebo, immediate brincidofovir, or brincidofovir after a delay of 24, 48, or 72 hours. The primary objective of this study was to assess the efficacy of immediate and delayed treatment with brincidofovir compared with placebo in preventing mortality in animals infected with the lethal rabbitpox virus. Secondary objectives were to evaluate incidence, severity and progression of clinical events associated with rabbitpox virus infection between the brincidofovir treatment groups and placebo-treated animals.

The brincidofovir doses used in this animal study were scaled to equivalent doses used in the clinical trials of brincidofovir for CMV and adenovirus in humans. Final data from the rabbitpox study together with efficacy data from a mouse model of smallpox will be submitted to the FDA for discussion of next steps.

About Smallpox

Smallpox is estimated to have killed more than one billion people worldwide prior to its eradication in 1980 following a global vaccination campaign. Smallpox stocks remain for research purposes in the United States and Russia; however, undeclared stocks are suspected to exist.

BARDA Contract for the Development of Brincidofovir for Smallpox

The Company initiated the development contract with the Biomedical Advanced Research and Development Authority (BARDA) in February 2011 to support early research and development of brincidofovir in animal models of smallpox. In September 2015, the Company executed an extension of its contract with BARDA for the development of brincidofovir to treat smallpox. The latest contract extension provided approximately $13.0 million in additional funding.

This project has been funded in whole or in part with funds from BARDA, office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. HHSO100201100013C.

BARDA Procurement of Brincidofovir for the Strategic National Stockpile

In April 2015, BARDA posted a notice of intent to award a sole source contract to Chimerix for procurement of up to 1.7 million courses of brincidofovir for the Center for Disease Control and Prevention's Strategic National Stockpile. BARDA's total estimated dollar value for the 60-month base period contract is approximately $100 million. If all options are exercised by BARDA, the total dollar value is estimated to be approximately $435 million over 5 years. Any award would be subject to negotiation and execution of a definitive agreement by the parties. Chimerix submitted a proposal to BARDA in August 2015, but its finalization was delayed due to the lack of an approved federal budget. The recent approval of a federal budget for fiscal year 2016 may allow final negotiations to resume with respect to the proposal.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is an oral nucleotide analog that has shown *in vitro* antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenoviruses. Brincidofovir has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. Brincidofovir has received Fast Track designation from the FDA for CMV, adenovirus, and smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (CMX001), a clinical-stage nucleotide analog, CMX157 which was licensed to ContraVir Pharmaceuticals in 2014, and early clinical candidates including CMX669. 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 Quarterly 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 Current Report on Form 8-K 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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