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

Data Demonstrated Statistically Significant Survival Benefit

DURHAM, N.C., July 23, 2015 (GLOBE NEWSWIRE) -- Chimerix, Inc. (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced that its investigational antiviral brincidofovir showed a survival benefit in a pivotal study of an animal model for smallpox.

Chimerix is developing brincidofovir as a medical countermeasure against smallpox, for which there is no antiviral agent currently approved. Brincidofovir has demonstrated broad-spectrum *in vitro* activity across five families of DNA viruses, and in addition to smallpox, is also being studied in two Phase 3 clinical trials for prevention of cytomegalovirus (CMV) and treatment of adenovirus infections in immunocompromised patients. The U.S. Food and Drug Administration (FDA) has granted Fast Track status to brincidofovir for smallpox, CMV, and adenovirus.

The pivotal smallpox study was conducted under the FDA's Animal Efficacy Rule, which allows for testing of investigational compounds in animal models to support the drug's effectiveness in diseases which are not ethical or feasible to study in humans. The primary objective of this study was to assess the efficacy of immediate and delayed treatment with brincidofovir after clinical signs of disease compared with placebo in preventing mortality in rabbits infected with the lethal rabbitpox virus - a well-characterized model of smallpox. The study met its primary endpoint. Rabbits treated with brincidofovir upon the first clinical sign of disease, and rabbits that received brincidofovir 24 or 48 hours after the first clinical sign of disease, demonstrated a statistically significant ($p < 0.05$) reduction in mortality compared to rabbits that received placebo. Final results from this study, including data on the incidence and severity of clinical and laboratory events in each cohort, are expected by the fourth quarter of 2015 and will be submitted to an upcoming medical conference and to the FDA for discussion of next steps.

The brincidofovir doses used in this animal study were scaled to equivalent doses used in the Phase 3 clinical trials of brincidofovir for CMV and adenovirus in humans, the SUPPRESS and AdVise trials, respectively. Additional data may be required prior to a new drug application (NDA) submission for smallpox.

"Data from this pivotal study support the potential for brincidofovir to contribute to the U.S. national security and public health preparedness for the treatment of smallpox, which is a Category A Priority Pathogen," said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix. "We look forward to continuing our work with BARDA and the FDA to advance brincidofovir as a medical countermeasure for smallpox."

BARDA Notice of Intent for Sole Source Contract to Procure Brincidofovir for Smallpox Treatment

In April 2015, BARDA announced its intent to award a procurement contract to Chimerix and stated that it anticipates announcing the award by the end of September 2015. The estimated period of performance for the 60-month base period is September 2015 through August 2020 for initial deliveries of brincidofovir to the U.S. Centers for Disease Control and Prevention's Strategic National Stockpile (CDC/SNS), according to the posted notice of intent. Options may be exercised at BARDA's discretion to achieve the potential delivery of a maximum of 1.7 million treatment courses. 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. Any award would be subject to negotiation and execution of a definitive agreement by the parties.

Following the initial notice of intent posting by BARDA in April, a protest was filed with the Government Accountability Office (GAO) opposing the award of a sole source contract with Chimerix for procurement of brincidofovir without full and open competition. This protest has been withdrawn.

About Smallpox

Smallpox is estimated to have killed more than one billion people worldwide prior to its eradication declared by the World Health Organization 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. Routine smallpox vaccination programs were discontinued after the global eradication in 1980, and with no antiviral agent approved for the treatment of smallpox, the U.S. population may be susceptible to a bioterror attack with devastating consequences.

About Brincidofovir (CMX001)

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 herpesvirus family and adenovirus. Brincidofovir has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. Based on the clinically and statistically significant Phase 2 results in cytomegalovirus (CMV) prevention, Chimerix initiated the 450 patient Phase 3 SUPPRESS trial, which completed enrollment in June 2015. If positive, data from SUPPRESS will support Chimerix's initial regulatory submission for brincidofovir for the prevention of CMV infection in adult hematopoietic cell transplant (HCT) recipients. Chimerix is also conducting AdVise, a Phase 3 trial in patients with adenovirus infection, an often-fatal viral infection with no approved treatment. Chimerix is working with the Biomedical Advanced Research and Development Authority (BARDA) to develop brincidofovir as a medical countermeasure against smallpox. 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 the FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens in the currently anticipated timelines or at all, and 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 in the currently anticipated timelines. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Chimerix's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Chimerix, and Chimerix assumes no obligation to update any such forward-looking statements.

For further information, please visit Chimerix's website, www.chimerix.com

CONTACT: Joseph T. Schepers

Executive Director,

Investor Relations and Corporate Communications

ir@chimerix.com

919-287-4125

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