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Chimerix to Provide Brincidofovir to Josh Hardy as First Patient in New Open-Label Study in Patients With Adenovirus Infections

Company Worked With FDA to Create Path Forward

DURHAM, N.C., March 11, 2014 (GLOBE NEWSWIRE) -- Chimerix, Inc. (Nasdaq:CMRX) today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) for the immediate initiation of a pilot trial of open-label brincidofovir for the treatment of adenovirus infections in immunocompromised patients. FDA has committed to work expeditiously with Chimerix on the design of a pivotal Phase 3 study that would be a continuation of this pilot study. Josh Hardy's story brought to public attention the often-devastating impact of adenovirus infection, and helped accelerate a discussion between the FDA and Chimerix regarding the need for additional clinical development to assess brincidofovir's potential in adenovirus infection. This study is expected to begin with Josh Hardy as the first patient enrolled on Wednesday, March 12, 2014.

"This 20-patient open-label study underscores Chimerix's mission to develop innovative antiviral therapies in areas of high unmet need - for everyone," said Kenneth I. Moch, President & CEO of Chimerix. "Being unable to fulfill requests for compassionate use is excruciating, and not a decision any one of us ever wants to have to make. It is essential that each individual in a health crisis be treated with equal gravity and value, a principle we have upheld by pursuing further clinical study of brincidofovir that will inform its use in adenovirus and other serious DNA viral infections."

"We are pleased to be providing access to brincidofovir in a manner consistent with our focus on progressing clinical development toward a potential regulatory approval that would make it widely available to patients who might benefit from its use," said Hervé Momméja-Marin, M.D., Vice President, Clinical Research of Chimerix. "We are grateful to the FDA for their continuous guidance and assistance in expediting brincidofovir's development path forward."

About Brincidofovir (CMX001)

Chimerix's lead product candidate, brincidofovir, has the potential to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by DNA viruses. Brincidofovir is an oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of DNA viruses that affect humans, including cytomegalovirus (CMV), adenovirus (AdV), BK virus and herpes simplex viruses. Brincidofovir has shown a favorable safety and tolerability profile, with no evidence of kidney or bone marrow toxicity in nearly 900 patients dosed to date.

In September 2013, data from Chimerix's Phase 2 trial of brincidofovir in the prevention of CMV in recipients of hematopoietic cell transplants (HCT) were published in *The New England Journal of Medicine* (N Engl J Med 369:1227-36). Building on these positive Phase 2 results in CMV, Chimerix initiated the Phase 3 *SUPPRESS* trial in the third quarter of 2013 which, if positive, will be used to support Chimerix's initial regulatory submission for the Accelerated Approval of brincidofovir for prevention of CMV infection in adult HCT recipients.

In late 2013, Chimerix presented data from the first exploratory trial of brincidofovir in early AdV infection. Brincidofovir initiated at the time of detection of AdV in the blood showed encouraging antiviral results and provided new data regarding the risk assessment for immunocompromised patients with AdV infection. A brincidofovir dose of 100 mg twice weekly, the dose being used in *SUPPRESS*, demonstrated a potent antiviral effect on levels of AdV in the blood, and a numeric decrease in overall mortality. Chimerix is also working with BARDA to develop brincidofovir as a medical countermeasure against smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to developing and commercializing novel, oral antivirals in areas of high unmet medical need. Chimerix's proprietary technology has given rise to two clinical-stage nucleotide analog lipid-conjugates, brincidofovir and CMX157, both of which have demonstrated the potential for enhanced activity and safety in convenient, orally administered dosing regimens. In the third quarter of 2013, Chimerix initiated the Phase 3 *SUPPRESS* trial of brincidofovir for the prevention of CMV infection in adult HCT recipients, also known as bone marrow transplants. Brincidofovir has shown broad-spectrum activity against all five families of DNA viruses that affect humans, including CMV, AdV, BKV and herpes simplex viruses. Brincidofovir has received Fast Track designation by the FDA, and the Phase 3 data, if positive, would be used

to support Accelerated Approval of brincidofovir for the prevention of CMV infection in adult HCT recipients. Chimerix is also working with BARDA to develop brincidofovir as a medical countermeasure against smallpox. Chimerix's second product candidate, CMX157, was licensed to Merck in July 2012 for the treatment of HIV infections. For further information, please visit Chimerix's website, www.chimerix.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Chimerix's filings with the Securities and Exchange Commission, including without limitation its most recent Annual Report on Form 10-K, its most recently filed Current Reports on Form 8-K 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. Chimerix undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

CONTACT: CHIMERIX CONTACT:

Joseph T. Schepers

Executive Director, Investor Relations

and Corporate Communications

jschepers@chimerix.com

919-287-4125

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