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Chimerix Announces Preliminary Data from Ongoing Phase 1 Dose Escalation Study of Intravenous Brincidofovir in Healthy Subjects

Study confirms drug levels for IV BCV 10 mg equivalent to oral BCV 100 mg

No gastrointestinal side effects seen with IV BCV at 10 and 25 mg doses

DURHAM, N.C., Jan. 06, 2017 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients, announced preliminary data from an ongoing Phase 1 study to investigate the safety, tolerability and plasma/intracellular concentration of intravenous (IV) brincidofovir (BCV) following single escalating doses in healthy adult subjects.

In this ongoing study, IV administration of BCV demonstrated a favorable tolerability profile at both doses tested to date. No drug related adverse events (AEs) or laboratory abnormalities were identified. Notably, gastrointestinal (GI) side effects were absent. Blood plasma concentrations of BCV which have previously demonstrated anti-viral potency in cytomegalovirus (CMV) prevention and adenovirus treatment were achieved with IV doses that were one tenth of those required with oral dosing. This suggests that even the lowest tested IV dose of brincidofovir should provide antiviral activity.

"Data from this ongoing study suggest that brincidofovir was generally safe and well tolerated at the 10 and 25 mg doses, and achieved target plasma concentrations," said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix. "These preliminary results build on our preclinical studies which showed that IV brincidofovir was associated with fewer GI side effects. We believe that IV brincidofovir represents a promising investigational option for the prevention and treatment of a broad range of life-threatening viral infections in immunocompromised patients."

A total of 40 healthy subjects will be randomized to receive either a single dose of IV BCV or IV placebo in one of four cohorts. To date, 16 subjects have enrolled into 2 dose groups; 8 subjects were randomized in each of Cohorts 1 (IV BCV 10 mg) and 2 (IV BCV 25 mg). It is anticipated that two additional cohorts will be enrolled.

As the new IV formulation of BCV progresses in clinical studies, BCV remains in development as an orally-administered lipid conjugate nucleotide for the treatment of adenovirus in hematopoietic cell transplant recipients and other immunocompromised patients, and as a medical countermeasure for the treatment of smallpox.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has shown *in vitro* antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenoviruses. BCV has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. BCV has received Fast Track designation from the FDA for adenovirus, CMV and smallpox. BCV has also received Orphan Medicinal Product Designation from the European Commission for the treatment of adenovirus and for the prevention of CMV disease, and the Committee for Orphan Medicinal Products has issued a positive opinion for an Orphan Designation 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 has produced BCV; CMX157, which was licensed to ContraVir Pharmaceuticals; and earlier-stage clinical candidates. Chimerix recently announced a new clinical candidate, CMX521, for the treatment and/or 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 BCV, that any clinical trials we may conduct will not demonstrate adequate efficacy and safety of BCV, that enrollment in clinical trials we may conduct may be insufficient or slower than we anticipate, that the FDA and other regulatory authorities may not approve BCV or BCV-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, BCV may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for BCV 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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