Chimerix Presents Results from Multiple Ascending Dose Study of IV Brincidofovir at IDWeek

October 5, 2018

DURHAM, N.C., Oct. 05, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today announced data from the company's Phase 1 study evaluating the safety and pharmacokinetics (PK) of multiple ascending doses (MAD) of intravenous (IV) brincidofovir (BCV) in healthy subjects. These data will be presented at IDWeek™ 2018, held October 3-7 in San Francisco, CA.

"This study shows that four weekly or twice-weekly doses of the IV formulation of brincidofovir are generally well tolerated, and the 10 mg dose provides similar blood levels as the oral 100 mg dose with no reported gastrointestinal side effects," said Garrett Nichols, MD, MS, Chief Medical Officer of Chimerix. "We have now opened two additional studies in stem cell transplant recipients in the U.S. and EU to confirm these promising results."

The Phase 1 study evaluated the safety and pharmacokinetics of IV BCV in 27 healthy individuals who were randomized 3:1 to receive IV BCV or placebo in sequential MAD cohorts. Individuals receiving IV BCV were given a 10 mg dose in a two-hour infusion twice a week for two weeks or a 20 mg dose in either a one- or two-hour infusion once a week for four weeks. Twice weekly doses of IV BCV at 10 mg provided similar blood levels of the drug as the oral BCV 100 mg dose previously studied in late-stage clinical trials, with no reported diarrhea or other gastrointestinal adverse events.

Other key findings include:

- Both doses of IV BCV were generally safe and well tolerated.
- No serious adverse events were reported; mild adverse events with 10 mg dose included headache and bruising at IV site of injection.
- Brincidofovir exposure was dose-proportional and no accumulation was observed.
- Mild alanine aminotransferase (ALT) increases were reversible upon cessation of drug, and were not associated with hyperbilirubinemia, as seen with oral BCV.

Poster Presentation Details:

- **Abstract Title:** *IV Brincidofovir (BCV): Pharmacokinetics (PK) and Safety of Multiple Ascending Doses (MAD) in Healthy Subjects* (1421)
- **Session:** Poster Abstract Session: PK/PD Studies
- **Location & Time:** S Poster Hall; Friday, October 5, 2018

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 cytomegalovirus (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, and Orphan Drug Designation from the FDA 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 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 our current or future clinical trials of brincidofovir may not be successful, 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. Similar risks and uncertainties apply to the Company's development of CMX521. 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 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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