

# Chimerix Announces Discovery and Demonstrated Preclinical Activity Supporting Ongoing Phase 1 Study of New Antiviral for Treatment and Prevention of Norovirus

June 12, 2018

- CMX521 is Active In Vitro Against All Strains of Norovirus Tested -
- Oral Dosing of CMX521 Inhibited Norovirus Replication in Animal Model -

DURHAM, N.C., June 12, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today announced results from preclinical studies supporting further evaluation of CMX521, the first direct-acting antiviral specifically for the treatment and prevention of norovirus. CMX521 showed activity *in vitro* against all strains of norovirus tested, suggesting broad efficacy against human noroviruses and supporting the ongoing Phase 1 study. The data will be presented in an oral and poster presentation at the 31<sup>st</sup>International Conference on Antiviral Research (ICAR) hosted by the International Society for Antiviral Research (ISAR) in Porto, Portugal.

"Norovirus is the most common cause of epidemic acute gastroenteritis worldwide, with roughly 700 million cases each year. There are currently no approved therapies for the treatment of chronic norovirus infection or for use as a prevention strategy to limit the spread of an outbreak," said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix. "Norovirus frequently impacts long-term care facilities and hospitals, causing ward shutdowns and widespread infection, and in immunocompromised stem cell and solid organ transplant recipients, norovirus can be deadly. We are encouraged by early data for CMX521, which suggest it may help prevent acute and treat chronic cases of norovirus."

Highlights from the presentations include the following:

- CMX521 is active in vitro against all noroviruses tested to date.
  - Targets a region of virus that is common to all strains.
- CMX521 has a promising safety profile with high safety margins for human exposure.
  - No genotoxicity or mitotoxicity observed.
- Oral administration delivers drug directly to target cells in the gut.
  - Oral CMX521 showed dose-dependent inhibition of norovirus replication in mouse gastrointestinal tissues and feces

"Antiviral drug discovery for norovirus is challenging; for example, a drug for norovirus prevention should ideally be fast-acting, work against all circulating strains and have an excellent safety profile," said Randall Lanier, PhD, Chief Science Officer of Chimerix. "CMX521 is a nucleoside antiviral that appears to meet all of these criteria. Our ongoing Phase 1 study will provide important data on pharmacokinetics, safety and tolerability, which will inform the dosing regimens in our Phase 2 efficacy study planned for 2019."

#### Presentation details:

Abstract title: Identification of a Novel Norovirus Antiviral (CMX521) Using High-Throughput Screening

• Poster: #88, Session 2

• Date:3:45-4:45 p.m., Thursday, June 14, 2018

Abstract title: CMX521: A Nucleoside with Pan-Genotypic Activity Against Norovirus

• Oral Session: #199, Emerging Infections and Clinical Evaluation of Antivirals

• Date: 9:40 a.m., Friday, June 15

## About CMX521

CMX521 is a nucleoside antiviral identified from the Chimerix Chemical Library as a potential treatment and/or prevention for norovirus, the most common cause of acute gastroenteritis worldwide. The ongoing Phase 1 study is evaluating the pharmacokinetics, safety and tolerability of CMX521. Study results are expected to be reported in the second half of 2018.

#### **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, <a href="https://www.chimerix.com">www.chimerix.com</a>.

#### **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 CMX521, that any clinical trials we may conduct may not demonstrate adequate efficacy and safety of CMX521, that the FDA and other regulatory authorities may not approve CMX521, and that marketing approvals, if granted, may have significant limitations on its use. As a result, CMX521 may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for CMX521 with other regulatory authorities. Similar risks and uncertainties apply to our development of brincidofovir and brincidofovir-based regimens. 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, 2018 and other documents subsequently filed with or furnished to the U.S. 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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