Chimerix, in Collaboration with the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina-Chapel Hill, Announces Late-Breaking Oral Presentation at International Conference on Antiviral Research

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CMX521 Significantly Reduced Lung Viral Titer and Clinical Symptoms in a SARS-CoV-2 Mouse Model

DURHAM, N.C., Feb. 24, 2022 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), in collaboration with the Rapidly Emerging Antiviral Drug Development Initiative at the University of North Carolina at Chapel Hill, today announced that preclinical data from the Company's CMX521 program will be featured in a late-breaking oral presentation session at the International Conference on Antiviral Research (ICAR) on Wednesday, March 23, 2022 from 12:15 – 1:00 pm PT.

"While we focus on the advancement of our oncology pipeline and progress toward a TEMBEXA procurement agreement with BARDA, this collaboration with READDI allows us to efficiently evaluate our antiviral library to identify molecules that might have value to patients," said Mike Sherman, Chief Executive Officer of Chimerix. "The joint effort between the research teams at both Chimerix and READDI has led to these very promising early results in an animal model that we believe supports rapid advancement of CMX521 to clinical proof-of-concept against SARS-CoV-2 where there remains a need for novel therapies with improved efficacy, safety and/or resistance profiles. This agent is particularly interesting in that it has demonstrated an attractive safety profile in a prior Phase 1 dose escalation trial in healthy volunteers."

"These compelling data encourage us to further investigate the potential of CMX521 as a prophylactic and as a therapeutic for SARS-CoV-2 infection," said John Bamforth, PhD of READDI and Director of Eshelman Institute for Innovation at the UNC Eshelman School of Pharmacy. "We are very excited about these data and also look forward to READDI's ongoing mission to identify novel antivirals active against entire families of viruses, including coronaviruses, flaviviruses and alphaviruses."

The presentation is titled, "The nucleoside analog antiviral CMX521 inhibits SARS-CoV-2 in human airway epithelial cell cultures and exhibits prophylactic and therapeutic efficacy against respiratory disease in a mouse model of SARS-CoV-2 infection", highlights *in vitro* activity and *in vivo* efficacy of this novel compound. *In vitro*, CMX521 was shown to inhibit SARS-CoV-2 replication in primary human airway epithelial cells with an average EC_{50} of 0.9μM. *In vivo,* studies were performed in an animal model used during development of a different antiviral therapy which has obtained Emergency Use Authorization for SARS-CoV-2 in the United States. The animal studies randomized mice to CMX521 or placebo at various times relative to viral infection to explore the potential for prophylactic and therapeutic efficacy.

Monotherapy prophylactic administration of aerosol CMX521 every eight hours starting eight hours prior to infection reduced average viral titers in lung on day four post-infection by 3.62 $\log_{10}$ (>99.9% reduction) and prevented weight loss/clinical progression versus placebo. Antiviral efficacy was also demonstrated with monotherapy treatment when CMX521 was initiated post-infection. CMX521 treatment significantly reduced SARS-CoV-2 in the lung (Kruskal-Wallis $p<0.0001$) and protected mice from clinical symptoms of disease including weight loss and adverse lung pathology ($p<0.0001$) at day four post-infection relative to placebo.

CMX521 is not mutagenic, clastogenic, or associated with mitochondrial toxicity. In addition, oral CMX521 demonstrated a favorable profile in GLP toxicology studies and was well-tolerated up to 2,400 mg in a healthy volunteer Phase 1 study for a different indication.

About READDI

Rapidly Emerging Antiviral Drug Development Initiative is a global public-private partnership founded at the University of North Carolina Chapel Hill by the UNC Eshelman School of Pharmacy, UNC School of Medicine, Gillings School of Global Public Health, Eshelman Institute for Innovation and the Structural Genomics Consortium. READDI was created to generate new broad-spectrum antiviral therapies to save lives in the current COVID-19 pandemic and to prevent emerging viral threats from becoming global catastrophes.

About Chimerix

Chimerix is a biopharmaceutical company with a mission to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. In June 2021, the U.S. Food and Drug Administration granted approval of TEMBEXA for the treatment of smallpox as a medical countermeasure. The Company has two other advanced clinical-stage development programs, ONC201 and dociparstat sodium (DSTAT). ONC201 is in development for recurrent H3 K27M-mutant glioma for its lead indication. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things, the results of current and future preclinical and clinical testing of CMX521. Among the factors and risks that could cause actual results to differ materially from those indicated in the forward-looking statements are risks that the current and future preclinical and clinical study data for CMX521 will not generate positive results or may not support accelerated, or any, regulatory approval; and additional risks set forth in the Company's filings with the Securities and Exchange Commission. These forward-looking statements represent the Company's judgment as of the date of this release. The Company disclaims, however, any intent or obligation to update these forward-looking statements.

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