Chimerix Reports Promising Topline Results from First Cohort of a Randomized COVID-19 Trial with DSTAT

February 25, 2021

– Conference Call at 8:30 a.m. ET Today –

DURHAM, N.C., Feb. 25, 2021 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company focused on accelerating the development of medicines to treat cancer and other serious diseases, reported topline results today from the first cohort of its randomized, double-blind, placebo-controlled Phase 2/3 study in hospitalized patients with Acute Lung Injury (ALI) and COVID-19 infection.

"The promising results of this first cohort of 12 COVID-19 ALI patients provides clinical support for DSTAT's proposed mechanism of action and suggest it may accelerate recovery from ALI and mitigate thrombotic events in COVID-19 patients," said Mike Sherman, Chief Executive Officer of Chimerix. "The fact this is a blinded, randomized trial provide a higher level of confidence than open label single arm studies. Nevertheless, we need to be mindful not to over-interpret data from 12 patients where random imbalances may favor the therapy arm. The second cohort of 12 patients, which is randomized 2:1 and explores a higher dose of DSTAT is now fully enrolled and we look forward to reporting topline data from this cohort in the second quarter."

Topline Results from First Cohort
The primary endpoint of the study is survival without the need for mechanical ventilation through day 28. The first cohort enrolled 12 patients randomized 1:1. One patient on DSTAT was ventilated and recovered. Two patients on placebo progressed to ventilation and died, one on day two and the other post day 28. No deaths were reported in patients on the DSTAT arm.

A secondary endpoint of the study was the proportion of patients who achieved at least a two-point improvement in the National Institute of Allergy and Infectious Disease (NIAID) ordinal scale, an assessment of clinical status. All six DSTAT patients met the improvement criteria compared to two of the six placebo patients as shown in the Kaplan-Meier curve below.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/e8d90702-1b5f-41d0-aa20-35c8707eff27

Of note, on day 28 three of the six placebo patients remained hospitalized and one had died. At day 28, one DSTAT patient was hospitalized. Two DSTAT patients who were discharged were subsequently lost to follow-up.

No patients on DSTAT had elevated values for IL-6, MCP-1, or D-dimer on therapy, but two patients on placebo had substantial increases in all of these biomarkers by day five. One of these placebo patients developed Acute Respiratory Disease Syndrome and died after day 28 while the other suffered a pulmonary embolism and recovered. These biomarkers are reflective of the lung inflammation and thrombotic complications associated with severe COVID-19, and these findings are consistent with the proposed mechanism of action for DSTAT.

DSTAT was observed to be generally safe and well tolerated. No patients on the DSTAT arm discontinued study treatment for adverse events compared to two patients on the placebo arm.

First Cohort Demographics
As an enrollment criterion, all patients were hospitalized with confirmed COVID-19 infection and required supplemental oxygen; some patients required more intensive supplemental oxygen (noninvasive ventilation/high-flow oxygen) which is generally associated with more severe disease.

Five of the six patients on the placebo arm required noninvasive ventilation/high-flow oxygen at baseline, compared to two of the six patients on the DSTAT arm. The median age of patients in cohort one was 63.0 years on the placebo arm and 50.5 years on the DSTAT arm. These random imbalances may favor the DSTAT arm.

The DSTAT arm was comprised of six males. The placebo arm was comprised of four males and two females. Being male has been associated with a higher risk of COVID-19 mortality. This random imbalance may favor the placebo arm.

About Phase 2/3 DSTAT Study in ALI Patients with COVID-19
The study is a randomized, double-blind, placebo-controlled, Phase 2/3 trial to determine the safety and efficacy of DSTAT in adults with severe COVID-19 who are at high risk of respiratory failure. Eligible patients have confirmed COVID-19 and require hospitalization and supplemental oxygen therapy. The primary endpoint of the study is the proportion of patients who survive and do not require mechanical ventilation through day 28. Additional endpoints include time to improvement as assessed by the NIAID ordinal scale, time to hospital discharge, time to resolution of fever, number of ventilator-free days, all-cause mortality, and changes in key biomarkers.

The Phase 2 portion of the study enrolled two cohorts of 12 patients each to confirm the maximum safe dose with reviews by the Data Safety Management Board (DSMB) after completion of each cohort. The second cohort is fully enrolled and the data will be compiled for review by the DSMB. Following review, the DSMB will recommend a dose for the third Cohort which will include approximately 50 additional patients (74 total). A formal analysis of all endpoints, including supportive biomarkers will be performed at the conclusion of the third cohort, completing the Phase 2 portion of the study. https://clinicaltrials.gov/ct2/show/NCT04389840

Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss fourth quarter and full-year 2020 financial results and provide a business update today at 8:30 a.m. ET. To access the live conference call, please dial 877-354-4056 (domestic) or 678-809-1043 (international) at least five minutes prior to the start time and refer to conference ID 1478364.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, www.chimerix.com. An archived webcast will be available on the Chimerix website approximately two hours after the event.

About Chimerix

Chimerix is a development-stage biopharmaceutical company dedicated to accelerating the advancement of innovative medicines that make a meaningful impact in the lives of patients living with cancer and other serious diseases. Our three most advanced clinical-stage development programs are BCV, ONC201 and DSTAT. BCV is an antiviral drug candidate developed as a potential medical countermeasure for smallpox and is currently under review for regulatory approval in the United States. ONC201 is currently in a registrational clinical program for recurrent H3 K27M-mutant glioma and a confirmatory response rate assessment is expected later this year. DSTAT is in development as a potential first-line therapy in acute myeloid leukemia and as a potential treatment for acute lung injury in hospitalized COVID-19 patients.

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 implications of the results from the first cohort of the Phase 2/3 study of DSTAT in hospitalized patients with COVID-19 infection and ALI. 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 results from future cohorts of the Phase 2/3 study will not be consistent with the promising results from the first cohort; risks that ongoing or future trials may not be successful or replicate previous trial results, or may not be predictive of real-world results or of results in subsequent trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for our drugs; risks that our drugs may be precluded from commercialization by the proprietary rights of third parties; 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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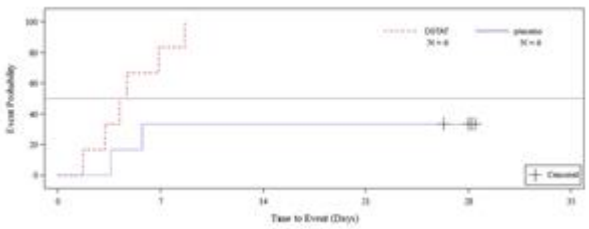
Kaplan-Meier curve



All six DSTAT patients met the improvement criteria compared to two of the six placebo patients.