Chimerix Announces Exclusive Worldwide License of Phase 3 Ready CX-01 for Development in Acute Myeloid Leukemia

July 31, 2019

Transformational Transaction Provides Key Program in First-Line Acute Myeloid Leukemia with Fast Track and Orphan Drug Designations and Potential Utility as a Platform Technology

Phase II Randomized Data Presented at ASCO 2019 Demonstrated Compelling Complete Response Rates, Event-Free Survival, and Overall Survival in Combination with Standard Chemo Compared to Standard Chemo Alone

Company Plans to Initiate Phase 3 Registrational Trial in mid-2020

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

DURHAM, N.C., July 31, 2019 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ: CMRX), today announced the completion of an exclusive worldwide license of CX-01 from Cantex Pharmaceuticals, Inc.Chimerix intends to move quickly into Phase 3 development of CX-01 for the treatment of Acute Myeloid Leukemia (AML) in the first-line setting. CX-01 has received Fast Track and Orphan Drug Designations from the U.S. Food and Drug Administration for the treatment of AML.

“We are pleased to have made such rapid progress in repositioning the company and transforming our pipeline with this important cancer therapy. We are excited to advance this promising product candidate in AML as it has shown compelling activity across multiple endpoints in first-line patients as opposed to later lines of therapy where most of the recent advances in this disease area have occurred. With more than 21,000 new cases of AML diagnosed annually in the U.S. alone and a five-year survival rate of less than 30%, the patient need is clear. CX-01’s mechanism of action, targeting multiple proteins involved in protecting and supporting the growth of cancer cells, provides opportunities for potential development across a range of hematologic malignancies,” stated Mike Sherman, Chief Executive Officer of Chimerix. “This transaction exemplifies our commitment to pursuing and accelerating programs where we can quickly address unmet patient needs with a meaningful clinical benefit.”

“While several new agents have been recently approved for AML, a backbone of cytotoxic chemotherapy continues to be necessary for treatment with curative intent. If our results are confirmed, combining CX-01 with chemotherapy has the potential to have a significant impact on the outcomes of patients suffering from one of the most challenging hematologic malignancies,” said Paul Shami, MD, clinical investigator at Huntsman Cancer Institute and Professor of Medicine at the University of Utah.

CX-01 is a new chemical entity derived from unfractionated heparin with very low anticoagulant activity. CX-01 targets key protein pathways important for AML blast cell migration to the bone marrow and retention of these cells in the marrow where they are protected from chemotherapy. CX-01 also binds with proteins involved in chemotherapy resistance and the delay in platelet recovery after chemotherapy. Together, these activities are understood to sensitize AML blasts to chemotherapy and improve clinical responses. These mechanisms of action support the potential for development in myelodysplastic syndrome, multiple myeloma, and lymphomas.

In a recently completed Phase II study, 75 patients over 60 years of age with newly diagnosed AML were randomized 1:1:1 to one of two doses of CX-01 (0.125 mg/kg/hr or 0.250 mg/kg/hr) plus standard 7+3 chemotherapy (7 days of cytarabine, 3 days of anthracycline) or to the control arm of standard 7+3 chemotherapy alone. Data presented at the 2019 ASCO conference indicated an advantage across multiple endpoints for patients treated with 0.25 mg/kg/hr CX-01. In the evaluable patient population, results of the 0.25 mg/kg/hr CX-01 arm compared favorably to the control arm: complete response rate (complete response or complete response without complete hematologic recovery) of 89% vs. 58% (p=0.03), median event-free survival of 23.4 months vs. 9.0 months (p=0.011), and median overall survival which had not yet been reached in the CX-01 arm vs. 11.2 months (p=0.042). These data were consistent with a single arm pilot study of first line therapy in patients with AML (n=12), including a complete response rate of 92%.

CX-01 was well tolerated with adverse events similar across all treatment arms. The most common serious adverse event was febrile neutropenia with three cases in each CX-01 treatment group and one case in the control group.

Stephen Marcus, M.D., CEO of Cantex, stated, “We are very pleased to be partnering with Chimerix and their world-class scientists. We believe that Chimerix management’s track record in developing novel cancer therapeutics makes Chimerix the perfect partner to aggressively advance the development of CX-01 for the treatment of AML and other hematologic malignancies.”

Transaction Terms

Under the terms of the agreement, Chimerix has exclusive worldwide rights to develop and commercialize CX-01. Chimerix will make an upfront payment of $30 million to Cantex. In addition, Chimerix has issued 10 million shares of Chimerix common stock to Cantex. Cantex is eligible for regulatory and commercial milestones of up to $587.5 million, and tiered royalties starting at 10%.

Conference Call

Chimerix management will host a conference call today at 8:30AM ET. To participate, please dial:

US and Canada: (877) 354-4056

International: (678) 809-1043
Conference ID: 9558159

A live, listen-only webcast of the conference call may also be accessed by visiting the Investors section of the Chimerix website, www.chimerix.com.

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. CX-01 is a new chemical entity targeting multiple proteins involved in cancer cell resistance to chemotherapy under development for the treatment of acute myeloid leukemia and other hematologic malignancies. Brincidofovir (BCV, CMX001) is an anti-viral drug candidate in development as a medical countermeasure for smallpox. For further information, please visit the Chimerix website, www.chimerix.com.

About Cantex Pharmaceuticals, Inc.

Cantex is a clinical stage biopharmaceutical company focused on developing and commercializing proprietary compounds that enhance the efficacy and safety of the treatment of cancer and other life-threatening disorders. CX-01, is a multi-targeted new chemical entity in development for the treatment of acute myeloid leukemia and myelodysplastic syndrome. Cantex's other clinical stage product, Dicopp®, a proprietary combination of disulfiram + copper, is currently in a clinical trial for metastatic pancreatic cancer. For more information, please visit www.cantex.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 and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include those relating to, among other things, the potential benefits to be derived from the license agreement with Cantex Pharmaceuticals, including statements related to the activity profile and opportunities for potential development of CX-01; Chimerix's ability to develop disease modifying and potentially curative treatments for diseases, including AML. 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 benefits of the agreement with Cantex may never be realized; risks that CX-01 may not obtain regulatory approval from the FDA or such approval may be delayed or conditioned; risks that development activities related to CX-01 may not be completed on time or at all; Chimerix's reliance on a sole source third-party manufacturer for CX-01; risks that ongoing or future clinical trials may not be successful or replicate previous clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for CX-01; risks that CX-01 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.

CONTACT:
Investor Relations:
Michelle LaSpaluto
919 972-7115
ir@chimerix.com
or
Will O'Connor
Stern Investor Relations
212-362-1200
Will@sternir.com

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