December 28, 2015

Chimerix Announces Top-Line Results From Phase 3 SUPPRESS Trial of Brincidofovir

- SUPPRESS Did Not Achieve Primary Endpoint for Prevention of Clinically Significant CMVÂ Infection After HCT -

- Detailed Data Analysis to Follow -

- Company to Hold Conference Call Today at 8:30 a.m. ET -

DURHAM, N.C., Dec. 28, 2015 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced that its Phase 3 SUPPRESS trial of brincidofovir in patients undergoing hematopoietic cell transplantation (HCT) did not achieve its primary endpoint for the prevention of clinically significant cytomegalovirus (CMV) infection through Week 24 after transplant.

During the on-treatment period through Week 14 after HCT, fewer patients in the brincidofovir arm had a CMV infection, consistent with the positive antiviral effect of the compound seen in the Phase 2 study. However, during the 10 weeks off treatment from Week 14 to Week 24, there was an increase in CMV infections in the brincidofovir arm compared to the control arm. There was also a non-statistically significant increase in mortality in the brincidofovir arm compared to the control arm.

Preliminary analysis suggests that the primary endpoint failures in both the prevention of CMV infections and mortality in the brincidofovir arm were driven by confirmed cases of graft-versus-host-disease (GVHD), which resulted in a significantly higher use of corticosteroids than in the control arm. Both GVHD and use of corticosteroids are risk factors for "late" CMV infection that occurs after discontinuation of the antiviral in HCT recipients.

The rate of study drug discontinuation for gastrointestinal events was < 10%, comparable to that observed in the Phase 2 trial of brincidofovir in a similar HCT population.

"While we are clearly disappointed in the top-line results from SUPPRESS, we remain committed to better understanding the full data set as we consider potential paths forward for brincidofovir," said M. Michelle Berrey, M.D., MPH, President and CEO of Chimerix. "With a strong cash position, an experienced leadership team, and brincidofovir patent exclusivity through 2034, we continue to believe there is a viable path forward for the development of brincidofovir."

W. Garrett Nichols, M.D., Chimerix's Chief Medical Officer, said, "The population of allogeneic stem cell transplant recipients is heterogeneous and complex; we will be evaluating the sub-groups of patients within SUPPRESS, such as T-cell depleted transplant recipients who have a lower risk of GVHD, to better understand these results and inform our next steps. We are reaching out to investigators and other experts to help us assess the complete data set to understand what may have caused the results of the SUPPRESS trial to differ substantially from those seen in the Phase 2 study. Additionally, we are in communication with the U.S. Food and Drug Administration and other regulatory bodies, and will share any updates on the brincidofovir clinical program when we can.Â With data currently in hand, we believe that brincidofovir may ultimately demonstrate a positive risk-benefit profile for the treatment of adenovirus and smallpox, as well as use in other populations in need of a novel compound for DNA viral infections."

A full analysis of the SUPPRESS trial results is ongoing and will be presented at the BMT Tandem Meetings in Honolulu, Hawaii, to be held on February 18-22, 2016.

Chimerix plans to continue the programs testing brincidofovir in serious adenovirus infections and in smallpox. Â In the open-label AdVise trial for patients with disseminated adenovirus infection, a < 40% mortality was reported in February 2015 at a mean of 10 weeks of observation. In an updated preliminary analysis of the full Cohort B population of HCT recipients with disseminated adenovirus infection, all-causeÂ mortalityÂ at day 90 remains < 40%, continuing to support a potential positive risk:benefit for the treatment of adenovirus infection. Â In an animal model of smallpox infection, the 100 percent survival data announced earlier this year supports continued development of a short course of brincidofovir for the treatment of smallpox.Â Pending the availability of complete data from SUPPRESS, including secondary endpoints in other dsDNA viral infections, Chimerix has elected to pause further enrollment in the Phase 3 SUSTAIN and SURPASS trials in kidney transplant recipients.

Brincidofovir is an oral nucleotide analog that has shown *in vitro* antiviral activity against all five families of DNA viruses that affect humans, including herpesviruses and adenovirus. The SUPPRESS trial, initiated in August 2013 and fully enrolled in June 2015, was informed by a successful Phase 2 trial conducted in HCT recipients.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss the top-line results of the SUPPRESS trial at 8:30 a.m. ET today. 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 16578861.

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. Â Â

About the Phase 3 SUPPRESS Trial

The SUPPRESS trial enrolled and treated 452 adult high-risk allogeneic HCT recipients from more than 40 key transplant centers in the U.S.,Â Canada and Europe. Subjects received twice-weekly brincidofovir or placebo (2:1 ratio) from the early post-transplant period through week 14 post-transplant, the period of highest risk for viral infections. All patients in the trial were CMV seropositive, placing them at high risk of CMV infection. The most common indications leading to stem cell transplantation in the SUPPRESS trial were acute myelogenous leukemia (43% of patients), myelodysplasia (17%), non-Hodgkin's lymphoma (10%), and acute lymphocytic leukemia (9%).

About Hematopoietic Cell Transplantation

More than 70,000 hematopoietic cell transplants are performed each year worldwide, most frequently to treat patients with certain cancers of the blood and bone marrow, or to address genetic diseases. Due to chemotherapy and the immune suppression associated with HCT, patients are highly susceptible to viral, bacterial and fungal infections. These complications are a significant cause of morbidity and mortality in the months following the transplant, and too often the high risk of infection in the first year after transplant results in patients and their families deciding to not undergo a potentially curative transplant.

About Cytomegalovirus

Cytomegalovirus is a member of the herpesvirus family and remains a significant cause of viral infections in transplant recipients.Â A majority of adults in the U.S. have evidence of a prior infection with CMV, which establishes a dormant or latent infection that cannot be cleared. Most individuals have an immune system that is able to prevent CMV from reactivating and causing disease. In individuals with weakened immune systems - such as transplant recipients - CMV commonly reactivates during the first weeks following the transplant, leading to potentially life-threatening infection of the lungs or other organ system. Stem cell transplant recipients are at high risk of CMV reactivation in the first few months after transplant, which increases their risk of mortality. No therapies are approved for the prevention of CMV in HCT recipients because of known toxicities associated with available CMV antivirals, including bone marrow suppression and renal impairment.

About Brincidofovir (CMX001)

Chimerix'sÂ lead product candidate, brincidofovir, is an oral nucleotide analog that has shownÂ in vitroÂ antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenovirus. Brincidofovir has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. Based on the clinically and statistically significant Phase 2 results in CMV prevention in stem cell or HCT recipients,Â ChimerixÂ initiated the 450 patient Phase 3 SUPPRESS trial, which completed enrollment inÂ June 2015 and announced topline results in December 2015.Â ChimerixÂ is also developing brincidofovir for the treatment of adenovirus infections, and is working with theÂ Biomedical Advanced Research and Development AuthorityÂ (BARDA) to develop brincidofovir as a medical countermeasure against smallpox. Brincidofovir has received Fast Track designation from theÂ FDAÂ for CMV, adenovirus, and smallpox.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (CMX001), a clinical-stage nucleotide analog, CMX157 which was licensed to ContraVir Pharmaceuticals in 2014, and early clinical

candidates including CMX669.Ä 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 that there may not be a viable continued development path for brincidofovir, that FDAÂ 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,Â ChimerixÂ may be unable to file for regulatory approval for brincidofovir with other regulatory authorities. 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 inÂ Chimerix'sÂ Quarterly Report on Form 10-Q for the quarter endedÂ September 30, 2015, as filed with theÂ U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available toÂ Chimerix, and ChimerixÂ assumes no obligation to update any such forward-looking statements.

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