Chimerix Initiates Phase 3 SUSTAIN and SURPASS Trials of Brincidofovir for Prevention of Cytomegalovirus Disease in Kidney Transplant Recipients

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DURHAM, N.C., Oct. 22, 2015 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced initiation of dosing in SURPASS (ClinicalTrials.gov ID: NCT02439957), one of the two Phase 3 trials in the brincidofovir kidney transplant program. Both the SUSTAIN (ClinicalTrials.gov ID: NCT02439970) and SURPASS trials are evaluating brincidofovir for the prevention of cytomegalovirus (CMV) disease in kidney transplant recipients; both trials are now actively enrolling. 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, and demonstrated a clinically and statistically significant reduction in CMV infection in a Phase 2 trial in hematopoietic cell transplant (HCT) recipients. Based on that successful study, Chimerix designed and conducted the pivotal SUPPRESS trial for the prevention of clinically significant CMV infection in patients undergoing HCT which completed enrollment in June. Topline data from SUPPRESS are anticipated in early 2016.

"SUSTAIN and SURPASS address the need for new CMV prevention therapies in the kidney transplant population," said W. Garrett Nichols, MD, MS, Chief Medical Officer of Chimerix. "We are excited about the opportunity to explore the potential for brincidofovir to prevent CMV disease in kidney transplant recipients, as well as to evaluate the potential to prevent other DNA viral infections and to preserve renal function in these patients. Initiation of these trials marks another significant milestone for the brincidofovir program following the completion of enrollment in SUPPRESS in June."

SUSTAIN is designed to demonstrate the safety and efficacy of brincidofovir for the prevention of CMV disease in kidney transplant recipients at high risk of CMV disease. It is a blinded, non-inferiority study of brincidofovir versus valganciclovir in kidney transplant recipients who have not been previously infected with CMV (CMV seronegative recipient, or "R-") and who have no immunity to CMV. These CMV seronegative patients who receive a kidney from a CMV seropositive (D+) donor are at high risk of CMV infection and disease. The primary endpoint of the study is CMV disease, with secondary endpoints related to renal function at one year, a measurement closely correlated with long-term kidney graft survival. The trial is expected to enroll approximately 750 patients with 1:1 randomization to brincidofovir or valganciclovir for 200 days following the transplant.

SUSTAIN is an important study as it will determine the safety and efficacy of brincidofovir in the population at highest risk of CMV disease (R-/D+) but which makes up less than 20 percent of patients who are receiving a kidney transplant. A majority of kidney transplant recipients in the US and Europe are CMV seropositive (R+) and are at increased risk of CMV reactivation and disease due to the medicines they receive to suppress the immune system and decrease the risk of rejecting the new kidney. The SURPASS trial will enroll these CMV seropositive (R+) transplant recipients and will be conducted at the same clinical sites as SUSTAIN.

SURPASS is a blinded, non-inferiority study of brincidofovir versus valganciclovir in kidney transplant recipients who are CMV seropositive (R+). The primary endpoint is CMV disease, with secondary endpoints related to renal function at six months, a measurement closely correlated with long-term kidney graft survival. The trial is expected to enroll approximately 520 patients with 1:1 randomization to brincidofovir or valganciclovir for 100 days following the transplant. The same dose of brincidofovir that was studied in the SUPPRESS trial in HCT recipients, 100 mg twice-weekly, will be studied in both the SUSTAIN and SURPASS trials.

In addition, Chimerix is continuing to establish the clinical pharmacology profile of brincidofovir. Data from a recent clinical study in healthy volunteers were presented during the American College of Clinical Pharmacy's Global Conference on Clinical Pharmacy in San Francisco, CA. This study evaluated the potential interaction between brincidofovir and midazolam, a drug metabolized by the liver enzyme CYP3A. This clinical study showed no significant interaction between brincidofovir and midazolam, which suggests that no significant CYP3A-mediated drug interactions would be expected when brincidofovir and drugs metabolized primarily by CYP3A are taken together. These data are of particular importance to the brincidofovir development program, since stem cell transplant (HCT) and kidney transplant patient populations are prescribed many medicines that are metabolized by CYP3A liver enzymes.

Cytomegalovirus Infection in Kidney Transplant Recipients

Cytomegalovirus (CMV) is a member of the herpesvirus family and is a significant cause of decreased renal function in kidney transplant patients. While graft survival has improved with advances in immunosuppressive medicines, ten-year graft survival rates are still below 50 percent. Together, SUSTAIN and SURPASS provide an opportunity to demonstrate the ability of brincidofovir to prevent CMV disease compared with the current standard-of-care, valganciclovir. In addition, these trials will evaluate the impact of brincidofovir on kidney function at 6 and 12 months following transplant. In the Phase 2 study of brincidofovir in HCT recipients, a statistically significant improvement in kidney function was seen in patients who received brincidofovir compared with those who received placebo.

About Brincidofovir (CMX001)

Chimerix's lead product candidate, brincidofovir, is an oral nucleotide analog that has shown *in vitro* 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 hematopoietic cell transplant (HCT) recipients, Chimerix initiated the 450 patient Phase 3 SUPPRESS trial, which completed enrollment in June 2015. Topline data from SUPPRESS are anticipated in early 2016. If positive, data from SUPPRESS will support Chimerix's initial regulatory submission for brincidofovir for the prevention of CMV infection in adult HCT recipients. Chimerix has also completed enrollment in AdVise, the open-label trial of brincidofovir for

the treatment of disseminated or localized adenovirus infection. AdVise completed enrollment in August 2015. Chimerix is working with the Biomedical Advanced Research and Development Authority (BARDA) to develop brincidofovir as a medical countermeasure against smallpox. Brincidofovir has received Fast Track designation from the FDA 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. 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 the FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens in the currently anticipated timelines or at all, and marketing approvals, if granted, may have significant limitations on their use. As a result, brincidofovir may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for brincidofovir with other regulatory authorities in the currently anticipated timelines. 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 June 30, 2015, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Chimerix, and Chimerix assumes no obligation to update any such forward-looking statements.

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