CHIMERIX

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Chimerix Announces Presentation of Detailed Results From Phase 3 SUPPRESS Trial at BMT Tandem Meetings

Brincidofovir Shows On-Treatment Antiviral Effect in HCT Setting Despite Trial Not Meeting Primary Endpoint

Company to Host Conference Call on February 22 at 8:00 a.m. EST to Provide Additional Analyses and Plans for Further Clinical Development

DURHAM, N.C., Feb. 20, 2016 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced detailed results from its Phase 3 SUPPRESS trial of brincidofovir for the prevention of cytomegalovirus (CMV) in patients undergoing hematopoietic cell transplantation (HCT).

As reported in December 2015, the SUPPRESS trial did not meet the primary endpoint of prevention of clinically significant CMV infection at Week 24 following HCT; however, a clear antiviral effect was seen at the end of the on-treatment period at Week 14, with patients who received brincidofovir experiencing fewer clinically significant CMV infections than patients in the placebo group (24 percent versus 38 percent, p=0.002). At the Week 24 primary endpoint assessment, the proportion of patients with clinically significant CMV infection on brincidofovir (51 percent) was similar to placebo (52 percent).

These data were presented today at the BMT Tandem Meetings, the combined annual meetings of the Center for International Blood and Marrow Transplant Research and the American Society of Blood and Marrow Transplantation, taking place in Honolulu, Hawaii.

The SUPPRESS trial was a double blind, placebo-controlled study in which 452 subjects at high risk for CMV were randomized and received brincidofovir or placebo twice-weekly for up to 14 weeks following allogeneic HCT, and then followed off drug for 10 weeks after treatment.

The lead investigator for SUPPRESS, Dr. Francisco Marty of Dana-Farber Cancer Institute in Boston, said, "This study shows that brincidofovir had a clear antiviral effect, preventing cytomegalovirus reactivation particularly in patients at higher risk for CMV infection."

The failure to meet the SUPPRESS trial's endpoint of prevention of CMV infection at Week 24 appears to be associated with CMV events in the post-treatment period among subjects on the brincidofovir arm, driven by higher use of corticosteroids and other immune suppressing therapies for the treatment of presumptive graft versus host disease (GVHD). GVHD is a potentially life-threatening condition in which donated bone marrow or stem cells view the recipient's body as foreign and attack the host. Diarrhea can be a symptom of GVHD in the gut, and is also a known side effect associated with brincidofovir that can be managed by a temporary dose-interruption, as described in the safety monitoring and management plan (SMMP) developed during the Phase 2 trial. In the SUPPRESS trial, diarrhea in brincidofovir-treated patients was more frequent and often presumed to be gut GVHD and was treated with corticosteroids, rather than temporarily interrupting study drug according to the SMMP. Among patients who were managed according to the SMMP, significantly fewer CMV infections and lower mortality were observed.

There was an eight-fold increase in the use of corticosteroids through Week 14 in the brincidofovir arm (median cumulative 26 mg/kg prednisone equivalent) compared to the placebo arm (median cumulative 3 mg/kg prednisone equivalent). The use of corticosteroids and other immunosuppressive therapies for the treatment of GVHD is known to increase the risk of infections, including CMV infections that occur when patients discontinue antiviral therapy. The rate of CMV infections thus was higher in the brincidofovir arm between Weeks 14 and 24 (22 percent versus 11 percent on placebo), when patients were no longer on study drug.

Of note, among patients who either underwent T-cell depletion or received alemtuzumab/ATG (approaches that decrease the risk of GVHD), those who were randomized to receive brincidofovir showed a lower incidence of CMV when compared to placebo, at a rate consistent with what was observed in the Phase 2 study of brincidofovir in the HCT setting.

Among the secondary efficacy endpoints, brincidofovir was not shown to prevent infection with non-CMV DNA viruses, such

as BK virus. There were no statistically significant differences in all-cause mortality in the trial (15.5 percent in the brincidofovir arm, 10.1 percent in the placebo arm, p=0.12); the numerical differences appear to be driven by higher use of corticosteroids and other immunosuppressive therapies in the subjects who received brincidofovir.

From a safety perspective, the most common adverse events reported for subjects randomized to brincidofovir were acute GVHD (presumed on the basis of symptoms or with biopsy), gastrointestinal (GI) events (predominantly diarrhea), and liver enzyme abnormalities. Although the rate of reported gut GVHD in the Phase 2 study of brincidofovir was higher than that in the placebo cohort, the excess was driven by the overdiagnosis of GVHD based on diarrhea alone. Incorporation of the Safety Monitoring and Management Plan (SMMP) in the final cohort of the Phase 2 study of brincidofovir 100 mg twice-weekly allowed 90 percent of subjects to successfully resume brincidofovir dosing. As seen in Phase 2, there was no evidence of bone marrow toxicity, kidney toxicity, or viral resistance to brincidofovir observed in the SUPPRESS trial.

"We are disappointed that the SUPPRESS trial did not confirm the benefits of brincidofovir in preventing CMV in these high-risk HCT recipients, but we are encouraged by the clear antiviral effects of brincidofovir during the on-treatment period, and in key subgroups of higher-risk patients in this study. We also saw more favorable results when the SMMP was appropriately implemented. With the promising data to date for brincidofovir in adenovirus and smallpox, we continue to believe in the near-term potential of brincidofovir to address DNA viral infections in HCT recipients and in other at-risk populations," said W. Garrett Nichols, MD, MS, Chimerix Chief Medical Officer. "We would like to thank the patients and investigators for their participation in SUPPRESS, and their important contribution to furthering our understanding of CMV management in the HCT setting."

Next Steps for the Brincidofovir Clinical Program

Chimerix will discuss the SUPPRESS data in full with the U.S. Food and Drug Administration (FDA) and foreign regulators, including the benefit-to-risk profile in specific sub-populations, as well as the current adenovirus and smallpox data, to determine next steps for the brincidofovir clinical programs. The development of an intravenous (IV) formulation of brincidofovir is progressing toward clinical testing, and has the potential to avoid the gastrointestinal side effects of orally-administered brincidofovir. Preclinical studies of IV brincidofovir have shown a lower risk of GI effects based on maintained body weight during dosing and no evidence of injury in preliminary review of the GI tract. If human studies continue to support these findings, dosing through the intravenous route during the first few weeks after transplant when patients are recovering from conditioning chemotherapy could be explored, with oral brincidofovir therapy available as patients are discharged home. With no preventive therapy approved for CMV in HCT recipients, the Company is committed to moving brincidofovir forward in this indication. Plans for brincidofovir in HCT recipients will be the subject of further discussions with the FDA and other regulators.

As previously announced in December 2015, enrollment in the Phase 3 SUSTAIN and SURPASS trials for prevention of CMV in kidney transplant recipients was paused pending an evaluation of the full SUPPRESS data set. These two studies were initiated in October of 2015 and were designed to evaluate brincidofovir for the prevention of CMV in kidney transplant recipients, and to assess the potential for improved kidney function as seen in the Phase 2 brincidofovir study in HCT recipients, potentially related to brincidofovir's activity against BK virus.

In light of the unexpected results in SUPPRESS, including the lack of confirmation of the activity against BK virus, Chimerix has elected to close the Phase 3 SUSTAIN and SURPASS trials, and to pursue Phase 2 trials of brincidofovir in kidney transplant recipients to confirm activity against BK virus and to explore management of brincidofovir-related adverse events in this population. The Company intends to apply learnings from SUPPRESS, as well as perspectives from investigators, key opinion leaders and regulators to refine and guide the development of potential future studies in solid organ transplant recipients.

"We remain committed to establishing the best path forward for the evaluation of brincidofovir in solid organ transplant patients, including kidney transplant recipients," said Dr. Nichols. "It is important that we take the appropriate steps to ensure the success of our clinical program evaluating brincidofovir in the prevention of viral infections in the solid organ setting, including potentially CMV, BK virus and adenovirus infections."

Chimerix anticipates receiving data from the AdVise trial of brincidofovir for adenovirus infections in mid-2016, along with the outcomes data from Study 305 of historic controlled patients from the same institutions. The Company plans to discuss these data with the FDA and other regulators to finalize development plans for the adenovirus program.

Conference Call and Webcast

Chimerix's management team will host a live conference call and webcast at 8:00 a.m. EST on Monday, February 22, 2016 to discuss the SUPPRESS trial results, as well as provide an update on the brincidofovir clinical program. 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 52881232.

A live webcast of the call and accompanying presentation slides will also be available on the Investors section of the Company's website, www.chimerix.com and an archived webcast will be available on the Chimerix website approximately two hours after the event.

About Brincidofovir

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 adenoviruses. Brincidofovir has not been associated with kidney or bone marrow toxicity in over 1,000 patients treated to date. 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 there may not be a viable continued development path for brincidofovir, that FDA 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, Chimerix 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 expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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