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Chimerix Announces Presentation at IDWeek™ of Detailed 24-Week Results from AdVise Trial of Brincidofovir for the Treatment of Adenovirus Infection in Allogeneic Hematopoietic Cell Transplant Recipients

- Results Show Early Virologic Response Associated with Better Overall Survival -

DURHAM, N.C., Oct. 27, 2016 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals in areas of high unmet medical need, today announced the presentation of detailed 24-week interim results from the AdVise trial of brincidofovir for the treatment of adenovirus (AdV) infection in allogeneic hematopoietic cell transplant (HCT) recipients at the annual Infectious Diseases conference, IDWeek™ held October 26-30, 2016 in New Orleans, LA.

The results will be presented by Dr. Michael Grimley, Associate Professor, Division of Bone Marrow Transplant and Immune Deficiency, Cincinnati Children's Hospital, on Saturday, October 29.

"This presentation builds upon the top-line 24-week AdVise results that we announced earlier this year. HCT recipients who were treated with brincidofovir experienced a rapid decline in adenovirus viral load, and overall survival was higher in subjects who had a rapid antiviral response compared with those who did not," said Garrett Nichols, MD, MS, Chief Medical Officer at Chimerix. "Importantly, these data continue to advance our scientific understanding of adenovirus infection, including key risk factors for rapid progression of disease within this complex population; these advances will help us predict which patients are most likely to benefit from brincidofovir as we work to design our next studies."

The AdVise trial was an open-label, multicenter study designed to evaluate the efficacy, safety and overall tolerability of brincidofovir for the treatment of AdV infection. In study 304, pediatric and adult patients were placed into one of three cohorts: Cohort A, comprised of allogeneic HCT recipients with asymptomatic or limited AdV infection; Cohort B, comprised of allogeneic HCT recipients with disseminated AdV disease; and Cohort C, comprised of autologous HCT recipients, solid organ transplant recipients and other immunocompromised patients. All subjects were to receive 12 weeks of oral brincidofovir and were followed for 24 weeks after completing treatment. This interim analysis examines outcomes at 24 weeks after the first brincidofovir dose (12 weeks after prescribed dosing duration) and includes 158 patients assigned to Cohorts A (23 adult and 43 pediatric patients) and B (35 adult and 57 pediatric patients).

The primary efficacy endpoint of the AdVise trial was all-cause mortality at Day 60 after the first brincidofovir dose in allo-HCT recipients with disseminated AdV disease, a group in which 50-80 percent mortality has been reported in the literature. All-cause mortality in Cohort B at Day 60 was 19 percent in pediatric subjects and 43 percent in adults.

Importantly, new data from an interim analysis at 24 weeks, presented at IDWeek™, showed marked declines in AdV viremia that were observed in both cohorts. Undetectable viremia at the end of treatment was achieved in 61 percent of patients in Cohort A, and in 49 percent of patients in Cohort B. Additionally, a robust antiviral response was observed despite very low baseline lymphocyte counts and CD4+ cell counts in this population. In patients with poor immune function, defined as baseline CD4+ cell counts below 50 cells/µL, 55 percent in Cohort A and 52 percent in Cohort B had a rapid virologic response (≥2 $\log_{10}$ copies/mL decline or undetectable levels of AdV at Week 4).

Post-Hoc Analyses Show Impact of Early Detection and Treatment

Post-hoc analyses were conducted to investigate the correlation between rapid virologic response to brincidofovir treatment and time to subsequent mortality.

- The analyses compared patients who achieved a ≥2-$\log_{10}$ copies/mL decline or undetectable AdV viremia at Week 4, or undetectable AdV viremia at Week 6 (responders), with patients who did not achieve these thresholds (non-responders).
- In patients with disseminated AdV disease who were alive at Week 4, 84 percent of pediatric patients and 50 percent of adult patients achieved a ≥2 log decline or undetectable AdV viremia by that time. This rapid virologic response was associated with improved survival at Week 24 in both pediatric and adult patients (75 percent of pediatric and 54

percent of adult responders survived to Week 24, compared with 29 percent and 15 percent of non-responders, respectively). All p-values < 0.05.

- In patients with disseminated AdV disease who were alive at Week 6, 68 percent of pediatric patients and 42 percent of adult patients achieved undetectable AdV viremia by that time. This response was associated with improved survival at Week 24 in both pediatric and adult patients (82 percent of pediatric and 70 percent of adult responders survived to Week 24, compared with 46 percent and 14 percent of non-responders, respectively).
- The first patient(s) at each participating site may have experienced delays between diagnosis and treatment with brincidofovir because of the time required to secure institutional review board approval, as one possible reason. Assessment of enrollment period as a covariate demonstrated a period effect with lower mortality in Cohort B pediatric patients enrolled in the last quartile (14 percent mortality at Week 24) compared to those enrolled at the beginning of the study (60 percent mortality at Week 24), reflecting the importance of rapid diagnosis and treatment before multiple organ failure; differences were less pronounced in adults.
- The most commonly reported treatment-emergent adverse events were gastrointestinal (GI) symptoms, increases in serum transaminases and bilirubin, and acute graft-versus-host disease (GvHD). No events were reported that were suggestive of drug-related nephrotoxicity or myelosuppression.

Additional Observations on Survival and Viremia Data

- All-cause mortality at 24 Weeks was lower in pediatric patients than adult patients in both cohorts. Pediatric all-cause mortality was 33 percent in Cohort A and 42 percent in Cohort B. Adult all-cause mortality was 48 percent in Cohort A and 71 percent in Cohort B.
- AdV-related mortality at Week 24 in pediatric patients was 9 percent in Cohort A and 14 percent in Cohort B. AdV-related mortality at Week 24 in adult patients was 4 percent in Cohort A and 46 percent in Cohort B.
- Any prior treatment with cidofovir in Cohort B appeared to have little impact on overall mortality (30 percent in patients with prior cidofovir use at Day 60, compared to 27 percent in patients with no prior use of cidofovir).

Brincidofovir was discontinued due to adverse events (AEs) in 20 percent of pediatric patients and 29 percent of adult patients, with GI events cited as the most common reason (5 percent and 14 percent respectively).

The most commonly reported fatal AEs in Cohort B were multi-organ failure (18 percent pediatric, 14 percent adults), acute GvHD (4 percent pediatric, 20 percent adults), AdV infection (4 percent pediatric, 14 percent adults), and respiratory failure (7 percent pediatric, 9 percent adults).

As previously communicated, in study 305 an attempt was made to compare survival outcomes with matched historical controls, but the baseline risk factors for the control patients (including several recognized co-morbidities) did not match the high-risk patients in AdVise and a meaningful difference in overall survival between the AdVise patients and historical controls was not observed.

The company plans to present full 36-week data from the AdVise study during the first quarter of 2017.

About Adenovirus

Adenovirus (AdV) causes gastrointestinal and upper respiratory infections, including the common cold, in individuals with a functional immune system. However, in people with a weakened immune system, adenovirus can lead to life-threatening infections, including pneumonia and hepatitis. Pediatric and adult patients who have undergone allogeneic hematopoietic cell transplants (HCT) are at especially high risk for serious or fatal AdV infections due to profound immunodeficiency. Mortality rates of 50 to 80 percent have been reported in the literature for disseminated AdV disease. Rates of AdV infection with virus detected in the blood or other body fluids are higher in pediatric transplant recipients than in adults, and have resulted in many medical centers instituting screening protocols to detect AdV infection before the virus causes serious disease. There is currently no approved therapy for AdV infection, and although progression to disseminated disease in pediatric HCT recipients occurs in a small proportion of patients with AdV viremia, mortality rates for pediatric patients with confirmed AdV disease is greater than 50 percent in the first three months after diagnosis.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a 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 adenovirus, cytomegalovirus (CMV) and smallpox. Brincidofovir has also received Orphan Medicinal Product Designation from the European Commission for the treatment of adenovirus and for the prevention of CMV disease, and the Committee for Orphan Medicinal Products (COMP) has issued a positive opinion for an Orphan Designation for the treatment of smallpox.

About Chimerix

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