CHIMERIX

February 22, 2017

Chimerix Announces Final Data from AdVise Trial of Brincidofovir at BMT Tandem Meetings

-- Results show higher survival rate in adenovirus-infected patients with a virologic response to brincidofovir --
-- Mortality rates were lower in pediatric patients than in adult patients --

DURHAM, N.C., Feb. 22, 2017 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX) today announced the presentation of final data from the AdVise trial of brincidofovir for the treatment of adenovirus (AdV) infection in allogeneic hematopoietic cell transplant (HCT) recipients at the BMT Tandem Meetings held February 22-26, 2017 in Orlando, FL.

"The final data highlight the clinical benefit of the early antiviral effect of brincidofovir on adenovirus," said Dr. Vinod K. Prasad, Professor of Pediatrics, Duke University School of Medicine, and an investigator in the AdVise trial. "Rapid declines in adenovirus viral load were observed over the first four weeks of treatment, even in patients whose immune systems had not yet recovered. Importantly, patients who had a virologic response to brincidofovir showed higher survival, as did those who were treated earlier in the disease course. Adenovirus infection is a serious problem in HCT patients and this study showed encouraging results, particularly in children."

The AdVise trial was an open-label, multicenter study designed to evaluate the efficacy, safety and overall tolerability of oral brincidofovir for the treatment of adenovirus infection. Pediatric and adult subjects were assigned to one of three cohorts:

- Cohort A, comprised of allogeneic HCT recipients with asymptomatic or limited adenovirus infection;
- Cohort B, comprised of allogeneic HCT recipients with disseminated adenovirus disease; and
- Cohort C, comprised of autologous HCT recipients, solid organ transplant recipients and other patients with serious adenovirus infections.

All subjects were to receive 12 weeks of oral brincidofovir and were followed for at least 36 weeks. This final analysis includes 158 allogeneic HCT recipients assigned to Cohorts A (23 adult and 42 pediatric patients) and B (35 adult and 58 pediatric patients).

In the AdVise trial, declines in AdV viral load of ≥2 $\log_{10}$ c/mL or below the limit of detection at Week 4 were observed in 76 percent of pediatric patients and 45 percent of adult patients. Notably, this antiviral effect was observed even in HCT recipients who did not yet have immune recovery. In Cohort A, 55 percent of patients with baseline low immunity (CD4 counts < 50 cells/µL) achieved ≥2 $\log_{10}$ c/mL decline or undetectable AdV at Week 4. In Cohort B, 52 percent of patients with baseline low immunity achieved ≥2 $\log_{10}$ c/mL decline or undetectable AdV over the same period of time.

In patients with disseminated disease, rapid virologic response, defined as undetectable AdV viremia at Week 6, was associated with nearly double the survival rate and lower adenovirus-associated mortality compared with subjects who did not have an antiviral response.

		Mortality		AdV-Associated Mortality
Pediatric	Responder*	7/28 (25%)	p=0.031	1/28 (4%)
	Non-responder	7/13 (54%)		2/13 (15%)
Adult	Responder*	5/10 (50%)	p=0.0004	0/10 (0%)
	Non-responder	13/14 (93%)		10/14 (71%)

*Responders defined as subjects with baseline AdV viremia still on study at Week 6 who had undetectable plasma AdV at Week 6; non-responders defined as subjects who did not achieve the specified cut-off. A Cox model incorporating age group was used to compare mortality at 36 weeks in responders and non-responders.

Diarrhea was the most commonly reported treatment emergent adverse event in the AdVise trial, reported in 38 percent of

adult and 43 percent of pediatric HCT recipients. Many subjects enrolled in the AdVise trial, particularly in the first few months of the study, were begun on therapy at a point when they had multiple organ failure or other diagnoses likely to negatively impact their ability to survive the first four weeks of treatment. There was therefore a significant improvement in survival observed for subjects enrolled in the fourth quartile who were begun on brincidofovir with lower viral loads and a shorter time from AdV diagnosis to initiation of treatment. In the anticipated Study 999, patients who are unlikely to survive four weeks will not be enrolled in the trial.

"AdVise is the first interventional trial in patients with serious adenovirus infections, a highly fatal disease after transplant. Because the median time to clear adenovirus from plasma in pediatric subjects was only 2-3 weeks, shorter courses of therapy with brincidofovir may deliver antiviral benefit and improve overall outcomes while limiting the risk of GI toxicity," said Garrett Nichols, MD, MS, and Chief Medical Officer at Chimerix. "We plan to conduct a small comparative study in about 100 patients with short course oral brincidofovir to optimize outcomes in serious adenovirus disease."

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 a high barrier to resistance, no myelosuppression and low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA for adenovirus, 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 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 medicines that improve outcomes for immunocompromised patients. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (BCV); CMX157, which was licensed to ContraVir Pharmaceuticals; and earlier-stage clinical candidates. Chimerix recently announced a new clinical candidate, CMX521, for the treatment and/or prevention of norovirus. 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 BCV, that any clinical trials we may conduct will not demonstrate adequate efficacy and safety of BCV, that enrollment in clinical trials we may conduct may be insufficient or slower than we anticipate, that the FDA and other regulatory authorities may not approve BCV or BCV-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, BCV may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for BCV 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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