CHIMERIX

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New Data on Chimerix's Brincidofovir Supports Safety and Antiviral Activity Against Multiple Life-Threatening DNA Viruses in Organ Transplant Recipients

Three Abstracts Presented at 2014 World Transplant Congress

DURHAM, N.C., July 31, 2014 (GLOBE NEWSWIRE) -- Chimerix, Inc. (Nasdaq:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, presented new data on its investigational antiviral, brincidofovir (BCV, CMX001), at the 2014 World Transplant Congress (WTC) in San Francisco.

Data presented at WTC support brincidofovir's antiviral activity and safety profile in hematopoietic cell transplant (HCT) and solid organ transplant recipients who were treated for viral infections including adenovirus (AdV), cytomegalovirus (CMV), BK virus, Epstein-Barr virus (EBV) and varicella zoster virus (VZV).

Chimerix Presentations at WTC include:

Brincidofovir for the Treatment of Serious or Life-Threatening Double-Stranded DNA Virus Infections in Patients Receiving Liver Transplant as Part of Multiorgan Transplantation

Presenter: Diana Florescu, MD, University of Nebraska Medical Center

- **Brincidofovir demonstrated antiviral activity against adenovirus (AdV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), BK virus (BKV), and varicella zoster virus (VZV) in pediatric and adolescent patients who received multiorgan transplants**

Ten patients who had received multiorgan transplants (liver ± kidney/pancreas/small bowel) ages six months to 15 years were treated with brincidofovir for life-threatening DNA virus infections including AdV, CMV, BK virus, Epstein-Barr virus (EBV) and varicella zoster virus (VZV) after failing existing antiviral therapies. Brincidofovir treatment duration ranged from one to 26 weeks and antiviral activity was observed against all five DNA viruses. Overall, liver and kidney function remained stable or improved in all patients while receiving brincidofovir and during follow-up. In this small, uncontrolled, multiorgan transplant patient population with life-threatening viral infections, the only serious adverse event attributed to brincidofovir was diarrhea in one patient which resolved on treatment. These clinical data support the continued evaluation of brincidofovir for the prevention or treatment of multiple viral infections in patients who have received solid organ transplants or who have other immune dysfunction, and complement previous *in vitro* potency of brincidofovir against all five families of DNA viruses that cause human disease.

Switch from Existing Antivirals to Brincidofovir Leads to Improving Renal Function

Presenter: Marion Morrison, MD, Chimerix, Inc.

- **Greater than 80% of patients who received prior cidofovir or foscarnet showed improvement in renal function during brincidofovir treatment**

The expanded access study of brincidofovir (BCV, CMX001), Study 350, enrolled immunocompromised patients with life-threatening DNA viral infection(s) and no other therapeutic options. Twenty-five percent (25%, n=66) of patients enrolled had received prior antivirals foscarnet or cidofovir, known to be nephrotoxic, providing an opportunity to evaluate the change in renal function during BCV therapy. Despite the heterogeneity and complexity of these patients, greater than 80% of patients who received cidofovir or foscarnet showed improvement in renal function during brincidofovir treatment, including patients with severe renal impairment (eGFR < 30 mL/min) when they began BCV. In patients who switched from prior cidofovir to brincidofovir (n=37) greater than 80% showed improvement in renal function measured by eGFR. In patients with severe renal impairment at baseline, 100% had measurable improvement in eGFR while on brincidofovir, with > 60% improving by a clinically significant 20 mL/min or more. These data support the lack of nephrotoxicity associated with brincidofovir, consistent with data from the Phase 2 CMV prevention trial which showed a dose-related improvement in GFR. Further study of brincidofovir is planned in kidney transplant recipients and other patient populations at high risk of renal impairment.

Brincidofovir Experience in Renal Transplant Patients for Treatment of Refractory CMV Infection

Presenter: Kathleen Mullane, DO, PharmD, University of Chicago

- **Brincidofovir demonstrated antiviral activity against CMV in kidney transplant patients who failed other antiviral treatments**

Patients who had failed previous antiviral treatment for CMV infection received brincidofovir under an expanded access protocol (Study 350). Five kidney transplant patients (ages 44-56) with refractory or resistant CMV infections received brincidofovir for 10-171 days (mean 91 days) at doses of 100-200 mg twice weekly. Three patients had a complete virologic response with undetectable CMV (< LOD 100c/mL), and one patient had a -2.4 $\log_{10}$ reduction in CMV viremia from Baseline.

The most common adverse events were diarrhea and nausea reported in three of five patients. One of the five patients discontinued for drug-related adverse events. In this small, uncontrolled subset of kidney transplant recipients, there were no remarkable shifts in renal function during treatment. These data support further evaluation of brincidofovir for the treatment and prevention of CMV in patients who receive a kidney transplant.

About Brincidofovir (CMX001)

Chimerix's lead product candidate, brincidofovir, is an oral nucleotide analog that has shown broad-spectrum *in vitro* antiviral activity against all five families of DNA viruses that affect humans, including viruses in the herpes virus family and AdV. Brincidofovir has shown no evidence of kidney or bone marrow toxicity in nearly 900 patients exposed to date. Building on the positive Phase 2 results in CMV prevention, Chimerix initiated the Phase 3 SUPPRESS trial in 2013. 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 recently initiated a Phase 3 trial in AdV, an often-fatal viral infection with no approved treatment; enrollment is ongoing for the pilot portion of that trial. Chimerix is also working with 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, AdV, 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 technology has given rise to brincidofovir (BCV, CMX001), a clinical-stage nucleotide analog lipid-conjugate, which has demonstrated potent antiviral activity and safety in convenient, orally administered dosing regimens. Chimerix is currently enrolling SUPPRESS, a Phase 3 study of brincidofovir for the prevention of CMV in HCT recipients. In addition, Chimerix is enrolling the pilot portion of a Phase 3 study of brincidofovir for treatment of disseminated AdV infection. Chimerix is working with the Biomedical Advanced Research and Development Authority (BARDA) to develop brincidofovir as a medical countermeasure against smallpox. For further information, please visit Chimerix's website, www.chimerix.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Chimerix's filings with the Securities and Exchange Commission, including without limitation its most recent Quarterly Report on Form 10-Q, its most recently filed Current Reports on Form 8-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Chimerix 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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