Chimerix Initiates AdAPT Study for Oral Brincidofovir and Advances IV Brincidofovir to Patient Studies

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- Pivotal AdAPT Study of Oral Brincidofovir for Adenovirus Now Enrolling -

- No GI Adverse Effects for IV Brincidofovir 10 mg -

- Announces First Antiviral Specific for Norovirus Now In Clinical Testing -

DURHAM, N.C., Jan. 05, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals for the growing population of immunocompromised patients, today provided an update on multiple clinical development programs including oral brincidofovir (BCV), intravenous (IV) BCV, and CMX521.

"We are especially pleased to begin 2018 with the initiation of AdAPT, a comparative study designed together with European regulators to demonstrate the superiority of brincidofovir's antiviral effect in pediatric transplant recipients facing life-threatening adenovirus infection. As we've seen in multiple other settings, clearance of adenovirus has a positive impact on survival in the first year after transplant. Positive data from AdAPT is expected to provide the basis for a European marketing approval, and if clinical benefits are confirmed, could be considered for an accelerated approval under the FDA's Subpart H guidance. Our team is committed to fulfilling the promise of brincidofovir and its potential as the first approved antiviral for adenovirus infections," stated M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix.

"We are also happy to report successful administration of 2-4 weeks of IV BCV without dose-limiting gastrointestinal events, supporting the progression to Phase 2 studies of IV BCV in virally infected transplant recipients. Specifically, twice-weekly doses of IV BCV 10 mg provide similar blood levels of the drug as the oral BCV 100 mg dose previously studied in late-stage trials, but did not result in any reported diarrhea. Proposals for these Phase 2 studies of IV BCV in virally-infected patients are currently being reviewed by regulators in Europe, and are expected to provide data later in the year."

"And finally, our new molecule, CMX521, is the first direct-acting antiviral for norovirus to progress to clinical-stage development. We look forward to sharing more on this compound as we complete initial clinical assessments," concluded Dr. Berrey.

Initiation of AdAPT Study of Oral Brincidofovir in Adenovirus

The Company reports the initiation of the AdAPT Study (Adenovirus after Allogeneic Pediatric Transplantation). This study is targeting enrollment of 141 pediatric allogeneic hematopoietic stem cell transplant (HCT) recipients with confirmed adenovirus (AdV) infection; patients will be randomized 2:1 to receive short-course oral BCV or local standard-of-care (SOC) treatment at approximately 30 sites in Europe and the United States.

The primary endpoint of the study is a comparison of the average adenovirus viral burden (as measured by AdV DNA levels in blood) over 16 weeks in subjects treated with short-course oral BCV versus those who receive local SOC. The study is 90% powered to show the superiority of reduced adenoviral burden in brincidofovir-treated patients compared to SOC. The study will also evaluate the correlation of AdV burden (and its clearance) with clinical outcomes including survival. Enrollment is estimated to complete in 2019.

IV Brincidofovir Progresses to Phase 2 Studies

The Company announces the successful completion of the multiple ascending dose (MAD) study of IV BCV in healthy subjects. This study evaluated the safety, tolerability and pharmacokinetics of IV BCV 10 mg given twice weekly and IV BCV 20 mg given once weekly in healthy subjects for two to four weeks. IV BCV was well-tolerated at all dose levels, with no dose-limiting clinical adverse events. Importantly, there was no diarrhea reported for IV BCV 10 mg dosed twice weekly, a dose that provides drug levels equivalent to oral BCV 100 mg which demonstrated antiviral activity in previous late-stage clinical studies. Proposals for studies of IV BCV in virally-infected patients have progressed to regulatory review in Europe and are expected to provide data in the second half of 2018.

Preparation Underway for European Regulatory Submission for Smallpox

In late November, the Company received advice from the European Medicines Agency (EMA) on the development plan for smallpox, in which the submission of a marketing application with data from completed studies, including the large rabbitpox efficacy study, VIR-041, was discussed. This rabbitpox study, as previously reported, demonstrated 100% survival in animals with confirmed viral infection treated with BCV, a clinically and statistically significant improvement compared with <50% survival in animals that received placebo. This study in combination with supportive mousepox study data was considered sufficient for review by EMA. The Company is in the process of preparing for a marketing application submission to EMA in early 2019. Chimerix intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), contingent upon the results of animal efficacy studies to be conducted in 2018.

CMX521 for Norovirus

Chimerix announces the initiation of its first-time-in-human study of CMX521, a nucleoside analog identified from the Chimerix Chemical Library, as a potential treatment and/or prevention for norovirus. The Phase 1 study will evaluate the pharmacokinetics, safety and tolerability of CMX521 in up to 50 adult subjects. The study also includes the collection of gut biopsy specimens, which will allow determination of active drug concentrations in the

target gut tissue. Study results are expected in mid-2018.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has 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 a low risk of nephrotoxicity. 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 adenovirus, CMV, and 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 and compound library have produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and a new clinical candidate, CMX521, the first direct-acting antiviral specifically for the treatment and 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 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. Similar risks and uncertainties apply to the Company's development of CMX521.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 press release 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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