



CHIMERIX

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Chimerix Commences Phase 2 Study of CMX001 for Prevention of AdV in Ped & Adult Hematopoietic Stem Cell Transplant Patients

- CMX001 Granted FDA Fast-Track Designation for Adenovirus Indication --

DURHAM, NC, JULY 13, 2011 - Chimerix, Inc., a biotechnology company developing orally-available antiviral therapeutics, today announced that patient dosing has begun in the AdV HALT Trial (A Randomized, Placebo-Controlled, Multi-site Phase 2 Study Evaluating the Safety and Efficacy of Preemptive Treatment with CMX001 for the Prevention of Adenovirus Disease Following Hematopoietic Stem Cell Transplantation [HSCT]). The company also announced that the U.S. Food and Drug Administration (FDA) has granted CMX001 Fast Track designation status for the development program for this indication.

The Phase 2 AdV HALT Trial is a randomized, placebo-controlled study intended to evaluate the safety and efficacy of preemptive treatment with CMX001 in order to prevent immunocompromised pediatric and adult patients with asymptomatic adenovirus infection from developing disease. Adenoviruses are a family of double-stranded DNA (dsDNA) viruses responsible for respiratory diseases, including pneumonia and bronchitis, as well as other infections including gastroenteritis and acute diarrheal diseases. In immunocompromised patients, including those who have undergone HSCT, adenovirus infections are recognized as a significant cause of morbidity and mortality. Immunocompromised pediatric HSCT patients are particularly susceptible to serious and/or fatal adenovirus infections.

"Pediatric HSCT patients are at increased risk of life-threatening adenovirus infections – yet we have no approved treatment options," said Joanne Kurtzberg, MD, Director, Carolinas Cord Blood Bank Division Chief, Pediatric Blood and Marrow Transplantation, Duke University Medical Center, and a lead investigator of the study. "It is well known that this population is less tolerant of the toxicities associated with conventional antiviral drugs, especially the kidney toxicity associated with cidofovir, and we hope CMX001 will be able to make a significant difference."

"We believe CMX001's rapidly evolving antiviral and safety profile provides strong support for this candidate's broad-spectrum, preemptive usage, which includes the often-overlooked pediatric population," said Kenneth I. Moch, Chimerix President and CEO. "To date, CMX001 has been administered to more than 550 subjects and has demonstrated activity against a broad spectrum of dsDNA viruses. It has been well tolerated and has not shown toxicity in the kidneys or on bone marrow function."

The AdV HALT Trial/CMX001-202 Design

The primary objective of the Phase 2 clinical study is to evaluate the safety and efficacy of preemptive treatment with CMX001 versus placebo for the prevention of AdV disease in hematopoietic stem cell recipients with asymptomatic AdV viremia. The multi-center, placebo-controlled study, which will be conducted at approximately 30 centers, is expected to enroll 48 pediatric and adult patients who have undergone hematopoietic stem cell transplant and have evidence of infection but no symptoms of disease. Under the protocol, subjects will be randomized to receive CMX001 or placebo once or twice weekly for at least six, but no more than 12, weeks. The dose of CMX001 or placebo given during the randomized treatment phase will be based upon the age and weight of the subject at the time of enrollment.

The primary endpoint will be "treatment failure", consisting of progression to AdV disease or increasing AdV viremia. Secondary endpoints include safety and tolerability of CMX001, as well as other measurements that include the percentage of subjects who have emergence or progression of cytomegalovirus (CMV), Epstein-Barr virus (EBV), or BK virus (BKV) viremia or disease during therapy. Drug pharmacokinetics and the development of viral resistance will also be assessed.

Additional information on study objectives, enrollment criteria and patient eligibility for the AdV HALT Trial is available at www.clinicaltrials.gov.

About Fast Track Designation

Chimerix has been granted two FDA Fast-Track Designations for CMX001: for the treatment of adenovirus disease and for the treatment of smallpox. The FDA's "Fast Track" program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious conditions and that demonstrate the potential to fill an unmet medical need. The designation typically enables a Company to submit a New Drug Application (NDA) on a "rolling" basis with ongoing FDA review

during the submission process. NDAs with Fast Track designation are also usually granted Priority Review by FDA at the time of NDA submission.

About Chimerix

Chimerix is developing novel antiviral therapeutics with the potential to transform patient care in multiple settings, including transplant, oncology, acute care and global health.

The company's lead candidate, CMX001, is being developed as a potential broad spectrum, oral antiviral product for the treatment or prevention of life-threatening double-stranded DNA (dsDNA) viral diseases. To date, more than 550 patients have been dosed with CMX001 in placebo-controlled clinical trials and open-label treatment protocols, including more than 250 individuals who have received CMX001 under Emergency Investigational New Drug Applications (EINDs) or as part of the CMX001-350 Open-Label Study to help treat life-threatening dsDNA viral diseases for which there were no other therapeutic options.

Clinical studies of CMX001 include an ongoing Phase 2 study of the prevention/control of CMV in adult hematopoietic stem cell transplant patients (CMX001-201); a Phase 2 study for the treatment of AdV infection in pediatric and adult hematopoietic stem cell transplant patients (AdV HALT Trial/CMX001-202); and an Open-Label Study (CMX001-350) for the treatment of dsDNA viral infections. The open-label study builds on Chimerix's extensive experience working with over 150 clinicians at over 80 leading institutions in the United States, Canada, Europe, and Israel who have sought CMX001 under EINDs for the treatment of immunocompromised patients.

CMX001 is also being developed as a medical countermeasure in the event of a smallpox release, including the potential to provide an important therapeutic option for the 80 million people in the U.S. currently estimated to be immunocompromised and thus not candidates to receive a smallpox vaccine. Chimerix has received federal funding for the development of CMX001 as a medical countermeasure against smallpox from the National Institute of Allergy and Infectious Diseases under Grant No. UO1-AI057233 and from the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. HHSO100201100013C.

Chimerix's second clinical-stage antiviral compound, CMX157, a potent nucleoside analogue with in vitro activity against HIV and hepatitis B, has the potential to directly address several limitations of current HIV therapies. Chimerix is developing CMX157 for the treatment of HIV and HBV infections, including those caused by multi-drug resistant viruses. A Phase 1 clinical study has been completed demonstrating that the compound is well tolerated and that the active antiviral, TFV-PP, was measurable in peripheral blood mononuclear cells (PBMCs) after a single dose and remained detectable for six days, indicating that it may be suitable for once-weekly dosing.

Led by a world-class antiviral drug development team, Chimerix is also leveraging the company's extensive chemical library to pursue new treatments for hepatitis C virus, influenza, malaria and other global public health needs.