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FDA Grants Fast Track Designation for CMX001 for the Prevention of Clinically Significant CMV Infection

RESEARCH TRIANGLE PARK, NC, March 12, 2013 – Chimerix, Inc., a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CMX001 for the prevention of cytomegalovirus (CMV) infection. CMX001 is the company's broad spectrum, oral nucleotide analog lipid-conjugate that blocks replication of double-stranded DNA (dsDNA) viruses.

The Fast Track program of the FDA is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track-designated drugs ordinarily qualify for priority review, thereby expediting the FDA review process.

CMX001 has completed Phase 2 clinical development for the prevention of CMV infection in adult hematopoietic stem cell transplant (HSCT) recipients. Chimerix is preparing to initiate SUPPRESS, its Phase 3 study of CMX001 for the prevention of CMV infection in adult HSCT recipients, in 2013. The company has previously received Fast Track designation for its CMX001 development programs for preemptive treatment of adenoviral disease in patients post HSCT and for the treatment of smallpox.

About Chimerix and CMX001

Chimerix is committed to the discovery, development and commercialization of novel, oral antiviral therapeutics designed to transform patient care in areas of high unmet medical need. The Company's proprietary lipid technology has given rise to two clinical-stage lipid acyclic nucleoside phosphonates, CMX001 and CMX157, which have demonstrated the potential for enhanced activity and safety in convenient, orally administered dosing regimens.

Chimerix's lead product candidate, CMX001, is a broad spectrum, oral nucleotide analog lipid-conjugate that blocks replication of double-stranded DNA (dsDNA) viruses, including cytomegalovirus (CMV), adenovirus (AdV), BK virus and herpes simplex virus. CMX001 has completed Phase 2 clinical development for the prevention of CMV in hematopoietic stem cell transplant (HSCT) recipients. Chimerix is also conducting a Phase 2 study in HSCT recipients which is evaluating CMX001 as a preemptive therapy for AdV disease, an often-fatal infection which has no approved therapies. Since 2009, Chimerix has made CMX001 available under expanded access regulations to over 80 transplant centers worldwide for the treatment of over 430 patients with life-threatening dsDNA viral infections. Chimerix anticipates initiating SUPPRESS, its Phase 3 study of CMX001 for the prevention of CMV infection in adults undergoing HSCT, in 2013.

Chimerix is also developing CMX001 as a potential medical countermeasure against smallpox under a contract from the Biomedical Advanced Research and Development Authority (BARDA).

Chimerix's second product candidate, CMX157, an oral nucleotide analog lipid-conjugate in Phase 1 development for the treatment of HIV infection, was licensed to Merck in July 2012.

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