Data Demonstrating the Safety and Efficacy of Chimerix’s Antiviral CMX001 Presented at BMT Tandem Meetings

- No evidence of CMX001-associated kidney toxicity was seen in stem cell transplant recipients who were enrolled in a 230-patient Phase 2 study to evaluate CMX001 for prevention of cytomegalovirus (CMV) infection. Subjects on CMX001 had stable to improved renal function while declining renal function was observed in the placebo cohort. This finding may be related to the antiviral effect of CMX001 against BK virus.

- Serum albumin levels can be used as a marker for differentiating potential CMX001-associated gastrointestinal symptoms from other etiologies.

- CMX001 was associated with control of BK viremia in a case report of a patient with BK virus-associated nephropathy (BKVN) following stem cell transplant.

RESEARCH TRIANGLE PARK, NC, February 19, 2013 – Chimerix, Inc., a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today released data from presentations at the BMT Tandem Meetings supporting the broad spectrum antiviral activity and emerging safety profile of CMX001. CMX001 is an oral nucleotide lipid-conjugate anticipated to start a Phase 3 study later this year.

“These findings demonstrate CMX001’s potential to be a safe and efficacious broad-spectrum antiviral for the treatment of double-stranded DNA viral infections,” said M. Michelle Berrey, MD, MPH, Chief Medical Officer of Chimerix. “As we progress CMX001 into a Phase 3 study for the prevention of cytomegalovirus infection in adults undergoing hematopoietic stem cell transplantation, these data support our desire to conduct additional clinical studies to evaluate the potential benefit of CMX001 against other double-stranded DNA viruses, including BK virus.”

These data were presented during the Allogeneic Transplants Poster Session at the BMT Tandem Meetings in Salt Lake City on Saturday, February 16, 2013.

The three presentations included:

Renal Safety of the Broad-Spectrum Antiviral, CMX001, in the Prevention of Cytomegalovirus Infection Post-Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Renal safety of CMX001 was assessed during Study 201, a Phase 2 study evaluating CMX001 for the prevention of CMV infection following allogeneic hematopoietic stem cell transplantation (HSCT). A prospective analysis found that placebo recipients experienced a decline in renal function during the randomized treatment period, while there appeared to be a dose-related improvement in renal function for the CMX001-treated subjects. The comparison between pooled placebo and the group receiving a CMX001 dose of 100 mg twice weekly reached statistical significance (p<0.05). The lack of renal toxicity as well as the potential activity of CMX001 against BK virus are significant findings from this report. CMX001 will be evaluated in the Phase 3 study, SUPPRESS, for prevention of CMV. SUPPRESS will also explore the potential for activity against BK virus in HSCT.
Monitoring Changes in Serum Albumin Concentrations as an Early and Objective Indicator of Potential CMX001-associated Gastrointestinal Adverse Drug Effects

In Study 201, diarrhea was found to be the dose-limiting side effect associated with CMX001. As GI adverse events are common in this patient population, differentiating potential drug-related diarrhea from other etiologies is important to limit the impact of GI-related adverse events on optimal dosing duration in this population. Decreases in serum albumin in association with worsening diarrhea can be used as a clinical and objective tool to discriminate drug-related diarrhea from diarrhea of other etiologies, prompting interruption of study drug in order to avoid progression to higher severity events. Monitoring serum albumin levels has been incorporated into the overall Safety Monitoring and Management Plan for CMX001 and will be incorporated in the Phase 3 study, SUPPRESS.

BK virus-associated nephropathy (BKVN), an under-recognized cause of renal dysfunction in severely immunosuppressed hematopoietic stem cell transplant (HSCT) patients: Report of 5 cases of BKVN and the potential role of CMX001 for treatment

BK virus-associated nephropathy, BKVN, is observed in patients with renal transplants and is related to kidney graft loss. In HSCT recipients, hemorrhagic cystitis (HC) is the most common BK virus manifestation. A recent retrospective analysis at Memorial Sloan-Kettering Cancer Center revealed five cases of HSCT recipients with BKVN identified through biopsy or autopsy, and suggested that BKVN may be an under-recognized cause of renal dysfunction in HSCT recipients. Through Chimerix’s expanded access study of CMX001, a recipient of HSCT was treated for BKVN with CMX001 100 mg twice weekly for six months. After 10 months of therapy, the patient has maintained stable renal function without requiring hemodialysis. This case report suggests that BKVN may be underdiagnosed in HSCT recipients and should be considered in patients with declining renal function. Furthermore, these data support the potential role of CMX001 for the treatment of BKV infection and BKVN.

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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