

## Chimerix and BARDA Reach Agreement Ending GAO Review of Smallpox Antiviral Contract

# - BARDA Deletes 12 Million Optional Courses from SIGA Sole Source Contract Allowing Opportunity for Competitive Procurement of a Second Smallpox Antiviral

**DURHAM, NC, June 27, 2011 -** Chimerix, Inc., a pharmaceutical company developing orally-available antiviral therapeutics, today announced an agreement with the Biomedical Advanced Research and Development Authority (BARDA) of the United States Department of Health and Human Services (HHS) that will resolve the Government Accountability Office (GAO) review of the recent sole source contract awarded to SIGA Technologies, Inc. for the development and delivery of a smallpox antiviral to the Strategic National Stockpile. This agreement allows BARDA the opportunity to competitively procure a second smallpox antiviral, consistent with the U.S. government's long-stated strategy of having two smallpox antiviral drugs for protecting the public against the intentional or unintentional release of the smallpox virus.

The original SIGA sole source contract was for a base amount of 1.7 million treatment courses of smallpox antiviral as well as an optional 12 million additional treatment courses. According to BARDA's initial justification for this sole source contract, the 12 million additional courses were designated for individuals who had "an uncertain immune response to smallpox." BARDA has concluded that it is in the U.S. government's interest to delete the 12 million optional courses from the SIGA contract. Accordingly, Chimerix has withdrawn its GAO protest of the SIGA sole source contract.

Chimerix's lead product CMX001 is being developed as a broad spectrum antiviral with particular emphasis on the ability to treat immunocompromised patients, which includes individuals infected with smallpox. A separate BARDA procurement of additional treatment courses at a future date will give Chimerix the opportunity to compete for a contract for the second smallpox antiviral. This resolution serves the nation's overall interests to have two antiviral drugs for use against smallpox.

"We are pleased to have reached a rapid resolution of the GAO protest so that all parties can continue with the important work of developing smallpox antivirals," said Kenneth I. Moch, President & CEO of Chimerix. "Chimerix is intensely focused on developing CMX001, for its dual-use potential and as a potent broad spectrum antiviral, to address the threat of smallpox release and the critical needs of immunosuppressed transplant and oncology patients with life-threatening viral infections."

### About CMX001

CMX001 is being developed as a potential broad spectrum oral antiviral for the treatment of life-threatening double-stranded DNA (dsDNA) viral diseases, including herpes viruses, adenoviruses and orthopox viruses. The growing body of evidence of CMX001's antiviral activity against all five families of dsDNA viruses that cause morbidity and mortality in humans, including smallpox, has strengthened the compound's potential as a dual-use product prescribed as a traditional pharmaceutical and stockpiled as a biodefense countermeasure. More than 500 patients have been dosed with CMX001 to date in ongoing placebo-controlled clinical trials and in open-label treatment protocols for the prophylaxis, preemption and treatment of dsDNA viral diseases. 250 patients have received CMX001 under Emergency Investigational New Drug Applications (EINDs), including for treatment of orthopox viruses. A significant number of the individuals receiving CMX001 in human testing have been immunocompromised as a result of disease or immunosuppressing therapies associated with stem cell or solid organ transplantation.

Clinical studies of CMX001 include: an ongoing Phase 2 study of the prevention/control of cytomegalovirus (a herpes virus) in adult hematopoietic stem cell transplant patients (CMX001-201); a Phase 2 study currently being initiated for the treatment of adenovirus infection in pediatric and adult hematopoietic stem cell transplant patients (AdV HALT Trial/CMX001-202); and an ongoing open-label study (CMX001-350) for the treatment of numerous dsDNA viral infections.

#### **CMX001 and Smallpox Antiviral Development**

CMX001 is a leading antiviral candidate as a medical countermeasure against 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.

### **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 antiviral product for the treatment of life-threatening double-stranded DNA (dsDNA) viral diseases. To date, more than 500 patients have been dosed with CMX001 in placebo-controlled clinical trials and open-label treatment protocols, including over 250 individuals who have received CMX001 to help treat life-threatening dsDNA viral diseases for which there were no other therapeutic options.

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, flu, malaria and other global public health needs.