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# **XOMA Awarded \$65 Million Biodefense Contract by NIAID to Advance Drug Candidates Against Botulism Toxins Into Clinical Trials**

## **First Human Monoclonal Antibody Drug Program to Target Multiple Botulinum Toxins**

BERKELEY, Calif., Sept. 9, 2008 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA) today announced that it was awarded a \$65 million multiple year contract from the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), to support XOMA's ongoing development of drug candidates towards clinical trials in the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. The contract is the third that NIAID has awarded to XOMA for the development of botulinum antitoxins and brings the program's total to nearly \$100 million.

This award furthers XOMA's plans to develop anti-botulism antibody products to protect against natural, accidental or intentional human exposure to botulism. In general, XOMA plans to initiate testing of its first drug candidate in human safety and animal efficacy studies in 2009. Depending on positive results, continued government funding and additional human safety studies, XOMA plans to file the data package necessary to begin production of drug candidates for the Strategic National Stockpile. Following positive discussions with the U.S. Food and Drug Administration, XOMA plans to prepare and submit a Biologics License Application (BLA).

- \* **Improved safety:** Current botulinum drugs for adults use antibodies harvested from animals that have been exposed to botulism. These animal-derived therapeutic antibodies can cause life-threatening immune reactions in some patients and have unpredictable variability in their efficacy. As a result, such antibodies require close monitoring of patients during administration which is expensive and may be impractical in situations involving large numbers of people. In contrast, XOMA uses next generation human monoclonal antibody technologies to achieve superior safety, potency and efficacy, and avoid the immune reactions associated with animal-derived antibodies.
  
- \* **Broad protection:** This program will be the first of its kind to combine multiple human antibodies to target a broad spectrum of the most toxic botulinum toxins. There are several families, or

serotypes, of botulinum toxin, each with unique physical and toxicity characteristics. XOMA will target the three most toxic serotypes of botulism, Types A, B and E. The antibodies are designed to bind to each toxin and enhance the clearance of the toxin from the body. The use of multiple antibodies increases the likelihood of clearing the harmful toxins by providing specific protection against each toxin type.

- \* Simple method of administration: Another goal of the program will be to develop an injectable form of highly potent antibodies that can be given at very low doses for mass casualty events. This would provide an easier method of administration and safety advantages compared to currently available therapies that use legacy technologies such as lower potency animal-derived antibodies given by time-consuming intravenous methods.
- \* High quality: XOMA is using its proprietary technologies and expertise to address the many technical challenges involved with a multiple antibody "cocktail" approach. These factors include matching the pharmacokinetics of the individual monoclonal antibodies to ensure the optimal potency and quality of each antibody within the cocktail. XOMA believes this will be the first highly characterized antibody cocktail to protect people from these potentially fatal botulinum toxins.
- \* Breakthrough research: This program is based on more than a decade of breakthrough research conducted at the University of California, San Francisco. This research demonstrated for the first time that binding alone with antibody fragments to the botulinum toxin was insufficient for protection, that whole antibody was required to clear toxin from the body, and that multiple whole antibodies were required for maximum survival at lowest doses. The program will use technology licensed to XOMA by The Regents of the University of California

XOMA will develop, evaluate and produce the clinical supplies to support an Investigational New Drug filing with the U.S. Food & Drug Administration and conduct preclinical studies required to support human clinical trials. The project is fully funded under Federal contract number HHSN272200800028C. XOMA expects to receive \$65 million in revenues as work is conducted over a six-year period.

"The continued support of NIAID demonstrates the determination of the U.S. government to engage innovative leaders in biopharmaceutical development, such as XOMA, to advance the development of novel compounds that address natural, accidental or intentional human exposure to infectious disease pathogens and their toxins," said Steven Engle, XOMA's Chairman and Chief Executive Officer. "Since initiating its biodefense programs in 2005, XOMA has used its innovative antibody technology to develop better and safer solutions. We plan to continue working with the government's biodefense development efforts toward future stockpiling initiatives."

## Botulinum Neurotoxin Symptoms

Botulism is a muscle-paralyzing disease caused by one of the most potent known toxins, a neurotoxin made by the bacterium *Clostridium botulinum*. Exposure to the botulinum neurotoxin can cause muscle paralysis that can eventually lead to death. Botulism can be acquired through consumption of contaminated foods or through infection of a wound by *C. botulinum*. Due to the risk posed by the botulinum neurotoxin as a biological weapon and the

severity of disease, it has been classified by the U.S. government as a Category A bioterrorism agent.

#### About NIAID

NIAID conducts and supports research-at NIH, throughout the United States, and worldwide- to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at [www.niaid.nih.gov](http://www.niaid.nih.gov).

#### About XOMA

XOMA discovers, develops and manufactures therapeutic antibody and other agents designed to treat inflammatory, autoimmune, infectious and cancerous diseases and is engaged in 16 active development projects. The company's expanding pipeline includes XOMA 052, an anti-IL-1 beta antibody, and XOMA 629, a synthetic antimicrobial peptide compound derived from bactericidal/permeability-increasing protein.

XOMA's proprietary development pipeline is primarily funded by multiple revenue streams resulting from the licensing of its antibody technologies, product royalties, development collaborations, and biodefense contracts. XOMA's technologies and experienced team have contributed to the success of marketed antibody products, including RAPTIVA(r) (efalizumab) for chronic moderate to severe plaque psoriasis, LUCENTIS(r) (ranibizumab injection) for wet age-related macular degeneration and CIMZIA(r) (certolizumab pegol) for Crohn's disease.

The company has a premier antibody discovery and development platform that incorporates leading antibody phage display libraries and XOMA's proprietary Human Engineering(tm) and bacterial cell expression technologies. Bacterial cell expression is a key breakthrough biotechnology for the discovery and manufacturing of antibodies and other proteins. As a result, more than 50 pharmaceutical and biotechnology companies have signed BCE licenses.

In addition to developing its own products, XOMA develops products with premier pharmaceutical companies including Novartis AG, Schering-Plough Research Institute and Takeda Pharmaceutical Company Limited. XOMA has a fully integrated product development infrastructure, extending from pre-clinical science to approval, and a team of 330 employees at its Berkeley location. For more information, please visit <http://www.xoma.com>.

Certain statements contained herein concerning current collaborations and/or product development or that otherwise relate to future periods are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. Among other things, XOMA may not be able to produce the required antibodies and/or formulation to the satisfaction of NIAID, and XOMA's work may not support further development. These and other risks, including those related to the results of discovery and pre-clinical testing; the timing or results of pending and future

clinical trials (including the design and progress of clinical trials; safety and efficacy of the products being tested; action, inaction or delay by the FDA, European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; XOMA's financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with XOMA's status as a Bermuda company, are described in more detail in XOMA's most recent filing on Form 10-K and in other SEC filings. Consider such risks carefully when considering XOMA's prospects.

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