

# Positive Clinical Findings Presented on XOMA 052 in Debilitating Eye Disease

# Results of Pilot Study in Patients With Uveitis of Behcet's Disease Presented at EULAR

ROME, June 17, 2010 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced positive results from an open-label pilot study of XOMA 052 in patients with uveitis of Behcet's disease who were suffering from vision-threatening exacerbations despite maximal doses of immunosuppressive medicines. All seven patients who enrolled in the trial displayed rapid reduction of intraocular inflammation and improvement in visual acuity or other ophthalmic measures following a single treatment with XOMA 052, a therapeutic antibody candidate that inhibits the inflammatory cytokine interleukin-1 beta (IL-1 beta). The preliminary results of the first clinical trial of XOMA 052 in patients with uveitis of Behcet's disease were presented today at the Annual Congress of the European League against Rheumatism (EULAR) in Rome, Italy.

Uveitis, or inflammation of the intraocular tissues of the eye, of Behcet's disease is one of the most severe forms of uveitis and affects approximately half of the patients with Behcet's disease. Unlike many forms of chronic uveitis, Behcet's uveitis is characterized by recurrent acute attacks or exacerbations. Without immediate treatment, major exacerbations of Behcet's uveitis may lead to retinal detachment, vitreous hemorrhage, glaucoma and eventual blindness. Symptoms include the accumulation of vitreous haze which can block eyesight or the loss of visual acuity and can manifest differently from patient to patient. For example, patients may go from 20/20 eyesight to loss of vision during the course of an exacerbation.

"Behcet's uveitis can lead to progressive and permanent loss of visual acuity. Unfortunately, there is no cure and current treatments are limited to corticosteroids and immunosuppressive drugs, all of which have significant side effects, especially when used on a chronic basis," explained Dr. Ahmet Gul, principal investigator of the pilot study and Professor of Medicine, Istanbul University, one of the largest centers of study for Behcet's disease in the world. "Over-expression of IL-1 beta and downstream pro-inflammatory cytokines play critical roles in Behcet's disease. Targeting IL-1 beta inhibits the inflammatory process and has the potential to improve eyesight in these patients without the toxic side effects of current therapies. We are encouraged with the data generated so far, notably that we saw very clear improvements in these patients following treatment with XOMA 052, despite the removal of immunosuppressive medicines."

Each of the seven patients presented with active exacerbations of uveitis despite receiving

maximal doses of immunosuppressive medicines. Each received a 0.3 mg/kg intravenous infusion of XOMA 052 and simultaneously stopped taking immunosuppressive drugs such as cyclosporine and/or azathioprine. All continued treatment with low doses of corticosteroids. Patients' status was measured using multiple objective parameters associated with ocular health, including patients' visual acuity, vitreous haze score, anterior chamber cells, fundus score, and the patients' flare score.

All seven patients demonstrated improvement in intraocular inflammation starting within one day of treatment with a single dose of XOMA 052 and achieved clinically significant improvement of retinal problems and vitreous haze four to 21 days following treatment. Visual acuity improvements were evident following treatment with XOMA 052, and six out of seven patients remained in remission 28 days after a single treatment. Five patients received a second infusion between days 29 and 95 to blunt a developing exacerbation, and all responded to the second infusion. The drug appeared to be safe, and no drug-related adverse events were reported.

"The results of the XOMA 052 study show great promise for Behcet's patients suffering from recurrent uveitis, which can cause permanent vision loss," said Joyce Kullman, Executive Director of the Vasculitis Foundation. "Given that there is no satisfactory standard of care for treating Behcet's uveitis and at present the only therapeutic options are limited, developing an effective therapy is critical. XOMA 052 may offer leading-edge promising care for our patients."

"We have watched with great interest over the last several months as mounting preclinical and clinical evidence clearly demonstrate the potential of targeting IL-1 beta to treat inflammation in a broad range of diseases like diabetes, cardiovascular and gout," said Patrick J. Scannon, M.D., Ph.D., XOMA's Executive Vice President and Chief Medical Officer. "These data in Behcet's uveitis, in which all patients treated with XOMA 052 have shown marked improvement, highlight yet another potential application of XOMA 052 in treatment of inflammatory-mediated diseases. While we recognize that larger studies must be conducted, we are very pleased with these results."

"While we remain focused on developing XOMA 052 in patients with Type 2 diabetes and cardiovascular disease, the generation of these initial positive results in an orphan indication could provide an accelerated regulatory pathway," noted Steven B. Engle, Chairman and Chief Executive Officer of XOMA. "We believe the results of this study provide additional evidence of the importance of the role of IL-1 in inflammatory diseases and the potential value of XOMA 052."

Behcet's (pronounced beh-CHETS) disease is an orphan disease that causes chronic inflammation of the blood vessels, or vasculitis. Major symptoms can affect the neurological, pulmonary, gastrointestinal and cardiovascular systems, and hallmarks of the disease include painful ulcers in the mouth and on the genitals. Behcet's disease most commonly affects men and women in their twenties, thirties and forties, and it is typically more severe in men. An estimated 5,000 to 15,000 patients in the United States have Behcet's, and the disease is more common in Turkey, eastern Mediterranean countries, Japan and Korea.

## About XOMA 052

XOMA 052 is a potent monoclonal antibody with the potential to improve the treatment of

patients with a wide variety of inflammatory diseases. XOMA 052 binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine involved in diseases including Type 2 diabetes, cardiovascular disease, rheumatoid arthritis, gout and auto-inflammatory diseases. IL-1 is a well-validated therapeutic target, with three marketed IL-1 inhibitors that have been used by more than 200,000 patients overall. By binding to IL-1 beta, XOMA 052 inhibits the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation.

XOMA is conducting two Phase 2 clinical trials of XOMA 052 in patients with Type 2 diabetes and a Phase 2 trial in Type 1 diabetes. The Phase 2 trials follow a successful 98 patient Phase 1 program in Type 2 diabetes patients in which XOMA 052 was shown to be well-tolerated, demonstrated evidence of biological activity in diabetes measures and cardiovascular biomarkers, and had a half-life that may provide convenient dosing of once per month or less frequently. The company has also demonstrated the potential for XOMA 052 in in vivo models of atherosclerosis and cardiac remodeling and in an in vitro model using human myeloma, or plasma cell cancer, cells.

### About XOMA

XOMA discovers, develops and manufactures novel antibody therapeutics for its own proprietary pipeline as well as through license and collaborative agreements with pharmaceutical and biotechnology companies, and under its contracts with the U.S. government. The company's proprietary product pipeline includes:

- -- XOMA 052, an anti-IL-1 beta antibody in Phase 2 clinical development for Type 2 diabetes, Type 1 diabetes and cardiovascular disease, with potential for the treatment of a wide range of inflammatory conditions.
- -- XOMA 3AB, an antibody candidate in pre-IND studies to neutralize the botulinum toxin, among the most deadly potential bioterror threats, under development through funding provided by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (Contract # HHSN266200600008C).
- -- A preclinical pipeline with candidates in development for several diseases.

In addition to its proprietary pipeline, XOMA develops products with premier pharmaceutical companies including Novartis AG, Schering Corporation, a subsidiary of Merck & Co., Inc. and Takeda Pharmaceutical Company Limited.

XOMA's technologies have contributed to the success of marketed antibody products, including LUCENTIS(R) (ranibizumab injection) for wet age-related macular degeneration and CIMZIA(R) (certolizumab pegol) for rheumatoid arthritis and Crohn's disease.

The company has a premier antibody discovery and development platform that incorporates an unmatched collection of antibody phage display libraries and proprietary Human Engineering(TM), affinity maturation, Bacterial Cell Expression (BCE) and manufacturing technologies. BCE 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, and several licensed product candidates are in clinical development.

XOMA has a fully integrated product development infrastructure, extending from pre-clinical science to approval, and a team of about 215 employees at its Berkeley, California location. For more information, please visit <a href="http://www.xoma.com">http://www.xoma.com</a>.

The XOMA Ltd. logo is available at <a href="https://www.globenewswire.com/newsroom/prs/?">https://www.globenewswire.com/newsroom/prs/?</a>
<a href="pkgid=5960">pkgid=5960</a>

#### Safe Harbor Statement

Certain statements contained herein concerning clinical trial results and 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, results of early-stage clinical trials may not be supported by later findings, and larger trials and/or other actions required for regulatory approval may not be economically feasible.

These and other risks, including those related to inability to comply with NASDAQ's continued listing requirements; the generally unstable nature of current economic conditions; the results of discovery research and preclinical 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 and licensing relationships; the ability of collaborators, licensees and other third parties to meet their obligations; XOMA's ability to meet the demands of the United States government agency with which it has entered into its government contracts; 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.

CONTACT: XOMA Ltd.

Company and Investor Contact: Carol DeGuzman 510-204-7270

deguzman@xoma.com

Canale Communications Media Contact: Carolyn Hawley 619-849-5375

carolyn@canalecomm.com