September 8, 2008

XOMA 052 Clinical Results Support New Type 2 Diabetes Therapeutic Approach of Targeting Inflammatory Damage to Insulin-Producing Cells

Data Presented At European Diabetes Conference Demonstrate Biological Activity, Positive Safety Profile and Potential Dosing of Once Per Month or Longer

ROME, Sept. 8, 2008 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA) announced interim data from two Phase 1 clinical studies of XOMA 052, an antibody drug candidate with an ultra high binding affinity of 300 femtomolar, which support a novel anti-inflammatory approach to Type 2 diabetes treatment that may preserve insulin-producing cells. XOMA 052 addresses inflammation as an underlying cause of diabetes by targeting Interleukin-1 beta (IL-1 beta), a master signaling protein which triggers inflammatory pathways in the body. This study is an important addition to the medical research indicating that decreasing inflammation may reduce disease progression in diabetes.

XOMA 052 demonstrated biological activity in patients with Type 2 diabetes as measured by diabetes and inflammatory markers. The interim analysis of two single-dose, dose-escalation, Phase 1 studies included 48 patients with Type 2 diabetes from five dose groups in a U.S. study and three dose groups in a European study. Forty patients received XOMA 052 and eight received placebo. Patients were followed for two to three months.

A summary of the results follows. Additional data from the interim analysis can be found in the Detailed Results section below. Slides from the EASD presentation will be available on the company's website, www.xoma.com.

Glucose control results: Glucose control is an important determinant in the health of diabetes patients. Glycosylated hemoglobin (HbA1c) is a standard measure of average glucose control over a three-month period. HbA1c reductions are defined as absolute changes of HbA1c from baseline. A sustained absolute reduction of 0.6 or greater percent is generally considered medically meaningful in patients with diabetes.

Although the number of patients in each dose group was limited, median HbA1c levels were reduced in all 5 groups and the reduction was as much as 0.6 percent at 28 days. A single dose of XOMA 052 reduced median HbA1c in 4 of 5 drug dose levels compared to placebo.

Insulin production results: The body controls the amount of glucose in the bloodstream by causing the pancreatic islet cells to produce insulin. Healthy individuals will rapidly produce

appropriate levels of insulin in response to large glucose increases while diabetes patients will not. In general, an increase over three months in the ability of islet cells to produce insulin is considered medically meaningful in patients with diabetes.

Tests of the body's insulin producing capability were performed in the European study of XOMA 052 using the glucagon-arginine-glucose (GAG) stimulation test. The GAG stimulation test is a standard measure of the health of insulin-producing islet cells and mimics the real-life conditions of a meal with multiple dietary components to evaluate the response of islet cells in making insulin.

The GAG stimulation test was performed at a European academic diabetes research and treatment center where it is used routinely. For the interim analysis, data were available from the two lowest dose groups. A single dose of XOMA 052 increased insulin production at 28 and 91 days compared to baseline, while placebo-treated patients showed no improvement.

Inflammatory results: Ultrasensitive C-reactive protein (usCRP) is a standard measure of systemic inflammation associated with multiple diseases and an indicator of cardiac risk. At 28 days, a single dose of XOMA 052 reduced usCRP as compared to placebo in all of the dose groups. These results indicate the ability of a relatively small amount of drug to show anti-inflammatory activity.

Safety and pharmacokinetic results: The safety and pharmacokinetic results showed that XOMA 052 was well tolerated at all five dose levels and had a potential dosing profile of once per month or longer in Type 2 diabetes patients. There was no evidence of drug-related serious adverse events or infusion reactions.

"XOMA 052 is the first anti-IL-1 beta specific drug to demonstrate biological activity against diabetes and inflammation in Type 2 diabetes patients," said Marc Y. Donath, M.D., a pioneer in anti-inflammatory approaches to Type 2 diabetes, Professor at the University Hospital of Zurich and European clinical trial principal investigator. "Bearing in mind that HbA1c reflects average blood glucose over a three month period, these levels of early reduction are particularly encouraging."

Dr. Donath continued, "If, as we hypothesize, the inhibition of IL-1 beta improves the condition of insulin-producing cells in diabetes patients by targeting inflammation, the implications would be very promising for the treatment of the disease. This study suggests that XOMA 052 may address this fundamental and still largely unexplored inflammatory pathway and warrants continued clinical investigation."

Alan Solinger, M.D., XOMA's Vice President of Clinical Immunology said, "Type 2 diabetes patients, their caregivers and advocates have long sought improved treatment options that go beyond glucose management and frequent insulin injections. Current approaches force more insulin out of 'tired' pancreatic beta cells or make peripheral cells more sensitive to insulin, whereas XOMA 052 targets inflammation -- a newly recognized mechanism in Type 2 diabetes. Showing an increase in insulin production three months after a single infusion is remarkable. If these increases are confirmed in larger studies, we could have a disease-modifying therapy."

"It is very exciting to see that a single dose of XOMA 052 had such positive biological activity and duration of effect, and was well tolerated," said Steven Engle, XOMA's Chairman and

Chief Executive Officer. "Clearly, the results exceeded our expectations for a Phase 1 study. Although the numbers of patients were limited and more studies are needed, the potency demonstrated to date is compelling and we are encouraged not only to proceed with additional studies in diabetes but also to expand our clinical development of XOMA 052 in other indications such as rheumatoid arthritis, acute gout and systemic juvenile idiopathic arthritis."

XOMA 052 Phase 1 Study Design

The oral presentation at the European Association for the Study of Diabetes (EASD), "XOMA 052, an Anti-IL-1 beta Antibody, in a Double-Blind, Placebo-Controlled, Dose Escalation Study of the Safety and Pharmacokinetics in Patients with Type 2 Diabetes Mellitus - A New Approach to Therapy," describes safety, pharmacokinetics and biological activity from an interim analysis of data from two ongoing single-dose, placebo-controlled, dose-escalation Phase 1 studies.

Each of the studies was designed to enroll 36 Type 2 diabetes patients into six dose level groups to evaluate the safety and pharmacokinetics of XOMA 052 and to measure diabetes and inflammation markers including HbA1c, CRP and, in the European study, insulin production. Each dose level group includes one patient who received standard of care plus placebo and five who received standard of care plus a single dose of XOMA 052 at 0.01, 0.03, 0.1, 0.3, 1.0, or 3.0 milligrams per kilogram body weight (mg/kg), depending on the group. Patients are followed for 56 days or longer.

XOMA initiated the European and U.S. studies separately in order to take advantage of resources at the University of Zurich, including the availability of specialized diabetes testing capabilities and the University's leadership in disease-modifying approaches to diabetes. Data from the ongoing European and U.S. studies were pooled for the analysis.

The interim analysis included data from 40 patients on drug and 8 on placebo in five dose groups. There were 10, 10, 10, 5, and 5 patients in the 0.01, 0.03, 0.1, 0.3, and 1.0 mg/kg dose groups, respectively, and 8 patients receiving placebo. According to the study design, patients were first evaluated for HbA1c at day 28.

The overall baseline demographics of the groups were mostly similar. However the dose group that received XOMA 052 at 1.0 mg/kg differed from the other four drug-treated dose groups in three respects: years of diabetes disease duration, C-peptide level -- a sensitive, well accepted and clinically validated assessment of islet-cell function -- and number of patients. The 1.0 mg/kg group had a longer mean disease duration (16.9 years versus a range of 5-10 years) and lower islet cell reserves as measured by C-peptide (2.0 ng/mL versus a range of 2.4-3.3 ng/mL).

It is generally understood that patients with a longer duration of diabetes disease have fewer remaining islet cells and, therefore, may be less responsive to a drug that targets the function of the islet cells. In addition, the lower level of C-peptide that was seen in the 1.0 mg/kg dosing group supports the view that patients in this group may have had fewer functioning islet cells than patients in the other dose groups.

XOMA expects the final analysis of the dose-escalating studies to include data from a total of 72 patients. Data from the three remaining dosing groups in the European study and from

the final dosing group in the U.S study have not been collected and will be analyzed after completion of the studies.

XOMA 052 Detailed Results:

Glucose control results: At 28 days after a single dose of XOMA 052, the median reductions from baseline in glycosylated hemoglobin (HbA1c) were 0.40, 0.45, 0.55, 0.60, and 0.20 percent for the 0.01, 0.03, 0.1, 0.3, and 1.0 mg/kg dose groups, respectively, compared to 0.30 percent for placebo.

Insulin production results: An increase in mean insulin production as measured by area-under-the-curve of 26 percent and 52 percent at 28 and 91 days, respectively, was observed in the 10 patients who received either 0.01 or 0.03 mg/kg of drug, while placebo-treated patients in those groups showed no improvement.

Inflammatory results: At 28 days after a single dose of XOMA 052, the median percent reductions in usCRP were 33, 46, 47, 36, and 26 for the 0.01, 0.03, 0.1, 0.3, and 1.0 mg/kg dose groups, respectively, compared to 4 percent for placebo.

Pharmacokinetic results: Based on the pharmacokinetic data, the half-life of the antibody was 22 days and pharmacokinetics were dose-proportional. The results from all samples were below the quantifiable range of the immunogenicity assay. This drug profile, when combined with XOMA 052's ultra high binding affinity of 300 femtomolar to its target, supports potential dosing of once per month or longer in Type 2 diabetes patients.

Planned Multi-Dose and Subcutaneous Studies of XOMA 052

The U.S. Phase 1 clinical trial in patients with Type 2 diabetes consists of three parts. The first part is a single IV dose study designed to evaluate the drug's safety and pharmacokinetics. The interim results of this part are summarized above.

Following the completion of the single dose study, XOMA plans to evaluate the subcutaneous administration of XOMA 052 at multiple dose levels and to evaluate repeated intravenous dose administration of XOMA 052 at multiple dose levels. XOMA plans to start this additional work in the fourth quarter of 2008 and expects results in the second half of 2009. Based on continued positive results, XOMA plans to expand the Type 2 diabetes program into studies with larger numbers of patients.

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 that is involved in the development of diabetes, rheumatoid arthritis, gout, and other diseases. By binding IL-1 beta, the drug blocks the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation. XOMA 052 is a humanized IgG2 antibody with a half-life of 22 days. Based on its binding properties, specificity to IL-1 beta and half-life, XOMA 052 may provide convenient dosing of once per month or longer. XOMA 052 was developed by XOMA using the Company's proprietary antibody technologies, capabilities and expertise. XOMA owns worldwide rights to the antibody and related intellectual

property.

Studies of XOMA 052 are being planned for acute, chronic and orphan indications, including its evaluation in two Phase 1 clinical studies in Type 2 diabetes. XOMA 052 could prove to be a disease-modifying therapy for diabetes by addressing inflammation as an underlying cause of the epidemic disease, whereas current therapies focus almost exclusively on improving the body's ability to produce and respond to insulin. XOMA plans to initiate clinical studies of XOMA 052 in rheumatoid arthritis, acute gout and systemic juvenile idiopathic arthritis (sJIA).

The central role of the IL-1 pathway in multiple diseases has been clinically validated by several inhibitors of the IL-1 pathway in development and by two FDA approved therapies based on IL-1 blockade. These disease indications include rheumatoid arthritis, systemic juvenile idiopathic arthritis, gout, Muckle-Wells syndrome, and others.

Conference Call to Discuss Interim Phase 1 Results

XOMA will host a conference call and webcast to discuss the data from the interim analysis today, September 8, 2008 at 8:30 am Eastern. The webcast can be accessed via XOMA's website at www.xoma.com and will be available for replay until close of business on November 7, 2008. Telephone numbers for the live audiocast are 877-407-9205 (U.S. and Canada) and 201-689-8054 (International). No conference ID is necessary. A telephonic replay will be available beginning approximately two hours after the conclusion of the call until close of business on September 26, 2008. Telephone numbers for the replay are 877-660-6853 (U.S./Canada) and 201-612-7415 (International). Two access numbers are required for the replay: account number 286 and conference ID # 296429.

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 marketing 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 interim data, lack of safety concerns, additional indications, timing of initiation and results of clinical trials and/or other aspects of 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, interim data may not be supported by final results or by results from later studies, safety concerns may arise at later stages of development, development in additional indications may not be warranted and timing of the initiation of, and/or availability of results from, clinical trials may vary for medical, regulatory or other reasons. 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; 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.

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