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XOMA 052 Clinical Results Support Novel Anti-Inflammatory Approach to Type 2 Diabetes Treatment

Clinical Data Presented At American Diabetes Association 69th Scientific Sessions

BERKELEY, Calif., June 6, 2009 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced new results which included additional data for up to three months and new measures of biological activity from Phase 1 clinical trials of a single dose of XOMA 052 given intravenously to patients with Type 2 diabetes. The new results provide further confirmation of the potential for XOMA 052 as an entirely new anti-inflammatory approach to the treatment of Type 2 diabetes. The results were presented at the American Diabetes Association (ADA) 69th Scientific Sessions in New Orleans, Louisiana by Marc Y. Donath, M.D., a pioneer in anti-inflammatory approaches to Type 2 diabetes, Professor at the University Hospital of Zurich and XOMA 052 European clinical trial principal investigator.

XOMA 052 is designed to address the inflammatory cause of Type 2 diabetes by targeting IL-1 beta, a master signaling protein which triggers inflammatory pathways in the body, which in diabetes results in reduced insulin production in pancreatic beta cells. By targeting the inflammatory component of Type 2 diabetes, XOMA 052 has the potential to be a novel, disease-modifying treatment for Type 2 diabetes.

The biological activity results presented at the ADA meeting included data from 39 Type 2 diabetes patients for which combined data were available in the U.S. and Switzerland. A total of 30 patients were randomized to receive a single I.V. dose of XOMA 052 at 0.01, 0.03 or 0.1 milligrams per kilogram of body weight (mg/kg), and nine patients received placebo. The U.S. patients were followed for approximately two months and the Swiss patients were followed for three months. Additional data were collected at the Swiss site including insulin and glucose measures during the oral glucose tolerance test (oGTT) and the glucose arginine glucagon (GAG) tests, and whole blood cytokine assays.

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

The studies demonstrated:

* XOMA 052 was well-tolerated, with no drug or dose-related serious adverse events or injection site reactions.
* Improvement in insulin production and secretion for patients receiving XOMA 052 for as long as 91 days.
* A durable reduction of high sensitivity C-Reactive Protein (hsCRP), a standard measure of inflammation which is associated with an increased risk of cardiovascular events, for as long as 91 days following a single infusion of XOMA 052.
* Consistent reduction in glycosylated hemoglobin(HbA1c), a standard measure of average glucose control over a three-month period for XOMA 052-treated patients as compared to placebo for as long as 91 days.
* A favorable immunologic profile, with XOMA 052 having positive effects on reducing the levels of pro-inflammatory cytokines such as TNF-alpha, IL-6 and IL-1alpha. In addition, XOMA 052 did not demonstrate a suppressive effect on protective cytokines including interferon-alpha and IL-1 receptor antagonist, which are needed for infection control and host defense.
* A pharmacokinetic profile, including a 22 day half-life, which suggests the potential for XOMA 052 dosing at monthly or less frequent intervals.

"It is well-recognized that IL-1 beta levels are up-regulated in response to elevated glucose. This causes an auto-inflammatory process in insulin-producing cells that can lead to their death and reduced insulin secretion," said Dr. Donath. "If, as we hypothesize, the inhibition of IL-1 beta improves the condition of insulin-producing cells in patients by breaking the vicious cycle of glucotoxicity, the implications would be very promising for the treatment of the disease."

"We continue to develop evidence supporting one of the most significant potential medical advances in decades -- a move from insulin therapy to anti-inflammatory treatment of patients with Type 2 diabetes. Our results have provided not only the safety data that is typical in a Phase 1 trial but also encouraging signs of biological activity," said Steven B. Engle, XOMA's Chairman and Chief Executive Officer. "Recently, our first U.S. patent covering XOMA 052 issued and we completed enrollment of the Phase 1 program with 98 patients. We look forward to initiating Phase 2 trials in the third quarter of 2009."

Detailed Results

The oral presentation at the ADA meeting, "XOMA 052, a potential disease modifying anti-IL-1 beta antibody, shows sustained HbA1c reduction three (3) months after a single injection with no increases in safety parameters in subjects with Type 2 diabetes," describes safety, pharmacokinetics and biological activity results from two single-dose, placebo-controlled, dose-escalation Phase 1 studies.

Results from three dose levels were reported for biological activity, and included 0.01, 0.03 and 0.1 mg/kg, or placebo. Patients were followed for 56 days in the U.S. and for up to 91 days in Switzerland. The overall baseline characteristics of the XOMA 052 and placebo groups were similar. Data from both studies were pooled for analyses of HbA1c and hsCRP where possible.

Inflammatory results: Previously reported data for the 28 day time point demonstrated a rapid and sustained reduction in hsCRP levels. At the day 56/63 time point, hsCRP was

reduced a median of 20%, 25% and 49% in the lowest to highest dose groups, and increased by approximately 33% in the placebo group. At day 91 in the Swiss patients, hsCRP levels were between 20% and 30% lower than baseline in all three treatment groups, as compared to returning to baseline for the placebo group.

Glycemic control results: Previously reported data for the 28 day time point demonstrated reduced median HbA1c levels for all XOMA 052 dose groups of as much as 0.6%. Two months after receiving a single dose of XOMA 052, there remained continued reductions of 0.5% in both the 0.03 and 0.1 mg/kg groups compared to a decrease of 0.2% in the placebo group, while there was a median increase in HbA1c of 0.15% in the lowest XOMA 052 dose group. At day 91 in the Swiss patients, continued HbA1c reductions of 0.5% and 0.65% in the 0.03 and 0.1 mg/kg groups, respectively, were reported, compared to an increase of 0.1% in the placebo group, and an increase of 0.3% in the lowest XOMA 052 dose group. One patient in the treatment group was removed from this analysis due to a baseline cancer diagnosis. Including this patient in the analysis, the median HbA1c reduction in the 0.1 mg/kg cohort was 1.1%.

Insulin production, secretion and utilization results: Initial clinical data evaluating the pancreatic production of insulin utilizing the standard oGTT and a test of maximal insulin secretion both yielded information that shows that after a single intravenous dose of XOMA 052 there was improved beta-cell function lasting out to day 91. This was also evaluated by utilizing the insulinogenic index which, at Day 28, showed improvement of at least 20% in the relative amount of insulin secreted compared to the glucose level.

Cytokine results: Positive new data from whole blood assays were presented. Whole blood assays demonstrated reductions in levels of pro-inflammatory cytokines including TNF-alpha, IL-6, IL-1 alpha. Further, there was no evidence of suppressive effects on protective cytokines including interferon-alpha and IL-1 receptor antagonist, which play an important role in host defense.

"These results demonstrate the potential for XOMA 052 to offer an entirely new approach for Type 2 diabetes patients by targeting inflammation, rather than current treatments that force more insulin out of "tired" pancreatic beta cells or make peripheral cells more sensitive to insulin," said Patrick J. Scannon, M.D., Ph.D., XOMA's Executive Vice President and Chief Medical Officer. "Further, some studies have shown that certain diabetes medications may increase the risk of cardiovascular events in a population already at risk due to obesity or other factors. The positive effect of XOMA 052 on reducing levels of the hsCRP cardiovascular risk marker in these trials suggests its potential for a beneficial systemic anti-inflammatory outcome, and warrants further investigation in additional trials."

Overview of XOMA 052 Phase 1 Trials

A total of 98 patients were enrolled in the U.S. and Swiss Phase 1 trials, and included 81 patients who received XOMA 052 and 17 placebo-treated patients. The U.S. trials included:

* An IV single-dose, dose-escalation part which enrolled 36 patients and evaluated XOMA 052 at 0.01., 0.03, 0.1, 1.0 and 3.0 mg/kg or placebo.
* A subcutaneous single-dose, dose-escalation part which enrolled 20 patients and evaluated 0.03, 0.1 and 0.3 mg/kg doses of

XOMA 052 or placebo.
* A subcutaneous multi-dose, dose-escalation part which enrolled 12 patients and evaluated 0.03 and 0.3 mg/kg doses of XOMA 052 or placebo administered at two week intervals for three doses.

The Swiss trial was an IV single dose, dose-escalation trial which evaluated XOMA 052 at the same doses of the U.S. single dose except the 3.0 mg/kg dose and enrolled 30 patients.

Enrollment has been completed in both the U.S. and Swiss Phase 1 trials; patient follow-up continues for several cohorts. XOMA plans to announce top line results from all three parts of the U.S. trial in July, and from the Swiss trial by September. The company also plans to initiate a Phase 2 trial of XOMA 052 in the third quarter of 2009.

About XOMA 052

XOMA 052 is a potent, humanized 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 the development of Type 2 diabetes, cardiovascular disease, rheumatoid arthritis, gout and other diseases. By binding to IL-1 beta, the drug inhibits the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation. XOMA 052 has 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 less frequently.

XOMA developed XOMA 052 using the company's proprietary antibody technologies, capabilities and expertise. XOMA owns worldwide rights to the antibody and related intellectual property. The company is actively pursuing a partnership for the development and commercialization of XOMA 052. XOMA was recently issued a U.S. patent for XOMA 052 and similar antibodies which provides patent coverage into 2027.

About the Interleukin-1 Pathway

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

About XOMA

XOMA discovers, develops and manufactures therapeutic antibody therapeutics designed to treat inflammatory, autoimmune, infectious and cancerous diseases. The company's proprietary product pipeline includes XOMA 052, an anti-IL-1 beta antibody, and XOMA 3AB, a biodefense anti-botulism antibody candidate.

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 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 leading antibody phage display libraries and XOMA's proprietary Human Engineering(tm) and Bacterial Cell Expression and manufacturing 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 about 200 employees at its Berkeley location. For more information, please visit http://www.xoma.com.

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

Forward-Looking Statements

Certain statements contained herein concerning the effects and possible dosing for XOMA 052 plans to initiate a XOMA 052 Phase 2 clinical program, timing of availability of 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, the effects of XOMA 052 may differ in later preclinical or clinical testing, dosing of XOMA 052 may be affected by later testing results, the initiation of a Phase 2 clinical trial and/or the timing of availability of results of clinical trials may be delayed or may never occur as a result of unavailability of resources, actions or inaction by our present or future collaboration partners, or unanticipated safety issues.

These and other risks, including those related to XOMA's ability to remain in compliance with or renegotiate the requirements of its loan agreements; the declining and generally unstable nature of current economic conditions; 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.

CONTACT: XOMA Ltd.
Company and Investor Contact:
Carol DeGuzman
510-204-7270
deguzman@xoma.com

Porter Novelli Life Sciences
Media Contact:
Carolyn Hawley
619-849-5375
chawley@pnlifesciences.com