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XOMA Announces Positive Results From U.S. Phase 1 Trial of XOMA 052 in Type 2 Diabetes

Results Support Initiation of Phase 2 Program With Multiple Dose Subcutaneous Regimen

Conference Call and Webcast At 4:30 pm ET Today

BERKELEY, Calif., July 14, 2009 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced positive results from single dose and multiple dose subcutaneous arms of the randomized, placebo-controlled U.S. Phase 1 clinical trial of XOMA 052 in Type 2 diabetes patients. Of the 98 patients evaluated in different parts of the Phase 1 clinical trial, XOMA is reporting today on the 26 patients who received active drug in both single and multiple doses by subcutaneous route of administration and all 17 placebo patients. The results continue to demonstrate that XOMA 052 is well tolerated in patients. Further, a multiple dose regimen of XOMA 052 showed clinically meaningful reductions in glycosylated hemoglobin, HbA1c, and high sensitivity C-reactive protein, hsCRP, compared to a single dose regimen. Generally, a more consistent response was seen across patients in the multiple dose regimen compared to single dose regimen. New positive biological activity was observed with sustained improvements noted in fasting blood glucose, with a reduction of 29 mg/dL at day 84, equating to approximately a 1% reduction in HbA1c, and standard biomarkers of systemic inflammation and cardiovascular risk. Pharmacokinetic results continue to support monthly or less frequent dosing and drug bioavailability in patients by subcutaneous injection was 62-70% compared to IV administration. These Phase 1 results support XOMA's plan to begin Phase 2 testing of XOMA 052 in Type 2 diabetes in the current quarter.

As important, this is the first study of an IL-1 targeting agent to demonstrate evidence of improved insulin sensitivity. An increase in insulin production was previously reported in earlier studies with XOMA 052, suggesting an additional benefit in diabetes patients.

The growing body of evidence for XOMA 052's anti-inflammatory effects also supports its potential in cardiovascular and other inflammatory diseases. Published studies show that IL-1 beta plays a key role in the initiation, growth and instability of plaque leading to heart attacks and other cardiovascular events.

"An anti-inflammatory approach to Type 2 diabetes and other cardiometabolic diseases is a potential breakthrough for treating these very common medical conditions," said 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 Swiss clinical trial principal investigator.

"These results confirm previous XOMA 052 findings in reducing inflammatory biomarkers and improving glycemic control. For the first time, they demonstrate the potential for XOMA 052 to break the vicious cycle of glucotoxicity by improving insulin sensitivity and restoring beta cell health through IL-1 beta regulation."

"We remain very excited about the data generated thus far from this Phase 1 program, including important new evidence of biological activity. Moreover, we are seeing these activities at a very low dose, at least ten times lower than many approved monoclonal antibodies," said Steven B. Engle, XOMA's Chairman and Chief Executive Officer. "While this Phase 1 trial has achieved its primary purpose of providing valuable safety and pharmacokinetic information, we are delighted to have seen the first evidence of improved insulin sensitivity as well as improvements in other biomarkers associated with Type 2 diabetes and cardiovascular disease. When combined with our previously reported results of improved insulin production, we believe XOMA 052 has demonstrated the potential to address two important arms of the diabetes disease process: insulin production and peripheral insulin sensitivity."

This is the first time XOMA is reporting data regarding the subcutaneous (SC) administration of multiple doses and single doses of XOMA 052 in Type 2 diabetes patients. Previously XOMA reported positive results from a study evaluating the intravenous (IV) administration of a single dose of XOMA 052 at different dose levels. The SC route of administration is particularly important for treating chronic diseases such as Type 2 diabetes.

"In the 0.03 mg/kg multiple dose cohort, we observed median reductions of over 50% in CRP and up to 0.6% in HbA1c at day 56, as well as rapid, meaningful and prolonged reductions in fasting blood glucose," said Patrick J. Scannon, M.D., Ph.D., XOMA's Executive Vice President and Chief Medical Officer. "Taken together, these data demonstrate, as expected, the potential for added benefit with multi-dose treatment using XOMA 052. In addition, the 0.03 mg/kg multiple dose median reduction of over 50% in CRP and up to 0.6% in HbA1c at day 56 compares favorably to reductions of 29% and 0.3%, respectively, for a single 0.1 mg/kg dose at the same time point. More patients responded to the multiple dose regimen as well. The bioavailability and pharmacokinetic results enable us to initiate our Phase 2 program using XOMA 052 in monthly or less frequent subcutaneous dose regimens."

XOMA 052 targets interleukin-1 beta (IL-1 beta), a master signaling protein that triggers auto-inflammatory pathways in the body and is believed to be an underlying cause of cardiometabolic diseases including Type 2 diabetes and cardiovascular disease.

A summary of the Phase 1 clinical trial design and detailed results follows.

Phase 1 Clinical Trial Design

The U.S. Phase 1 study enrolled 68 Type 2 diabetes patients and had three parts: multiple dose by subcutaneous injection; single dose by subcutaneous injection; and single dose by intravenous injection. Each dose level group included one patient who received standard of care plus placebo and five patients who received standard of care plus XOMA 052. Of the 98 patients enrolled in the Phase 1 studies, a total of 81 patients have been dosed with XOMA 052 along with 17 placebo patients, which includes patients treated in a Swiss intravenous Phase 1 trial with the same entry criteria as the U.S. trial.

In the multi-dose regimen, the doses given were 0.03 and 0.3 milligrams per kilogram of body weight (mg/kg) and they were three times two weeks apart. In the single dose subcutaneous regimen, the doses were 0.03, 0.1 and 0.3 mg/kg doses. Patients on the multi-dose regimen were followed for 84 days including 56 days after their last dose. Patients on the single dose regimens were followed for 56 days.

In designing the multiple dose study, the decision to dose every 2 weeks and give three doses was driven by pharmacokinetic information requirements to design the Phase 2 study. It is expected that XOMA 052 can be given every other month or less frequently. The 84 day length of the study was chosen to capture the nearer-term results. Of course, a longer study in Phase 2 may show additional benefits as we do not know how far the increase in some of the benefits extends.

In the multiple dose study, a tenfold range of doses was chosen for safety and pharmacokinetic analysis. The lower dose level of 0.03 mg/kg times three is comparable to the 0.1 mg/kg intravenous dose which worked well. The 0.3 mg/kg times three doses is comparable to the 1.0 mg/kg intravenous dose which had less activity.

Detailed Results

The results presented today include hsCRP, a biomarker for cardiovascular risk, HbA1c, which measures glucose control over two to three months, for diabetes. FDA recognizes HbA1c as an approvable endpoint for diabetes medications. For the first time, XOMA is also reporting results from evaluations of key diabetes measures including fasting blood glucose, FBG, which measures blood glucose in a fasting state at a single time point, and Homeostasis Model Assessment Insulin Resistance, HOMA IR, a ratio of fasting glucose to fasting insulin reflecting peripheral insulin sensitivity. In addition, XOMA is reporting results of erythrocyte sedimentation rate ESR, a biomarker of systemic inflammation that confirms the hsCRP results.

Safety results: The safety results continue to show that XOMA 052 appears to be well tolerated by single dose and multiple dose subcutaneous administration at the dose levels tested. There were no reported serious adverse events, no notable changes in laboratory parameters, no reported serious infections, no evidence of neutropenia, no reports of drug-related hypoglycemia, no change in weight, and no evidence of immunogenicity or neutralizing antibodies. Adverse events were generally mild and similar between the XOMA 052 and placebo groups. No maximum tolerated dose was identified.

Bioavailability and pharmacokinetic results: The multiple dose subcutaneous route of administration showed 62% bioavailability and the single dose subcutaneous showed a 70% bioavailability for a range of 62-70%. The pharmacokinetic results demonstrate a 23 day half-life in the systemic circulation, typical for monoclonal antibodies and consistent with monthly or less frequent dosing. There were no drug-related serious adverse events or evidence of drug-related hypoglycemia, injection site reactions or immunogenicity.

Please see Table 1 below.

Anti-inflammatory results: At day 56, reductions in hsCRP were observed in every XOMA 052-treated patient in both multiple dose groups. ESR reductions in the multiple dose groups were rapid, persistent and consistent with the hsCRP results.

Glycemic control results: The greatest glycemic control, as measured by HbA1c and FBG, was observed at the 0.03 mg/kg multiple dose cohort, with every patient demonstrating improvement in HbA1c at day 56. The sustained reduction in FBG in this group resulted in a 29 mg/dL decrease at day 84, which equates to approximately a 1% reduction in HbA1c. Combined with the HbA1c data, this progressive reduction in FBG indicates that HbA1c should continue to decrease over time. As previously reported with the high dose IV cohort, no evidence of glycemic control was observed in the 0.3 mg/kg multiple dose group, which appears consistent with reduced activities at higher doses of several other IL-1 targeting agents.

Table 1. XOMA 052 and Placebo SC Administration
Median Change from Baseline at Day 56

		Anti-inflammatory		Glycemic Control	
Study Treatment		hsCRP (%)	ESR (%)	FBG (mg/dL)	HbA1c (%)
	Placebo (N = 17)	8	27	13	-0.1
Multi-dose	0.03 mg/kg (N = 5)	-57	-13	-27	-0.6
	0.3 mg/kg (N = 5)	-54	-50	20	0.2
Single Dose	0.03 mg/kg (N = 5)	-50	-40	-11	-0.3
	0.1 mg/kg (N = 6)	-29	-17	-27	-0.3
	0.3 mg/kg (N = 5)	-55	-33	18	0.1

By Day 84, HOMA-IR was reduced by a median of 10% and 24% in the 0.03 and 0.3 mg/kg multidose groups, respectively, compared to a median increase of 87% in the placebo group. In conjunction with fasting blood glucose profile, this provides preliminary evidence of increased insulin sensitivity for subjects treated with XOMA 052.

"The biological activity seen at very low doses may reflect the ultra-high affinity of XOMA 052 for IL-1 beta, when compared with the doses reported for other IL-1 targeting agents," Dr. Scannon said. "Using this activity information along with the encouraging safety profile from our Phase 1 trial, we have the opportunity to explore a well-informed range of low doses as well as less frequent dosing regimens in our Phase 2 program."

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 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, XOMA 052 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.

Conference Call and Webcast

XOMA will hold a conference call and webcast today at 4:30 PM Eastern time to discuss these results. 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, will participate on the call with XOMA management. The webcast can be accessed via XOMA's website at http://investors.xoma.com/events.cfm and will be available for audio and slide replay until close of business on October 14, 2009. Telephone numbers for the live audiocast are 888-523-1245 (U.S./Canada) and 719-457-2734 (international). A telephonic replay will be available beginning approximately two hours after the conclusion of the call until close of business on July 21, 2009. Telephone numbers for the replay are 888-203-1112 (U.S./Canada) and 719-457-0820 (international), passcode # 3435934.

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 of and possible dosing for XOMA 052, timing of initiation 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 data, dosing of XOMA 052 may be affected by later testing results, and the timing of initiation of clinical trials may be delayed or may never occur as a result of such factors, 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.

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