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# Interim Three Month Data From Ongoing Six Month XOMA 052 Phase 2a Trial Support Safety and Biological Activity

BERKELEY, Calif., Jan. 6, 2011 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced that it has conducted an interim review of three-month data from a Phase 2a clinical trial of XOMA 052 in a small group of 74 patients with Type 2 diabetes focused on evaluating safety where XOMA 052 was shown to be well-tolerated, the primary goal of the study. This Phase 2a trial was designed as an exploratory trial focused on overall safety and kinetics and was not designed to show statistically significant differences in measures of biological activity. XOMA 052 is being studied in an ongoing 420 patient, six month Phase 2b dose-ranging clinical trial where results are expected by the end of this quarter and the primary goal of the study is reduction in levels of hemoglobin A1c. The primary goal of the Phase 2a trial was to gain additional XOMA 052 safety information in Type 2 diabetes patients on a background of stable metformin monotherapy. In this study, XOMA 052 was well tolerated with no significant differences in adverse events, lab abnormalities and vital signs between XOMA 052 and placebo and no drug-related adverse events. At the time of this three month interim review, evidence of biological activity was observed, including a reduction in C-reactive protein levels and a modest reduction in hemoglobin A1c levels. XOMA 052 is designed to inhibit the pro-inflammatory cytokine interleukin-1 beta that is believed to be a primary trigger of pathologic inflammation in Type 2 diabetes. XOMA is jointly developing XOMA 052 in collaboration with Servier.

"The interim data from this ongoing trial in a small group of patients treated over three months continue to support the hypothesis that reducing inflammation through IL-1 inhibition is a safe approach to treating diabetic patients," said Marc Y. Donath, M.D., Professor and Chief, Department of Endocrinology, Diabetes and Metabolism at University Hospital Basel, Switzerland, a pioneer in the therapeutic use of IL-1 inhibition in patients with Type 2 diabetes and principal investigator in the landmark study reported in the New England Journal of Medicine in 2007.

The primary goal of the Phase 2a trial is to gain additional XOMA 052 safety information in Type 2 diabetes patients on a background of stable metformin monotherapy. Secondarily, the trial is designed to explore the kinetics of XOMA 052's effects on several measures of biological activity. Most of the kinetics will not be evaluable until completion of the study. A total of 74 patients were treated, 55 on XOMA 052 at a single dose level and 19 on placebo, on days 0, 14, 28 and 56. In the final three months of the trial, patients in the XOMA 052 group receive the same, higher or lower dose level for an additional four doses. Patients in the placebo group will continue to receive placebo. XOMA anticipates reporting the Phase

2a results from the full six months' treatment in the second quarter of 2011.

The interim data measured at day 84 indicate that XOMA 052 was well-tolerated, with no significant differences between the XOMA 052 and placebo groups in observations of adverse events including hypoglycemia, hyperglycemia, infections, injection site reactions, lab abnormalities or alterations in vital signs. There were no drug-related adverse events. Even though this Phase 2a trial is an exploratory trial not powered to show statistically significant differences in measures of biological activity, C-reactive protein levels decreased by a median of 49% in the XOMA 052-treated group and 2% in the placebo group. Median reduction from baseline in hemoglobin A1c levels at day 84 was 0.2% in the XOMA 052 group versus 0.1% in the placebo group. C-reactive protein is a biomarker of cardiovascular risk. Hemoglobin A1c is a measure indirectly reflecting blood glucose levels as averaged over a 90 to 120 day period.

"We are encouraged by these results, which are consistent with those observed in our Phase 1 program, and we look forward to obtaining the full six month data from this trial and our Phase 2b trial, also in Type 2 diabetes patients," said Steven B. Engle, XOMA's Chairman and Chief Executive Officer. "The results we have reported to date in a proof-of-concept Phase 2 trial in patients with Behcet's uveitis, an orphan indication, and in Type 2 diabetes patients, support continued XOMA 052 development as an entirely new approach to the treatment of Type 2 diabetes."

"We are pleased to see these initial results of the ongoing Phase 2 program for XOMA 052. We look forward to evaluating the results of longer-term treatment from this trial and the larger, ongoing Phase 2b dose-ranging trial as we advance this exciting antibody in clinical development for multiple indications," said Emmanuel Canet, M.D., Ph.D., Servier's President, Research & Development.

XOMA 052 and Interleukin-1 Inhibition

XOMA 052 is a potent monoclonal antibody with the potential to improve the treatment of patients with a wide variety of inflammatory diseases and other diseases including cancer. XOMA 052 binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine involved in Behcet's uveitis, diabetes, cardiovascular disease, rheumatoid arthritis, gout, and other 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.

To date, nearly 600 patients have been enrolled in XOMA 052 clinical trials. XOMA has completed enrollment in two Phase 2 clinical trials in patients with Type 2 diabetes and expects top line six month results from the Phase 2b trial in this quarter. The Phase 2 trials follow a successful 98 patient Phase 1 program in Type 2 diabetes 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 cardiovascular disease 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:

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XOMA 052, a potent anti-IL-1 beta antibody entering Phase 3 clinical development in

XOMA 3AB, an antibody candidate in pre-IND studies to neutralize the botulinum toxi

A preclinical pipeline with candidates in development for autoimmune, cardio-metabo
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The company has a premier antibody discovery and development platform that incorporates an unmatched collection of antibody phage display libraries and proprietary Human Engineering™, 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, 60 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 at its Berkeley, California location. For more information, please visit www.xoma.com.

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

About Servier

Servier is the leading independent French pharmaceutical company, established in 1954 by its founder, Dr. Jacques Servier. The group is established in 140 countries and 88% of Servier products are prescribed outside of France. Sales turnover in 2010 reached 3.7 billion euros. More than 25% of Servier's turnover is invested in Research and Development. Servier R&D counts 19 International Centers of Therapeutic Research, and its principal therapeutic research orientations are cardiovascular diseases, diabetes, neuropsychiatric disorders, cancer and osteoarticular diseases. Servier has an extensive history of more than 150 successful partnerships for product discovery development, regulatory approval and availability for patients. More information is available at: http://www.servier.com

Forward-Looking Statements

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, larger trials and/or other actions required for regulatory approval may not be economically feasible, and results of clinical trials may in any

event not be consistent with preclinical or interim results.

These and other risks, including the generally unstable nature of current economic and financial market 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.

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