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XOMA Announces Initiation of Its Phase 2 Clinical Program for XOMA 052 in Type 2 Diabetes and Cardiovascular Disease

BERKELEY, Calif., Oct. 1, 2009 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA) today announced plans for the Phase 2 clinical development of its anti-inflammatory drug candidate to interleukin-1 beta (IL-1 beta), XOMA 052, designed for the treatment of the inflammatory cause of cardiovascular, diabetes, autoimmune and other diseases. The clinical trials are designed to further evaluate the use of multiple dose regimens on the safety, pharmacodynamics and efficacy of XOMA 052 in cardiometabolic and other diseases, and based on positive results, select doses for pivotal Phase 3 studies.

"Only one year ago, we presented initial groundbreaking anti-diabetic and anti-inflammatory results at the European Association for the Study of Diabetes annual meeting. Based on positive and exciting results in two Phase 1 studies conducted in 98 patients, XOMA plans to maintain its leadership position in the development of IL-1 beta targeting agents for cardiovascular and diabetic disease with the initiation of our Phase 2 program," said Steven B. Engle, XOMA's Chairman and Chief Executive Officer. "In the Phase 2a portion of the program, we will initiate several smaller trials to further characterize XOMA 052's biological activities, understand the timing and level of the therapeutic effects in different populations and collect additional safety data. In the Phase 2b portion of the program, we plan to initiate at least one large dose-ranging trial to provide results supporting the design of a pivotal Phase 3 study.

The Phase 2a program includes the following clinical trials:

* Phase 2a Extended Safety and Biological Activity Study: This randomized, placebo-controlled trial is designed to enroll approximately 80 Type 2 diabetes patients on a stable regimen of metformin therapy. Patients will be randomized to multiple dose regimens of XOMA 052 or placebo by subcutaneous administration (SC). Diabetes outcomes include glycosylated hemoglobin (HbA1c) levels and fasting blood glucose (FBG) levels. Several cardiovascular biomarkers including C-reactive protein (hsCRP) will be evaluated. This trial is scheduled to begin in the fourth quarter of 2009. Ongoing evaluations of biological activity are planned at pre-specified time points or enrollment milestones. Interim results may be available by third quarter of 2010.

* Phase 2a Cardiometabolic Study: This randomized, placebo-controlled trial is in the final stages of design. It is intended to provide more details about beta cell and

endothelial functions in Type 2 diabetes patients. XOMA anticipates initiating this trial in the first quarter of 2010.

The Phase 2b program is expected to include several studies including a dose-ranging study. This randomized, double-blind, placebo-controlled clinical trial is designed to select an appropriate dose for Phase 3 evaluation and expand the safety database. The primary endpoint for the study will be the mean reduction in HbA1c at six months. Additional diabetes and cardiovascular outcomes will be evaluated. XOMA plans to initiate this trial when resources permit.

For competitive reasons, XOMA is limiting public disclosure of its Phase 2 program to certain studies and selected details within those studies.

"We are pleased to move forward with our XOMA 052 Phase 2 program based on the positive results observed in Phase 1 trials," said Patrick J. Scannon, M.D., Ph.D., XOMA's Executive Vice President and Chief Medical Officer. "The Phase 1 results demonstrate that XOMA 052 is well tolerated with a pharmacokinetic profile that supports monthly or less frequent dosing. Patients receiving multiple XOMA 052 doses had a more consistent response compared to patients who received a single dose or placebo, and the subcutaneous route of administration was overall superior to the intravenous route of administration. Improvements were observed in diabetes measures including HbA1c and FBG, and inflammatory markers including hsCRP, a biomarker associated with increased cardiovascular risk, and ESR, a standard measure of systemic inflammation."

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.

About XOMA

XOMA discovers, develops and manufactures therapeutic antibodies designed to treat inflammatory, autoimmune, infectious and oncological 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 has multiple revenue streams resulting from the licensing of its antibody technologies, product royalties, development collaborations, and biodefense contracts. 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 unmatched capabilities in library construction, proprietary antibody humanization and affinity enhancement and Bacterial Cell Expression (BCE) 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 licenses to our BCE technology.

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 and a team of approximately 190 employees at its Berkeley, California 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 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.

These risks, including those related to inability to comply with NASDAQ's continued listing requirements; 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
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