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XOMA Expands Development Strategy for XOMA 052 to Include Cardiovascular Diseases

BERKELEY, Calif., Nov. 6, 2009 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced the expansion of its development strategy for its XOMA 052 antibody to interleukin-1 beta (IL-1 beta) to include effects on cholesterol lowering, reducing plaque deposits and damage to heart muscle and resulting long-term effects that can lead to heart attack, stroke and congestive heart failure. The strategy is supported by results from XOMA 052 Phase 1 trials demonstrating improvement in biomarkers associated with cardiovascular risk, ongoing clinical trials in cardiovascular disease with other IL-1 targeted agents, animal studies with XOMA 052 that have demonstrated significant reductions in plaque formation and improvements in lipid levels, and positive results with another IL-1 targeted agent in an animal model of cardiac remodeling after heart attack. XOMA's current XOMA 052 program is focused on Type 2 diabetes and this expansion represents an enormous increase in the number of patients who could be helped by this general anti-inflammatory approach.

In XOMA's Phase 1 XOMA 052 trials, patients with Type 2 diabetes had improvements in high-sensitivity C-reactive protein (hsCRP) and erythrocyte sedimentation rate (ESR), biomarkers of systemic inflammation associated with cardiovascular risk as well improvement in diabetic parameters(1). Two ongoing clinical trials of anakinra, another agent targeting IL-1, in acute coronary syndromes provide further support for a new anti-inflammatory approach to cardiovascular disease(2,3). Recently reported preclinical animal results have demonstrated that XOMA 052 treatment resulted in reduction in the formation of atherosclerotic plaque(4). Other recent preclinical animal results with XOMA 052 have shown reductions in total cholesterol without reduction in high density lipoprotein, and reduction in triglycerides and free fatty acids(5). Recently published results demonstrated that treatment with anakinra in a mouse model of heart attack resulted in amelioration of the adverse cardiac remodeling, and a statistically significant improvement in survival compared to control animals(6).

"XOMA 052 results demonstrating improved cardiovascular biomarkers in our Phase 1 trials and significant improvements in plaque formation and dyslipidemia in established mouse models, together with the growing recognition of systemic inflammation as a cardiovascular risk factor as recently demonstrated in the JUPITER study, support an expanded strategy for the development of XOMA 052 in cardiovascular diseases," said Patrick J. Scannon, M.D., Ph.D., XOMA's Executive Vice President and Chief Medical Officer.

"Despite many recent advances in prevention and treatment, cardiovascular disease remains the leading cause of death in the United States, demonstrating the ongoing need for

new therapies," said Steven B. Engle, XOMA's Chairman and Chief Executive Officer. "While we remain focused on developing XOMA 052 in Type 2 diabetes, we believe expanding our development strategy to include cardiovascular diseases, to be implemented as resources permit, will lay the groundwork to dramatically expand the potential for this product candidate."

Inflammation is a critical component of many diseases and IL-1 has been demonstrated to be one of the key cytokines involved in the pro-inflammatory process. At normal physiological levels, IL-1 is an important part of the host defense system. In elevated amounts, IL-1 has been demonstrated to have a pathologic role in initiating, maintaining or exacerbating inflammatory conditions including Type 2 diabetes, cardiovascular disease, rheumatoid arthritis, gout and other diseases.

References

(1) Feldstein J, Urquilla P, Der K et al. XOMA 052, a potential diseases-modifying anti-interleukin-1 beta regulatory antibody, shows reductions in hs-CRP, HbA1c and FPG after subcutaneous injection in a randomized, blinded, placebo-controlled trial in subjects with type 2 diabetes mellitus. International Diabetes Federation 20th World Congress Abstract D-0856:273; 2009

(2) http://www.clinicaltrials.gov/ct2/show/NCT00789724, November 3, 2009

(3) Crossman. Trials 9:8; 2008

(4) Roell M, White M, Issafras H et al. XOMA 052, a monoclonal antibody that regulates interleukin-1 beta (IL-1 beta) activity: an example of a new class of regulatory antibody drugs that may confer a unique advantage in the treatment of type 2 diabetes mellitus. Diabetologia 52: Suppl1; Abstract 370, 2009

(5) Owyang A, Gross L, Yin J et al. XOMA 052, and anti-IL-1 beta antibody, improves glucose control, beta cell function and survival, and insulin sensitivity, and dyslipidemia in the diet-induced mouse obesity model. American Diabetes Association 69th Scientific Sessions; Abstract 310-OR, 2009

(6) Abbate A, Salloum F, Vecile E et al. Anakinra, a recombinant human interleukin-1 receptor antagonist, inhibits apoptosis in experimental acute myocardial infarction. Circulation 117: 2670-2683; 2008

About XOMA 052

XOMA 052 is potent 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 reducing 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 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:

* XOMA 052, an anti-IL-1 beta antibody in Phase 2 clinical development for Type 2 diabetes, Type 1 diabetes and cardiovascular disease, with potential for the treatment of a wide range of inflammatory conditions
* XOMA 3AB, an antibody candidate in pre-IND studies to neutralize the botulinum toxin, among the most deadly potential bioterror threats, under development through funding provided by the National Institutes of Allergy and Infectious Diseases of the National Institutes of Health
* A preclinical pipeline with candidates in development for inflammatory, autoimmune, infectious and oncological diseases

In addition to its proprietary pipeline, XOMA develops products with premier pharmaceutical companies including Novartis AG, Schering-Plough Research Institute and Takeda Pharmaceutical Company Limited.

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 an unmatched collection of antibody phage display libraries and proprietary Human Engineering(TM), 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, more than 50 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, and a team of about 200 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.

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