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XOMA Initiates Gevokizumab Phase 2 Study for Moderate to Severe Acne Vulgaris

BERKELEY, Calif., Dec. 21, 2011 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA) today announced it has begun dosing patients in its Phase 2 proof-of-concept study to evaluate the efficacy and safety of gevokizumab (XOMA 052), a potent inhibitor of interleukin-1 beta (IL-1 beta), for the treatment of the inflammatory lesions seen in moderate to severe acne vulgaris. Approximately 170 patients will be randomized to receive one of two dose levels of gevokizumab or placebo administered subcutaneously over a three-month period. The primary study efficacy endpoint is the mean absolute change from baseline in inflammatory facial lesion count after three months of therapy. Additional study information has been submitted for publication on www.clinicaltrials.gov

"XOMA's Phase 2 proof-of-concept program is designed to expand the value of gevokizumab, the company's lead clinical asset, by demonstrating its potential in diseases characterized by interleukin-1 beta over-expression. This is the first in a series of clinical studies that we plan to conduct in separate indications over the next 12 to 18 months," commented John Varian, Interim Chief Executive Officer of XOMA Ltd. "Upon completion of this series of proof-of-concept studies, we believe we will have sufficient evidence to initiate a further development program in at least one of these indications."

Moderate to severe acne vulgaris is estimated to affect approximately three to four million people in the U.S. Acne is characterized by the presence of a bacteria known as *Proprionumbacterium acne*, which promotes the production of proinflammatory substances including IL-1 beta in experimental models of the disease.

Moderate to severe acne that does not respond to topical agents is often treated with orally administered antibiotics. For the most severe, non-responsive acne, isotretinoin (an oral retinoid drug) treatment may be prescribed, although it is only available through a restricted distribution program due to its side effect profile.

About Gevokizumab and Interleukin-1 Inhibition

Gevokizumab (XOMA 052) is a potent monoclonal antibody with the potential to treat patients with a wide variety of inflammatory and other diseases. Gevokizumab binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine that has been shown to be involved in non-infectious uveitis including Behçet's uveitis, cardiovascular disease, and other auto-inflammatory diseases. By binding to IL-1 beta, gevokizumab inhibits the activation of the IL-1 receptor, thereby modulating the cellular signaling events that produce

inflammation.

Gevokizumab has been studied in nearly 500 patients, with approximately 300 patients on treatment for six months, and has been shown to be well-tolerated. As previously reported, in a proof-of-concept Phase 2 trial of gevokizumab in Behçet's uveitis, all seven patients displayed rapid reduction of intraocular inflammation and improvement in visual acuity or other ophthalmic measures after a single treatment and following discontinuation of immunosuppressive drugs such as cyclosporine and/or azathioprine. Five of the patients were retreated with gevokizumab due to a recurring uveitis exacerbation and all responded again to treatment. Due to its ability to reduce C-reactive protein, gevokizumab also has potential for the treatment of cardiovascular and other inflammatory diseases.

About XOMA

XOMA is a leader in the discovery and development of novel antibody therapeutics. The company's proprietary product pipeline includes:

- Gevokizumab (XOMA 052), a humanized antibody that binds to the inflammatory cytokine interleukin-1 beta, or IL-1 beta. XOMA plans to enter gevokizumab into Phase 3 clinical development in non-infectious uveitis affecting the intermediate and/or posterior segments of the eye, and has initiated a Phase 2 proof-of-concept trial for the treatment of moderate and severe acne vulgaris. Les Laboratoires Servier is XOMA's development and commercialization partner for gevokizumab. XOMA holds rights to gevokizumab in the U.S. and Japan for all non-cardiovascular and non-diabetes indications, including acne vulgaris, uveitis and Behçet's uveitis.
- Antibodies against botulinum toxins, led by XOMA 3AB, a novel combination of three antibodies to prevent and treat botulism poisoning caused by exposure to botulinum neurotoxin Type A, among the most deadly bioterror threats. XOMA 3AB is in a Phase 1 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). Development of these antibodies has been funded in whole or in part with funds from NIAID, NIH, Department of Health and Human Services under Contract No. HHSN266200500004C, Contract No. HHSN266200600008C, Contract No. HHSN272200800028C, Contract No. HHSN266200600011C, Contract No., HHSN272200800026C, and Contract No. HHSN2722011031C.
- A preclinical pipeline with candidates in development for autoimmune, cardio-metabolic, inflammatory and oncological diseases. Among these are two new classes of fully human monoclonal antibodies that activate (XMetA) or sensitize (XMetS) the insulin receptor in vivo, which represent distinct new therapeutic approaches to the treatment of patients with diabetes.

XOMA has a premier antibody discovery and development platform that incorporates an unmatched collection of antibody phage display libraries and proprietary optimization and expression and manufacturing technologies that it uses for its own pipeline and in collaborations with pharmaceutical and biotechnology companies. XOMA's fully integrated product development infrastructure extends from preclinical science to approval and is located in Berkeley, California. For more information, please visit 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 Phase 2 clinical trials or 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, clinical trials may not be successful in achieving their goals, whether due to lack of efficacy or for safety, statistical or other reasons, and results of earlier-stage clinical trials may not be supported by results of later-stage trials.

These and other risks, including those related to the generally unstable nature of current economic and financial market 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 or licensing relationships; the ability of collaborators, licensees and other third parties to meet their obligations and their discretion in decision-making; XOMA's ability to meet the demands of the United States government agency with which it has entered into its government contracts; competition; market demand for products; scale-up, manufacturing 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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