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XOMA Finalizes Plans for Gevokizumab Phase 3 Clinical Program in Pyoderma Gangrenosum

BERKELEY, Calif., April 28, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today that based on its meeting with the U.S Food and Drug Administration (FDA), the Company is finalizing its plans for a gevokizumab Phase 3 program in pyoderma gangrenosum (PG), a rare neutrophilic dermatosis of painful expanding necrotic skin ulcers. During the meeting, the Company and the FDA reviewed the data generated from XOMA's pilot trial in six PG patients. The pilot study was designed to determine if gevokizumab, an IL-1 beta modulating antibody, should be explored in pivotal studies in patients with active PG. XOMA is incorporating the FDA's verbal and written responses regarding the clinical design of the studies into a final Phase 3 program, which it will submit to the Agency for any final comments.

The Phase 3 program is expected to include two double-blind, placebo-controlled clinical studies, each of which is designed to enroll approximately 60 patients with active PG. The primary endpoint is complete wound closure of the target ulcer at approximately four months. XOMA anticipates conducting these parallel studies in the United States and several other countries.

"The interest we have received from the medical community and the patients who suffer from pyoderma gangrenosum ulcerations reflect their desire to have access to therapeutic options that have been studied specifically in and are approved for this under-served patient population. We were very pleased the FDA agreed PG is a serious rare condition that has been identified as an unmet medical need with no approved therapies and that the input we received has allowed us to design a Phase 3 program we believe we can successfully execute in our targeted PG population," stated Paul Rubin, Senior Vice President, Research and Development and Chief Medical Officer of XOMA. "While we await final comments on our protocol, we are actively engaged in site identification and pre-study start-up activities to ensure their investigators and clinical staff are prepared to enroll eligible patients as quickly as possible once we launch the studies."

Gevokizumab has been granted Orphan Drug Designation by the FDA for the treatment of PG.

About Gevokizumab

Gevokizumab is a potent monoclonal antibody with unique allosteric modulating properties

and has the potential to treat patients with a wide variety of inflammatory diseases. Gevokizumab binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine, and modulates the cellular signaling events that produce inflammation. IL-1 beta has been shown to be involved in diverse array of disease states, including non-infectious uveitis (including Behçet's uveitis), cardiovascular disease, and other auto-inflammatory diseases.

Gevokizumab currently is being studied in a global Phase 3 clinical program, termed EYEGUARD™, which is being conducted by SERVIER and XOMA. This program is designed to determine gevokizumab's ability to treat acute non-infectious uveitis (NIU) involving the intermediate and/or posterior segment of the eye in EYEGUARD-A, to prevent disease flares in patients with Behçet's uveitis in EYEGUARD-B, and to prevent disease flares in NIU patients who are controlled with steroids in EYEGUARD-C.

XOMA has a Proof-of-Concept (POC) program underway in which the Company is exploring the efficacy and safety of gevokizumab in multiple indications. Separately, SERVIER initiated a Phase 2 study to determine gevokizumab's ability to reduce arterial wall inflammation in patients with marked atherosclerotic plaque inflammation and who have experienced an acute coronary syndrome event in the previous twelve months, as well as POC studies in polymyositis/dermatomyositis, giant cell arteritis, and Schnitzler syndrome. Information about gevokizumab clinical studies can be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

About Pyoderma Gangrenosum

Pyoderma gangrenosum (PG) is a rare neutrophilic dermatosis of painful expanding necrotic skin ulcers. The U.S. Department of Health and Human Services' National Institutes of Health's Office of Rare Disease Research lists PG occurring in about 1 per 100,000 people. Claims data compiled over the past three years indicate the number of diagnosed PG patients has ranged between 11,000 and 14,000 annually. Approximately 50 to 70 percent of the PG patient population has an underlying systemic condition, while the remainder is idiopathic (unknown cause). The most prevalent underlying condition is inflammatory bowel disease (IBD), most commonly ulcerative colitis and Crohn's disease. The prognosis for PG is directly linked to the patient's response to therapy for the underlying disease. Physicians treat patients with systemic therapies that are approved for the underlying disease and topical therapies applied directly to the ulcers; however the ulcers may take up to two years to heal. Despite the ongoing use of systemic therapy, up to 46 percent of patients experience a relapse.

About XOMA Corporation

XOMA has built a portfolio of innovative therapeutic antibodies, both in late-stage clinical development and in preclinical research. XOMA focuses its antibody research and development on allosteric modulation, which offers opportunities for new classes of therapeutic antibodies to treat a wide range of human diseases. XOMA's lead product candidate, gevokizumab (IL-1 beta modulating antibody), is in a global Phase 3 program in non-infectious uveitis with its partner SERVIER and multiple proof-of-concept studies in other IL-1-mediated diseases. XOMA's scientific research also produced the XMet program, which consists of three classes of preclinical antibodies, including Selective Insulin Receptor Modulators (SIRMs) that could have a major effect on the treatment of diabetes.

More detailed information can be found at www.xoma.com.

About SERVIER

Founded in 1954, SERVIER is an independent French pharmaceutical research company. Its development is based on the continuous pursuit of innovation in the therapeutic areas of cardiovascular, metabolic, neurologic, psychiatric, bone and joint diseases, as well as cancer. In 2013, the company recorded a turnover of 4.2 billion euros. 91% of SERVIER drugs are consumed internationally. 27% of turnover from SERVIER drugs were reinvested in Research and Development in 2013. With a strong international presence in 140 countries, SERVIER employs more than 21,000 people worldwide. The SERVIER Group contributed 35% to the 2013 French trade surplus in the pharmaceuticals sector.

Forward-Looking Statements

Certain statements contained in this press release including, but not limited to, statements related to anticipated timing of initiation and completion of clinical trials and proof-of-concept trials, sales of approved products, and the positive outcome of our clinical trials or receipt of marketing approval by the U.S. FDA 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, and 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. Potential risks to XOMA meeting these expectations are described in more detail in XOMA's most recent filing on Form 10-Q and in other SEC filings. Consider such risks carefully when considering XOMA's prospects. Any forward-looking statement in this press release represents XOMA's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. XOMA disclaims any obligation to update any forward-looking statement, except as required by applicable law.

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