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XOMA Initiates Pivotal Phase 3 Gevokizumab Study in Patients With Pyoderma Gangrenosum

BERKELEY, Calif., Nov. 4, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced its pivotal Phase 3 gevokizumab study in patients with active pyoderma gangrenosum (PG), a rare neutrophilic dermatosis of expanding necrotic skin ulcers, is open for patient enrollment. The objective of the study is to assess the efficacy and safety of gevokizumab in treating the active ulcers caused by this rare and debilitating disease. The FDA granted orphan drug designation to gevokizumab for PG in February 2014.

"We have reached another important milestone in our gevokizumab development activities with the launch of the first of two pivotal gevokizumab studies in pyoderma gangrenosum, one of the indications under the neutrophilic dermatoses umbrella for which there are no available therapies approved by the FDA. Patients with PG experience deep and painful skin ulcers that often become chronic wounds. In our pilot study, five of the six patients enrolled responded to gevokizumab, and four experienced complete wound closure by three months," stated Paul Rubin, MD, Senior Vice President, Research and Development and Chief Medical Officer at XOMA. "We believe gevokizumab has the potential to help PG patients reduce the amount of time it takes to heal from this painful and unsightly condition. With the first U.S. only study open for enrollment, we will complete the necessary steps to open the second pivotal PG Phase 3 study, which will include both U.S. sites and centers outside of the United States."

The Phase 3 randomized, placebo-controlled study will enroll 58 patients with active PG to receive gevokizumab 60 mg or placebo dosed subcutaneously once monthly, in addition to their current treatment regimen of low-dose corticosteroids and/or immunosuppressants. The primary endpoint is complete closure of the PG target ulcer determined at Day 126 with confirmation a minimum of two weeks later at Day 140.

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 ranges between 11,000 and 14,000 annually in the United States. 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 conditions are

ulcerative colitis and Crohn's disease. The prognosis for PG is linked directly 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 that are 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 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 and other 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 a diverse array of disease states, including Behçet's disease uveitis, non-infectious uveitis, cardiovascular disease, and other auto-inflammatory diseases.

Gevokizumab currently is being studied in multiple indications, including three global Phase 3 clinical programs in Behçet's disease uveitis, non-infectious uveitis and pyoderma gangrenosum. Information about all gevokizumab clinical studies can be found at www.clinicaltrials.gov and www.clinicaltrialsregister.eu.

About XOMA Corporation

XOMA's portfolio of innovative product candidates is the result of the company's focus on allosteric modulation, which offers opportunities to develop new classes of therapeutic antibodies with the potential to treat a wide range of human diseases. XOMA is developing its lead product gevokizumab (IL-1 beta modulating antibody) with SERVIER through a global Phase 3 program in Behçet's disease uveitis, non-infectious uveitis and pyoderma gangrenosum as well as ongoing 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 antibodies, including XOMA 358, an allosteric monoclonal antibody that reduces both the binding of insulin to its receptor and downstream insulin signaling, that could have a major effect on the treatment of abnormal metabolic states.

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

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, Proof-of-Concept trials, anticipated size of clinical trials, regulatory approval of unapproved product candidates, anticipated market interest in biologic therapies, sufficiency of our cash resources and anticipated levels of cash utilization, or statements 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-K 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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