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# XOMA Receives Orphan Drug Designation From U.S. FDA for Pyoderma Gangrenosum

BERKELEY, Calif., Feb. 24, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today gevokizumab, the Company's IL-1 beta modulating antibody, has been granted Orphan Drug Designation by the U.S. Food & Drug Administration (FDA) for the treatment of pyoderma gangrenosum (PG).

Orphan drug designation is granted by the FDA Office of Orphan Products Development (OOPD) to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees. The OOPD also works on rare disease issues with the medical and research communities, professional organizations, academia, governmental agencies, industry, and rare disease patient groups.

"Selecting pyoderma gangrenosum as our next Phase 3 indication reflects our commitment to creating and capturing value from gevokizumab, particularly in indications where patients have few effective treatment options," stated John Varian, Chief Executive Officer of XOMA. "We intend to present what we believe are compelling data from our pilot study in PG and to solicit feedback from the FDA about the requirements for a Phase 3 program in this rare disease."

**About Gevokizumab**

Gevokizumab is a potent monoclonal antibody with unique allosteric modulating properties and 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 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-anterior non-infectious uveitis (NIU) 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 and immunosuppressants 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. The Company reported promising data in January 2013 from the interim analysis of a Phase 2 study in moderate to severe inflammatory acne. Data from the National Eye Institute's study of gevokizumab in patients with active non-infectious anterior scleritis is expected in 2014. XOMA anticipates full results from its two POC studies in patients with erosive osteoarthritis of the hand in the first quarter of 2014. 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 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, which has four classifications based upon the type of skin ulcers manifested. 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. 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. Patients receive a combination of topical and systemic therapy to treat the ulcers, which 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**

*"Since the company's creation, all of our profits are ploughed back into research"*Jacques Servier, Founding President of the Group.

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. With a strong international presence in 140 countries, Servier employs more than 22,000 people worldwide. In 2012, the company recorded revenue of 3.9 billion euros, and 92% of Servier drugs are consumed internationally. The Servier Group contributed 57% to the 2012 French trade surplus in the pharmaceuticals sector. The Company reinvested 25% of its revenues into R&D in 2012.

More information is available at: www.servier.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 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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