

September 30, 2014



## **XOMA Initiates U.S. Clinical Trial of Gevokizumab in Patients With Behcet's Disease Uveitis - EYEGUARD(TM)-US**

- EYEGUARD-US is a randomized withdrawal study, conducted at U.S. clinical sites, to determine the efficacy and safety of gevokizumab in treating Behçet's disease uveitis patients
- Study is open to Behçet's disease uveitis patients experiencing an ocular inflammatory episode or patients whose ocular inflammation currently is controlled

BERKELEY, Calif., Sept. 30, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced that its EYEGUARD-US supplemental clinical study is open for enrollment to patients at study sites located in the United States. The objective of this trial is to assess the efficacy and safety of gevokizumab in treating Behçet's disease uveitis.

"To ensure we designed a study that meets the needs of the U.S. clinicians treating patients who suffer from Behçet's disease uveitis, we worked closely with key opinion leaders to create a protocol that reflects how they treat patients with this serious disease," stated Paul Rubin, M.D., Senior Vice President, Research and Development, and Chief Medical Officer of XOMA. "It was important that the study design allows for the inclusion of patients experiencing active inflammatory episodes, as well as patients who are currently under control but may benefit from an alternative therapy."

The study is titled "A Randomized-Withdrawal, Double-Masked, Placebo-Controlled Study of the Efficacy and Safety of Gevokizumab in Treating Subjects with Behçet's Disease Uveitis" (EYEGUARD-US). Up to 28 patients will receive gevokizumab on an open-label basis to determine if they respond to therapy. At Day 28, those who respond to gevokizumab will be randomized, one to one, in a double-masked fashion to either gevokizumab 60 mg or placebo, dosed subcutaneously once monthly. The study's primary endpoint is the time to first ocular exacerbation following randomization.

"Opening EYEGUARD-US is a crucial step in our strategy to pursue Behçet's disease uveitis as our first indication for gevokizumab in the U.S.," commented John Varian, Chief Executive Officer of XOMA. "This strategy makes us less dependent on our EYEGUARD-A and C studies in the broader non-infectious uveitis population, which continue to enroll more slowly than hoped. EYEGUARD-US is designed as a well-controlled study to supplement data from the Phase 3 EYEGUARD-B study being performed by our partner SERVIER outside the U.S. and the ex-U.S. data previously generated from two Phase 2 trials of Behçet's disease uveitis patients."

Mr. Varian added, "Upon receipt of successful results from the EYEGUARD-B study, we plan to request a pre-BLA meeting with FDA. EYEGUARD-US is designed to supplement the Agency's need for information in U.S. patients, including potentially serving as a second pivotal study."

More details on the study design can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About Behçet's Disease and Behçet's Disease Uveitis**

Behçet's (pronounced beh-CHETS) disease is an orphan disease that causes chronic inflammation of the blood vessels, or vasculitis. Major symptoms can affect the neurological, pulmonary, gastrointestinal and cardiovascular systems, and hallmarks of the disease include painful ulcers in the mouth and on the genitals. Behçet's disease most commonly affects men and women in their twenties, thirties and forties, and it is typically more severe in men. Behçet's disease is also referred to as the "Silk Road" disease because it is most common among people from countries along this ancient trade route, including Turkey, eastern Mediterranean countries, Japan and Korea. An estimated 5,000 to 15,000 patients in the United States have Behçet's disease.

Behçet's disease uveitis (BDU) is one of the most severe forms of non-infectious uveitis and affects approximately 60% of the patients with Behçet's disease. BDU is characterized by recurrent acute attacks or exacerbations. Without immediate treatment, major exacerbations of BDU may lead to retinal detachment, vitreous hemorrhage, glaucoma and eventual blindness. Symptoms include the accumulation of vitreous haze that can block eyesight or the loss of visual acuity and can manifest differently from patient to patient. Available treatments for BDU are limited to corticosteroids and off-label use of immunosuppressive drugs, both of which can have significant side effects when used on a chronic basis.

### **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 diverse array of disease states, including non-infectious uveitis (including Behçet's disease 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 disease uveitis in EYEGUARD-B, and to prevent disease flares in NIU patients who are controlled with steroids in EYEGUARD-C. XOMA launched EYEGUARD-US to study gevokizumab in the U.S. Behçet's disease uveitis patient population and could use the data from this study to support a Behçet's disease uveitis-first BLA filing in the United States.

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](http://www.clinicaltrials.gov) and [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu).

### **About XOMA Corporation**

XOMA's innovative product candidates are the result of the Company's expertise in developing allosteric modulating monoclonal antibodies, which has created 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 for Behçet's disease uveitis and non-infectious uveitis and ongoing proof-of-concept studies in other IL-1-mediated diseases. XOMA's scientific research also has produced the XMet program, which consists of three classes of preclinical antibodies, including Selective Insulin Receptor Modulators (SIRMs) that are being investigated for the treatment of abnormal metabolic states. XOMA's extensive antibody expertise includes antibody discovery, optimization, cell line and process development.

More detailed information can be found at [www.xoma.com](http://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.

More detailed information can be found at [www.servier.com](http://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, anticipated size of clinical trials, regulatory approval of unapproved product candidates, whether EYEGUARD-US will serve as a pivotal study, 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.

CONTACT: XOMA Corporation

Company and Investor Contact:

Ashleigh Barreto

510-204-7482

barreto@xoma.com

Juliane Snowden

The Oratorium Group, LLC

jsnowden@oratoriumgroup.com

Source: XOMA Corporation