

March 4, 2014



## **XOMA Provides Update on Gevokizumab Proof-of-Concept Program**

- Results from two Phase 2 erosive osteoarthritis of the hand studies do not support movement to pivotal development
- FDA End of Phase 2 meeting for pyoderma gangrenosum indication scheduled for March 2014
- Conference call to be held today at 6:00 p.m. Eastern / 3:00 p.m. Pacific

BERKELEY, Calif., March 4, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, provided an update on its gevokizumab development program. Based on results from the Company's Phase 2 program in patients with erosive osteoarthritis of the hand (EOA), XOMA does not intend to launch pivotal development for the broad EOA indication. The Company will conduct a review of the full dataset to determine if there is a segment of the patient population that best responds to gevokizumab therapy prior to initiating any potential additional clinical studies in this indication. Gevokizumab appeared to be well tolerated, and the most common adverse events were comparable between both the gevokizumab and placebo groups. XOMA will continue to focus its efforts on completing the EYEGUARD™ Phase 3 clinical program, preparing to initiate its Phase 3 program in patients with pyoderma gangrenosum (PG), and assessing gevokizumab in pilot studies of other rare diseases that are in need of new therapeutic options.

"We launched our proof-of-concept program for gevokizumab just over two years ago. We developed a thoughtful plan that would allow data derived from well-designed clinical studies using gevokizumab to lead us to the best opportunities to follow our ongoing Phase 3 studies in non-infectious and Behçet's uveitis. While we are disappointed in today's results, the new information we received from these Phase 2 studies informs our next decisions. The data we generated in our erosive osteoarthritis of the hand studies enabled our decision not to initiate large Phase 3 studies for this indication. In contrast, the data that we generated last fall in pyoderma gangrenosum allowed us to select this orphan indication as our next Phase 3 effort," stated John Varian, Chief Executive Officer of XOMA. "The data Servier and we are generating in six additional indications we have disclosed, as well as other indications we haven't yet disclosed, will continue to light our pathway forward."

XOMA conducted two separate double-blind, placebo-controlled clinical studies in patients with EOA. The first study (Study 160) enrolled 85 patients who were diagnosed with EOA and who had a high-sensitivity C-reactive protein (CRP) level  $\geq 2.5$  mg/L. CRP is recognized as a biomarker for generalized inflammation. The second study (Study 162) enrolled 92 patients who met the criteria for the first study but did not have elevated CRP. In both studies, patients were randomized 2:1 to receive either gevokizumab 60mg or placebo,

dosed subcutaneously once monthly. Both studies were designed to determine if gevokizumab could improve the pain, stiffness, and physical function associated with EOA, based upon the Australian/Canadian Osteoarthritis Hand Index (AUSCAN™) scoring scale. AUSCAN is a validated self-administered questionnaire specifically designed to assess the three dimensions of pain, disability, and joint stiffness of osteoarthritis of the hand using a series of 15 questions. Study 160 assessed the change in AUSCAN score from baseline at Days 84 and 168 in addition to assessing improvements of the effected joints from baseline using radiographic and MRI images taken at Days 84 and 168. Study 162 assessed the change in AUSCAN score from baseline at Day 84, the results in the second study did not show the same strength as the Day 84 results from Study 160.

The initial results from Study 160 showed separation between the gevokizumab and placebo scores favoring gevokizumab over the 84-day period. While the gevokizumab-treated patients continued to show an improvement in all AUSCAN measures over their baseline scores after 168 days of therapy, the placebo treated patients showed a greater improvement over the final three months of the study, eliminating the separation seen between placebo and actively treated patients by the Day 168 time point. The Company's primary analyses and other objective measures, such as MRIs and radiographs, did not suggest a significant drug-related benefit after six months.

XOMA has begun analyses of relevant patient subgroups, and these data have shown placebo response was driven by patients with milder disease at baseline. Comparisons of patients with more severe pain (visual analog scale  $\geq 75/100$ ) at baseline show a consistent trend favoring gevokizumab in all components of their AUSCAN scores. In both proof-of-concept studies, gevokizumab demonstrated a statistically significant effect on CRP levels over the full study periods. It is possible these observations, as well as further analyses, could provide a reasonable group to study in future trials but it is too early to tell at this point.

Gevokizumab was generally well tolerated, and there were no drug-related serious adverse events reported in these studies. The most common adverse events were headache, pain, arthralgia, urinary tract infections, upper respiratory tract infections and pneumonia, and they were comparable between gevokizumab and placebo.

"We have rapidly advanced our pyoderma gangrenosum clinical program since we launched our pilot study in June of 2013, and our End of Phase 2 meeting with the Food and Drug Administration will be taking place in March. We expect we will be able to announce our Phase 3 clinical program in this rare and serious indication during April," commented Paul Rubin, MD, Senior Vice President Research and Development and Chief Medical Officer of XOMA.

### **Investor Conference Call and Webcast**

XOMA will host a webcast today, March 4, 2014, at 6:00 p.m. ET / 3:00 p.m. PT. The webcast can be accessed via the Investors and Media section of XOMA's website at <http://investors.xoma.com/events.cfm> and will be available for replay until close of business on May 4, 2014.

Telephone numbers for the live audiocast are 877-369-6589 (U.S./Canada) and 408-337-0122 (international).

## **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-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 or has explored the efficacy and safety of gevokizumab in multiple indications: pyoderma gangrenosum, pustular psoriasis, moderate to severe inflammatory acne, erosive osteoarthritis of the hand, active non-infectious scleritis, autoimmune inner ear disease. 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, Schnitzler syndrome, and giant cell arteritis. 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 Erosive Osteoarthritis of the Hand**

Erosive osteoarthritis of the hand (EOA) is caused by the breakdown of the body's natural balance between cartilage formation and degradation, which leads to the narrowing of the space between the first and second joints in the fingers. Patients with EOA experience high degrees of pain, including throbbing, swelling, and prolonged periods of morning stiffness. Over time, the joints become deformed, impacting hand function and ultimately reducing EOA patients' quality of life. Approximately two million people in the U.S. have been diagnosed with EOA, and the disease affects women twelve times more often than men for reasons that are not understood by the scientific or medical community.

## **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**

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 significant effect on the treatment of diabetes.

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

## **Forward-Looking Statements**

Certain statements contained in this press release including, but not limited to, statements related to anticipated research and clinical trials, anticipated timing of initiation and completion of clinical trials and proof-of-concept trials, anticipated size of clinical trials, 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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