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XOMA Announces Encouraging Interim Results From Gevokizumab Phase 2 Study for Moderate to Severe Acne Vulgaris

BERKELEY, Calif., Jan. 7, 2013 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced preliminary top-line data from an interim analysis of its Phase 2 proof-of-concept (POC) study to evaluate the safety and efficacy of gevokizumab, a potent modulator of interleukin-1 beta (IL-1 beta), for the treatment of the inflammatory facial lesions seen in patients with moderate to severe acne vulgaris.

The Phase 2 POC study is a double-blind randomized comparison of gevokizumab 0.2mg/kg and 0.6mg/kg versus placebo given subcutaneously once per month for three consecutive months. Investigators have enrolled a total of approximately 125 patients to date, and the interim results are based on up to 92 patients with available data. In line with FDA guidance, inflammatory lesion counts, the primary endpoint in this trial, and overall acne severity as assessed by responder analysis of the Investigator Global Assessment (IGA), defined as at least a two-point improvement on a five-point scale, were measured at different time points up to Day 84. The study was designed to have 80 percent power to detect at least an absolute difference of 15 versus placebo in the mean inflammatory lesion count at Day 84 with statistical significance defined as $p \leq 0.10$.

The 0.6mg/kg dose group showed a statistically significant reduction of 19 in mean inflammatory lesion count on Day 42 compared to a reduction of 13 in the placebo treated group ($p=0.077$). Each of the groups had a mean baseline of approximately 31 inflammatory lesions. The magnitude of the difference was substantially maintained throughout the study, but differences at later measurement points were not statistically significant. The 0.6mg/kg dose group demonstrated both a clinically and statistically significant improvement in IGA at Day 84, showing a 31 percent responder rate versus a 5 percent responder rate in the placebo group ($p= 0.031$). The 0.2mg/kg dose group showed no clinically or statistically significant differences from placebo at any time point in inflammatory lesion count or in IGA.

Gevokizumab appeared to be well tolerated in the trial, and incidence of adverse events was comparable between both active groups and placebo. The study was dosed in a mg/kg fashion with mean patient weights of approximately 74 kg, thus actively treated patients received mean absolute doses at the 0.2mg/kg and the 0.6mg/kg of around 15 mg and 45 mg respectively.

"The preliminary results of this initial proof-of-concept trial are encouraging as we demonstrated clear activity according to the IGA parameter, and we also established a no-

effect dose. The data from our analysis of inflammatory lesion count demonstrate statistical significance at the 0.6mg/kg dose for the Day 42 measurement. I believe the safety profile and preliminary activity results seen with gevokizumab clearly warrant further evaluation in moderate to severe inflammatory acne, including with higher doses we are using in our other studies. The study also provided key information on placebo response rates in this specific acne population, and this knowledge will be useful in the design of future trials," offered Paul Rubin, M.D., Senior Vice President of Research and Development and Chief Medical Officer of XOMA.

"We designed XOMA's Phase 2 proof-of-concept program to expand our understanding of the potential for gevokizumab to treat several different diseases characterized by IL-1 beta over-expression. We are encouraged by these preliminary top-line results, which demonstrate gevokizumab's potential to treat inflammatory lesions and affect the physicians overall assessment associated with moderate to severe acne vulgaris," commented John Varian, Chief Executive Officer of XOMA. "We await the complete data from this trial and the results from our Phase 2 POC studies in erosive osteoarthritis of the hand and non-infectious scleritis, which are expected later this year. At that time, we and our partner, Servier, expect to be able to determine our next indication to follow non-infectious uveitis into Phase 3 development."

The data from inflammatory lesion count at each visit, as well as Investigator Global Assessment at Day 84, are available on the home page of the XOMA website, www.xoma.com.

About moderate to severe acne vulgaris

Moderate to severe acne vulgaris is estimated to affect approximately three to four million people in the U.S. Acne is characterized by the presence of a bacterium known as *Proprionumbacterium acne*, which promotes the production of proinflammatory substances including IL-1 beta in experimental models of the disease.

Moderate to severe acne that does not respond to topical agents is often treated with orally administered antibiotics. For the most severe, non-responsive acne, isotretinoin (an oral retinoid drug) treatment may be prescribed, although it is only available through a restricted distribution program due to its side effect profile.

About Gevokizumab

Gevokizumab (XOMA 052) 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 that has been shown to be involved in non-infectious uveitis, including Behçet's uveitis, cardiovascular disease, and other auto-inflammatory diseases. By binding to IL-1 beta, gevokizumab inhibits the activation of the IL-1 receptor, thereby modulating the cellular signaling events that produce inflammation. Gevokizumab has been studied in over 500 patients, with approximately 300 patients on treatment for six months, and has been shown to be well-tolerated. Information about gevokizumab clinical studies can be found at www.clinicaltrials.gov.

About XOMA

XOMA combines a portfolio of innovative therapeutic antibodies, both in late-stage clinical development and in preclinical research, with its recently launched commercial operations. 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 is developing its lead product gevokizumab (IL-1 beta modulating antibody) with Servier through a global Phase 3 program in non-infectious uveitis and 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 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.

The XOMA Corporation logo is available at https://www.globenewswire.com/newsroom/prs/?pkgid=5960

About Servier

Servier is a privately run French research-based pharmaceutical company. Current therapeutic domains for Servier medicines are cardiovascular, metabolic, neurological, psychiatric and bone and joint diseases, as well as oncology. Servier is established in 140 countries worldwide with over 20,000 employees and a 2011 turnover of €3.9 billion. Servier invests 25% of its turnover in R&D.

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 XOMA's Phase 2 POC program, the data generated by studies in that program and the indications of future Phase 3 studies on gevokizumab, 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-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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