

XOMA Announces Perindopril and Amlodipine Fixed-Dose Combination Meets Primary Endpoint in Phase 3 PATH Trial

BERKELEY, Calif., Nov. 20, 2012 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA) today announced the 837-patient Phase 3 PATH trial (**P**erindopril **A**mlodipine for the **T**reatment of **H**ypertension) has demonstrated the fixed-dose combination (FDC) of perindopril arginine combined with amlodipine besylate is statistically significantly superior to either compound alone in reducing both sitting diastolic and sitting systolic blood pressure after six weeks of treatment. This FDC, containing a patent-protected proprietary form of perindopril, was licensed by XOMA as part of a U.S. commercial and development rights agreement signed with Servier for their perindopril franchise. Servier markets the fixed-dose combination product, COVERAM[®], in 91 countries outside the U.S.

"The perindopril/amlodipine FDC is an important asset in Servier's cardiovascular franchise. We believe that based upon our previous conversations with FDA, the positive PATH results combined with the body of existing clinical data for this FDC will support an NDA submission," stated John Varian, Chief Executive Officer of XOMA. "We are extremely proud of our team for completing this trial ahead of schedule and now will be working to identify appropriate potential ways to move this FDC forward to the U.S. market. XOMA does not intend to directly market this FDC, but rather intends to sublicense this product to a third-party organization that is dedicated to commercializing products for the cardiovascular marketplace."

The FDC appeared to be well tolerated in the trial, and there were no unexpected serious adverse events reported. The most common adverse events included mild to moderate edema, cough and headache, which are known side effects of the individual components of the FDC.

Perindopril, an angiotensin converting enzyme inhibitor (commonly called an ACE inhibitor), has been studied in seven landmark clinical trials involving more than 54,000 patients. This body of clinical evidence supports its beneficial impact in treating essential hypertension and stable coronary artery disease. Amlodipine, a calcium channel blocker (commonly called a CCB), is the most-prescribed antihypertensive in the U.S. Because ACE inhibitors and CCBs target different cardiovascular functions, physicians often use them in combination to treat their hypertensive patients.

About the Perindopril Franchise

In January 2012, XOMA acquired U.S. rights to the perindopril franchise from Les Laboratoires Servier, XOMA's partner for its lead antibody product candidate, gevokizumab (formerly XOMA 052). The agreement includes the angiotensin converting enzyme (ACE) inhibitor perindopril, currently marketed under the trade name of ACEON®, and a portfolio of three fixed-dose combination product candidates where perindopril is combined with other active ingredient(s). The proprietary form of perindopril in each of the combination product candidates provides patent protection until 2023. The first product candidate XOMA elected to develop is a fixed-dose combination of perindopril arginine and amlodipine besylate.

About ACEON

ACEON is indicated for the treatment of patients with essential hypertension. ACEON may be used alone or given with other classes of antihypertensives, especially thiazide diuretics. In clinical studies, the most common adverse events (incidence greater than or equal to 5%) were cough, dizziness and back pain.

ACEON is indicated for treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or nonfatal myocardial infarction. ACEON can be used with conventional treatment for management of coronary artery disease, such as antiplatelet, antihypertensive or lipid-lowering therapy. In clinical studies, the most common adverse events leading to discontinuation were cough, drug intolerance, and hypotension.

Perindopril erbumine has been available as a generic product in the U.S. since November 2009.

IMPORTANT SAFETY INFORMATION

Boxed Warning

WARNING: AVOID USE IN PREGNANCY

When pregnancy is detected, discontinue ACEON as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury to or death of the developing fetus.

Contraindications

ACEON is contraindicated in patients known to be hypersensitive (including angioedema) to this product or to any other ACE inhibitor.

ACEON is also contraindicated in patients with hereditary or idiopathic angioedema.

For complete prescribing information, please visit <u>www.aceon.com</u>.

About Hypertension

Hypertension affects approximately one billion individuals worldwide. As the population ages, the prevalence of hypertension will increase even further. Hypertension is a major risk factor for atherosclerotic vascular diseases. The relationship between blood pressure and risk of cardiovascular events is continuous, consistent, and independent of other risk factors. Despite this evidence, current control rates of hypertension remain far below the Healthy People 2010 goal of 50%.

Recent clinical trials have demonstrated that effective blood pressure control can be achieved in most patients with hypertension; however, for many patients this can only be accomplished with a combination of multiple antihypertensive drugs. ^{1,2,3} The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7), issued under the auspices of the National Heart, Lung, and Blood Pressure Institute in the United States, recommends that consideration be given to initiating treatment with two drugs in combination if the patient's blood pressure is more than 20/10 mmHg above goal (i.e., Stage 2 hypertension). ⁴ The primary objectives of this recommendation are to accelerate patients to goal and to avoid multiple drug titration steps and multiple patient visits.

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 Les Laboratoires Servier (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. In order to retain significant value from its scientific discoveries, XOMA initiated commercial operations in January 2012 through the licensing of U.S. commercial rights to Servier's ACEON (perindopril erbumine) and a patent-protected portfolio of product candidates.

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

Forward-Looking Statements

Certain statements contained in this press release including, but not limited to, statements related to anticipated ability to license the perindopril/amlodipine fixed-dose combination to a third-party, continued sales of approved products, and anticipated regulatory approval of unapproved product candidates, 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.

Footnotes

- 1. Cushman WC, Ford CE, Cutler JA, et al. Success and predictors of blood pressure control in diverse North American settings: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). J Clin Hypertens 2002;4:393-404.
- 2. Julius S, Kjeldsen SE, Weber M, et al. Outcomes in hypertensive subjects at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. Lancet 2004;363:2022-2031.
- 3. Sever PS, Dahlöf B, Poulter NR et al. Rationale, design, methods and baseline demography of participants of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT). J Hypertens 2001;19:1139-1147.
- 4. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC7 report. JAMA 2003;289:2560-2572.

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