

# XOMA Transfers Perindopril Franchise Rights to Symplmed

BERKELEY, Calif., July 3, 2013 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, announced today it has transferred U.S. development and commercialization rights to the perindopril franchise to Symplmed Pharmaceuticals, LLC ("Symplmed"). Under the terms of the agreement, XOMA will receive an equity position in Symplmed and up to double-digit royalties on sales of the fixed-dose combination ("FDC") containing perindopril arginine and amlodipine besylate, if it is approved by the U.S. Food and Drug Administration ("FDA"). Symplmed will, under a sublicense agreement, immediately assume U.S. marketing responsibilities for ACEON<sup>®</sup> (perindopril erbumine), and XOMA will continue to manage and be reimbursed for sales and distribution within its established commercial infrastructure.

Symplmed was founded by former XOMA employees, Erik Emerson and Jeffrey Feldstein, MD, who serve as Chief Executive Officer and Chief Medical Officer, respectively, and Dr. August J. Troendle. Both Mr. Emerson and Dr. Feldstein have significant experience developing and marketing FDA-approved cardiovascular therapeutics and have been directly involved with the ACEON commercialization activities. In addition, Mr. Emerson and Dr. Feldstein managed the 837-patient Phase 3 PATH trial (Perindopril Amlodipine for the Treatment of Hypertension), which demonstrated that the 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. Servier markets the FDC product, COVERAM®, in 91 countries outside the U.S. Symplmed intends to complete the New Drug Application for the FDC and submit it to the FDA for review by year-end 2013. Symplmed will be responsible for all future FDC development costs, and XOMA will have no further financial obligations related to the FDC product or Symplmed's operations.

"Our partner, Servier, and we recognize the importance of this valuable franchise. Erik and Jeff have demonstrated strong dedication to the perindopril franchise and are leaving XOMA to launch Symplmed and move the franchise forward in a focused manner. This structure provides XOMA the opportunity to share in their success, while retaining our focus on developing innovative therapeutic options for the specialist prescriber under the leadership of Tom Klein, our newly appointed Chief Commercial Officer," commented John Varian, Chief Executive Officer of XOMA. "The experience the XOMA team gained by establishing a commercial infrastructure backbone will serve the company well as we move closer to commercializing novel therapeutics discovered by XOMA's scientists."

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. <sup>1,2,3</sup> 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). <sup>4</sup> 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 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.

# **About Symplmed**

Symplmed Pharmaceuticals commercializes pharmaceutical products with a focus on helping patients achieve treatment goals. Symplmed's pharmaceutical portfolio is anchored by the perindopril franchise, which has generated powerful clinical outcomes data from over 54,000 patients participating in 7 landmark trials. In order to better serve physicians, patients and payers, Symplmed has developed a patent pending technology, known as DyrctAxess. Symplmed's combination of technology and well-established clinical products provide the opportunity to commercialize more efficiently with a stronger focus on patient, physician and payer benefits.

For more information on Symplmed and DyrctAxess, please refer to <a href="www.symplmed.com">www.symplmed.com</a>.

# **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 2012 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 anticipated ability to license the perindopril/amlodipine fixed-dose combination to a third-party, continued sales of approved products, the success of Symplmed's business, 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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