Savient Receives Positive CHMP Opinion for KRYSTEXXA(R) Approval in the EU

If Granted a Marketing Authorization, KRYSTEXXA Will Address a Significant Unmet Need for Certain Patients with Refractory Chronic Gout in the European Union

BRIDGEWATER, N.J. and DUBLIN, Oct. 19, 2012 /PRNewswire/ -- Savient Pharmaceuticals, Inc. (NASDAQ: SVNT) and its wholly owned subsidiary, Savient Pharma Ireland Limited, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has completed its scientific assessment and has issued a positive opinion recommending approval of a marketing authorization in the European Union for KRYSTEXXA® (pegloticase) for the treatment of severe debilitating chronic tophaceous gout in adult patients who may also have erosive joint involvement and who have failed to normalize serum uric acid with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these medicines are contraindicated. This opinion will be transmitted to the European Commission, which has the authority for granting marketing authorizations in the EU. If such marketing authorization is granted, KRYSTEXXA will address a significant unmet medical need for certain patients with refractory chronic gout (RCG) in the European Union.

"This is a major milestone in our ongoing commitment to advance care for patients who suffer from this burdensome and debilitating disease. The CHMP's positive opinion marks an important step forward in addressing the significant unmet medical need that currently exists in Europe; and we look forward to receiving the final decision from the European Commission," said Louis Ferrari, President and Chief Executive Officer of Savient.

The positive CHMP opinion was based upon a detailed evaluation of the Marketing Authorization Application (MAA), which included safety and efficacy data from Savient's two pivotal Phase III studies, and a long-term open label extension study of KRYSTEXXA, as well as non-clinical and chemistry, manufacturing and control information.

ABOUT REFRACTORY CHRONIC GOUT

Symptoms of gout are caused by the body's response to the presence of high uric acid levels which can lead to the formation of uric acid crystals in the joints and surrounding tissue, which form when uric acid levels in the blood are elevated (a condition called hyperuricemia). The longer hyperuricemia persists, the higher the risk of developing gout. Symptoms of gout may include painful flares, pain or swelling in the joints (known as "gouty arthritis") or deposits of uric acid crystals under the skin, called "tophi." Although most cases of gout can be controlled with conventional urate-lowering therapy, when uric acid levels remain high and symptoms persist despite treatment efforts, chronic gout may be defined as refractory.

In cases of severe debilitating chronic tophaceous gout, these symptoms have a major influence on patient health-related quality of life due to the frequency and severity of episodes and the recurrent pain, and can also lead to disfigurement associated with this condition.

ABOUT KRYSTEXXA®

KRYSTEXXA® (pegloticase) is a PEGylated uric acid specific enzyme for administration by intravenous infusion. The active substance pegloticase is a covalent conjugate of uricase produced by a genetically modified strain of Escherichia coli and monomethoxypoly(ethylene glycol). Pegloticase catalyzes the conversion of uric acid into the inert highly water-soluble metabolite allantoin, with hydrogen peroxide and carbon dioxide as oxidative by-products. Allantoin is eliminated by renal excretion, thereby rapidly lowering serum uric acid. This induces a concentration gradient between serum uric acid and tissue/joints deposits of monosodium urate resulting in the migration of urate from tissues/joints, which makes it accessible to conversion to allantoin.

IMPORTANT SAFETY INFORMATION ABOUT TREATMENT WITH KRYSTEXXA®

KRYSTEXXA® is not indicated for the treatment of asymptomatic hyperuricemia. Patients who are at risk of having a condition known as G6PD deficiency should be screened by their physician prior to starting therapy with KRYSTEXXA.

Discontinue oral urate-lowering therapies before instituting KRYSTEXXA and do not institute oral urate-lowering therapy while the patient is on KRYSTEXXA therapy.

Possible side effects of KRYSTEXXA include:

- Anaphylaxis which occurred in some patients treated with KRYSTEXXA. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis. Patients should be pre-medicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA.
- Infusion reactions which occurred in some patients treated with KRYSTEXXA. The risk of an infusion reaction is higher in patients who have lost therapeutic response. Because the risk of infusion reactions is higher in patients who lose therapeutic response to KRYSTEXXA, monitor serum uric acid before each infusion and consider discontinuing treatment if levels rise above 6mg/dL, particularly when two consecutive levels above 6 mg/dL are observed.
- As with other urate-lowering therapies, an increase in gout flares was seen in some patients treated with KRYSTEXXA. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion. Patients receiving re-treatment may be at increased risk for anaphylaxis and infusion reactions and should be monitored carefully.

The most commonly reported serious adverse reactions are anaphylaxis, infusion reactions and gout flares. Most common adverse reactions: gout flares (77%), infusion reactions (26%), nausea (12%), contusion or ecchymosis (11%), nasopharyngitis (7%), constipation (6%), chest pain (6%), anaphylaxis (5%), and vomiting (5%).

In the United States, the Full Prescribing Information and Medication Guide is available at http://www.krystexxa.com/.

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and commercializing KRYSTEXXA® (pegloticase) for the treatment of chronic gout in adult patients refractory to conventional therapy. **Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA and its uses from Duke University ("Duke") and Mountain View Pharmaceuticals, Inc. ("MVP"). Duke developed the recombinant uricase enzyme and MVP developed the PEGylation technology used in the manufacture of KRYSTEXXA. MVP and Duke have been granted U.S. and foreign patents disclosing and claiming the licensed technology** and, in addition, Savient owns or co-owns U.S. and foreign patents and patent applications, which collectively form a broad portfolio of patents covering the composition, manufacture and methods of use and administration of KRYSTEXXA. Savient also supplies Oxandrin® (oxandrolone tablets, USP) CIII in the U.S. For more information, please visit the Company's website at www.savient.com.

FORWARD-LOOKING STATEMENTS

All statements other than statements of historical facts included in this press release are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding the safety and efficacy of KRYSTEXXA®, the potential to expand the clinical utility of KRYSTEXXA, status of our KRYSTEXXA marketing efforts in the US and additional plans related thereto both in the US and EU, market demand and reimbursement for KRYSTEXXA, our view of the refractory chronic gout (RCG) market size in the US and EU, and our market expansion plans outside the US and EU are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate. Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to, developments that may arise in the litigation with Tang Capital; our ability to commercialize KRYSTEXXA; the risk that the market for KRYSTEXXA is smaller than we have anticipated; our ability to retain the personnel; our reliance on third parties to manufacture KRYSTEXXA; competition from existing therapies and therapies that are currently under development, including therapies that are significantly less expensive than KRYSTEXXA; our ability to gain market acceptance for KRYSTEXXA among physicians, patients, health care payers and others in the medical community; whether we are able to obtain financing, if needed; economic, political and other risks associated with foreign operations; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry and other important factors and other important factors set forth more fully in our reports filed with the Securities and Exchange Commission, to which investors are referred for further information. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date of publication of this press release. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.

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