FDA Approves KRYSTEXXA(TM) (pegloticase) for the Treatment of Chronic Gout in Adult Patients Refractory to Conventional Therapy

--First FDA Approved Treatment to Show Significant Clinical Improvement within Six Months of Therapy -- Savient to Host Conference Call on September 15, 2010 at 8:00 a.m. Eastern Time

EAST BRUNSWICK, N.J., Sept 14, 2010 /PRNewswire via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced that the U.S. Food and Drug Administration (FDA) has approved KRYSTEXXA(TM) (pegloticase), a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Chronic gout that is refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

"KRYSTEXXA is the first-ever and only treatment approved by the FDA for adult patients who suffer with chronic gout that is refractory to conventional therapy," said Paul Hamelin, R.Ph., President of Savient Pharmaceuticals. "The clinical data have demonstrated that many patients treated with KRYSTEXXA 8 mg administered every two weeks can experience within six months of treatment significant positive clinical improvement reversing the course of this severe, crippling and debilitating disease. A statistically significant proportion of patients in our pivotal clinical trials achieved a lowering of their serum uric acid level to a mean of 0.7 mg/dL and achieved a complete response for the resolution of tophi within the first six months of therapy. We believe that the approval of KRYSTEXXA is a significant step towards realizing our mission of transforming the lives of the patients in the U.S. suffering with chronic gout refractory to conventional therapy, as many of them finally have a treatment that gives them hope of reversing this severely debilitating disease."

Savient expects KRYSTEXXA to be available by prescription in the U.S. later this year and believes it is well advanced in its preparations for the U.S. launch of KRYSTEXXA. Specific timing for the launch of KRYSTEXXA will be determined within the context of the Company's commercialization plan and by the progress and status of the Company's efforts to pursue a strategic transaction for the sale of Savient. KRYSTEXXA was granted an Orphan Drug designation by the FDA in 2001 that the Company expects will provide the drug seven years of orphan drug market exclusivity. The composition, manufacture and methods of use and administration of KRYSTEXXA are also the subject of a broad portfolio of patents and patent applications that the Company expects will provide protection into 2026.

About the Pivotal Clinical Trial Results Supporting FDA Approval

The recommended dose and regimen of KRYSTEXXA for adult patients is 8 mg given as an intravenous infusion every two weeks. KRYSTEXXA should not be administered as an intravenous push or bolus.

The efficacy and safety of KRYSTEXXA were studied in patients with chronic gout refractory to conventional therapy in two replicate, multicenter, randomized, double-blind, placebo-controlled clinical studies of six months duration. Patients were randomized to receive KRYSTEXXA every 2 weeks or every 4 weeks or placebo in a 2:2:1 ratio. The primary endpoint in both trials was the proportion of patients who achieved plasma uric acid (PUA) less than 6 mg/dL for at least 80% of the time during month 3 and month 6. The data in both clinical studies demonstrated that a greater proportion of patients treated with KRYSTEXXA every 2 weeks achieved urate lowering to below 6 mg/dL than patients receiving placebo. During the first six months of treatment, 47% ($P<0.001$) and 38% ($P<0.001$) of patients in the KRYSTEXXA arms of the two clinical studies achieved the primary efficacy endpoint, compared with 0% of patients in the placebo arm.

The effect of treatment with KRYSTEXXA on tophi was a secondary efficacy endpoint of the clinical studies and was assessed using standardized digital photography, image analysis and a central reader blinded to treatment assignment. Tophi are deposits of monosodium urate crystals in people with longstanding high levels of uric acid in the blood and are commonly seen in conjunction with gout. Seventy one percent (71%) of patients had baseline tophi. A pooled analysis of data from both clinical studies at month 6 demonstrated that 45% ($P<0.02$) of patients with tophi treated with KRYSTEXXA every 2 weeks achieved a complete response, defined as 100% resolution of at least one target tophus, no new tophus appearing and no single tophus showing progression, compared to 8% of patients receiving placebo.

Important Safety Information about Treatment with KRYSTEXXA

The full prescribing information for KRYSTEXXA contains a boxed warning regarding anaphylaxis and infusion reactions. Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. KRYSTEXXA should only be administered in a healthcare setting and by healthcare providers prepared to manage anaphylaxis. Patients being treated with KRYSTEXXA should be pre-medicated with antihistamines and corticosteroids prior to infusion and should be closely monitored for an appropriate period of time after administration. Since the risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response, patients' serum uric acid levels should be monitored prior to infusions and discontinuation of treatment should be considered if such levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

KRYSTEXXA is contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency due to the risk of hemolysis and methemoglobinemia. It is recommended that patients at higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) be screened for G6PD deficiency before starting KRYSTEXXA.

As with most uric acid lowering therapeutics, an increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued, however, gout flare prophylaxis (i.e., non-steroidal anti-inflammatory drugs [NSAID] or colchicine upon initiation of treatment) is recommended for at least the first 6 months of therapy unless medically contraindicated or not tolerated. In months 1 through 3, gout flares occurred in 74% of patients taking KRYSTEXXA every 2 weeks and in 51% of patients who received placebo. During the next three months of therapy (months 4 through 6), gout flares occurred in 41% of patients treated with KRYSTEXXA every 2 weeks and in 67% of patients who received placebo.

KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. As such, caution should be exercised when using KRYSTEXXA in patients who have congestive heart failure and such patients should be monitored closely following infusion.

As with all therapeutic proteins, there is a potential for immunogenicity with KRYSTEXXA. Due to this, patients receiving re-treatment may be at increased risk of infusion reactions and should be monitored carefully for such reactions. The impact of anti-PEG antibodies on patients' responses to other PEG-containing therapeutics is unknown.

The most commonly reported adverse reactions (occurring in at least 5% of KRYSTEXXA-treated patients) were gout flare, infusion reaction, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Savient will conduct a post-approval observational safety study in 500 patients treated for one year to further evaluate the frequency and severity of infusion reactions, anaphylaxis and immune complex-related adverse events, and to identify serious adverse events associated with KRYSTEXXA therapy.

Savient has worked with the FDA to create a Risk Evaluation and Mitigation Strategy (REMS) program to help physicians, healthcare providers and patients make treatment decisions for adults who suffer with chronic gout that is refractory to conventional therapy based on the KRYSTEXXA comprehensive and current benefit:risk information. The KRYSTEXXA REMS program consists of a communication plan for health care providers and a medication guide for patients.

Full prescribing information for KRYSTEXXA can be found at www.krystexxa.com.

Conference Call Information

Savient's management team will host a live conference call and webcast on September 15, 2010 at 8:00 a.m Eastern Time. To participate by telephone, please dial (888) 357-3694 (Domestic) or (973) 890-8276 (International). The conference identification number is 11498851. The live and archived webcast can be accessed on the investor relations section of the Savient website at www.savient.com. Please log on to Savient's website fifteen minutes prior to the start of the call to ensure adequate time for any downloads that may be necessary.

A telephone replay will be available from 12:00 p.m. Eastern Time on September 15, 2010 through 11:59 p.m. Eastern Time on September 22, 2010 by dialing (800) 642-1687 (Domestic) or (706) 645-9291 (International) and entering conference ID number 11498851.

About KRYSTEXXA(TM)

KRYSTEXXA(TM)(pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia. **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. Full prescribing information for KRYSTEXXA can be found at www.krystexxa.com.

About Savient Pharmaceuticals, Inc.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing KRYSTEXXA(TM) (pegloticase) for the treatment of chronic gout in patients refractory to conventional therapy. Savient also manufactures and supplies Oxandrin(R) (oxandrolone tablets, USP) CIII in the U.S.

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 likelihood of our being able to identify an appropriate strategic transaction for the sale of Savient, the clinical benefits of KRYSTEXXA(TM), the availability of KRYSTEXXA for prescription, our preparations for and the timing of launch for KRYSTEXXA, our plans to conduct a post-approval observational safety study for KRYSTEXXA, the Risk Evaluation and Mitigation Strategy (REMS) program for KRYSTEXXA and orphan drug market exclusivity and patent protection for KRYSTEXXA 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, whether we are able to find a buyer for Savient, whether we are able to reach agreement on a definitive acquisition agreement with such a buyer, whether the conditions to closing in any such definitive agreement are satisfied, reliance on third parties to manufacture, market and distribute many of our products; our ability to commercialize KRYSTEXXA; our ability to gain market acceptance for KRYSTEXXA among physicians, patients, health care payors 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 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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