Savient Pharmaceuticals Completes Puricase(R) Phase 3 Studies for Treatment-Failure Gout

EAST BRUNSWICK, N.J., Oct 16, 2007 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ: SVNT) announced today the completion of the in-life portion of its two pivotal Phase 3 clinical trials for Puricase(R) (pegloticase) in patients with treatment-failure gout, an orphan indication. Puricase is a pegylated recombinant mammalian urate oxidase that is being developed to control hyperuricemia and its clinical consequences in patients for whom conventional therapy is contraindicated or has been ineffective. At this time there is no alternative therapeutic option for the management of treatment-failure gout patients other than symptomatic relief.

"The completion of the in-life portion of the Phase 3 studies is an important milestone for both the Company and for treatment-failure gout patients," commented Christopher Clement, President and Chief Executive Officer. "We believe the level of patient commitment during the study period and the high rate of enrollment in our open label extension protocol underscores the critical void in treatment options for patients who suffer from this condition that Puricase may uniquely address. As we move forward over the next several weeks, we will focus our resources on assembling and analyzing the Phase 3 data. We remain on track to make our next public statement regarding the Phase 3 studies when we report top-line results in December."

The two Phase 3 pivotal trials assessed the safety and efficacy of a six-month course of Puricase therapy in patients with treatment-failure gout, under the auspices of a Special Protocol Assessment from the U.S. Food and Drug Administration. The two Phase 3 studies included over 200 patients at more than 50 clinical sites across the United States, Canada and Mexico. The studies consisted of two replicate protocols; each a randomized, double-blinded, placebo controlled study of six months duration in which Puricase or placebo was administered by a two-hour intravenous infusion. Approximately 110 patients were randomized into each study and a total of 212 patients received at least one dose of study medication (Puricase or placebo). Each study had three arms: placebo, Puricase 8 mg administered every two weeks, or Puricase 8 mg administered every four weeks. In order to maintain blind to the treatment assignment, all patients received an intravenous infusion every two weeks.

On a rolling basis, as patients completed their participation in the Phase 3 studies, all completed patients were invited to enroll in a twelve-month open label extension protocol offering a choice among three options: observation, in which patients could use any gout drug except Puricase; Puricase 8 mg every two weeks; or Puricase 8mg every four weeks. After six months in the open label extension protocol, patients are allowed to switch arms. Nearly all patients who completed the Phase 3 trials have opted to enroll in the open label extension, selecting either the every two week, or the every four week 8 mg Puricase treatment arms. The open label extension protocol is ongoing. A follow-on open label extension protocol for another twelve months is planned, regardless of whether patients choose to continue to receive Puricase or whether they enter the observation arm of the study.

"We are very pleased with the completion of the Phase 3 program and we look forward to studying the data set," said Zeb Horowitz, M.D., Sr. Vice President and Chief Medical Officer. "In parallel, we will continue to closely observe our patients in the open label extension protocol to learn as much as we can about the safety and efficacy of long term use of Puricase, and to monitor the clinical outcomes for patients who have chosen to discontinue Puricase dose administration. It is our hope that if clinical benefit beyond control of uric acid has been attained through Puricase treatment, such clinical benefit could prove to be durable. This would be a wonderful outcome for patients who currently have limited or no therapeutic options."

Separately, the Company announced that pegloticase has become the official generic name for Puricase assigned by the USAN Council, replacing the previously used name of PEG-uricase.

ABOUT GOUT

According to the National Institutes of Health, gout accounts for approximately 5 percent of all cases of arthritis and is one of the most painful rheumatic diseases. There are approximately 5 million Americans that suffer with gout, and of that, there are approximately 25,000-100,000 treatment-failure patients for whom conventional therapy is contraindicated or has been ineffective. Gout results from deposits of needle-like crystals of uric acid in connective tissue and in the joints. These

deposits lead to inflammatory arthritis, which causes joint swelling, redness, heat, pain, and stiffness and damage to the affected joints. In patients for whom conventional therapy is contraindicated or has been ineffective, the disease can become chronic, progressively worsen and cause debilitating flares of pain and swelling, development of tophi, loss of joint functionality, renal dysfunction and/or kidney stones.

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals is a biopharmaceutical company engaged in developing and distributing pharmaceutical products that target unmet medical needs in both niche and broader markets. The Company's lead product development candidate, Puricase(R) (pegloticase) for treatment-failure gout, has reported positive Phase 1 and 2 clinical data. Patient dosing in the Phase 3 clinical studies began in June 2006; patient enrollment was completed in March 2007; and the Phase 3 clinical studies were completed in October 2007. Savient's experienced management team is committed to advancing its pipeline and expanding its product portfolio by in-licensing late-stage compounds and exploring co-promotion and co-development opportunities that fit the Company's expertise in specialty pharmaceuticals and biopharmaceuticals with an initial focus in rheumatology. Savient also manufactures and supplies Oxandrin(R) (oxandrolone tablets, USP) CIII in the U.S. **Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc**. Further information on Savient can be accessed by visiting: http://www.savient.com.

FORWARD-LOOKING LANGUAGE

This news release contains 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 Savient's control. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions help identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements involve substantial risks and uncertainties and are based on current expectations, assumptions, estimates and projections about Savient's business and the biopharmaceutical and specialty pharmaceutical industries in which Savient operates. Such risks and uncertainties include, but are not limited to, Savient's stock price and market conditions, delay or failure in developing Puricase(R) and other product candidates, difficulties of expanding Savient's product portfolio through in-licensing, introduction of generic competition for Oxandrin(R), fluctuations in buying patterns of wholesalers, potential future returns of Oxandrin or other products, Savient's continuing to incur substantial net losses for the foreseeable future, difficulties in obtaining financing, potential development of alternative technologies or more effective products by competitors, reliance on third-parties to manufacture, market and distribute many of Savient's products, economic, political and other risks associated with foreign operations, risks of maintaining protection for Savient's intellectual property, risks of an adverse determination in ongoing or future intellectual property litigation, and risks associated with stringent government regulation of the biopharmaceutical industry. Savient may not actually achieve the plans, intentions or expectations disclosed in Savient's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that Savient makes. Stockholders should not place undue reliance on the forward-looking statements, which speak only as to the date of this press release. Savient's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that Savient may make. Except as required by law, Savient does not assume any obligation to update any forward-looking statements.

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