Puricase(R) (pegloticase) Meets Pre-Specified Primary Efficacy Endpoint in Two Replicate Phase 3 Studies

Pooled Analysis of Secondary Endpoints Shows Statistical Significance in the Reduction of Gout Tophi and Trends in Improvement of Other Secondary Clinical Measures

EAST BRUNSWICK, N.J., Dec 13, 2007 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ:SVNT) is pleased to announce statistically significant positive results for the Puricase (pegloticase) Phase 3 program in treatment-failure gout patients, which has been conducted under the auspices of a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). Puricase 8 mg administered by a two-hour intravenous infusion every two weeks or every four weeks met the primary efficacy endpoint in the Intent to Treat (ITT) and Per Protocol analyses in each of two replicate, six-month Phase 3 clinical trials, (the studies are termed, Gout Outcomes and Urate Therapy, GOUT 1 and GOUT 2). The primary efficacy endpoint specified under the Special Protocol Assessment was normalization of plasma uric acid during months three and six of the clinical trials. Moreover, the every two week dose group also attained statistical significance for the a priori definition of reduction of gout tophi in the pre-specified pooled analysis, while the every four week dose group revealed a favorable numerical trend for this secondary endpoint. Analysis of other secondary efficacy endpoints also showed favorable numerical trends in one or both pegloticase dose groups. There were no expedited reports of serious adverse events during the Phase 3 trials.

The treatment-failure gout population is characterized by very severe gout symptoms such as frequent crippling gout flares and gout tophi representing progressive disease, as well as a very high degree of co-morbidity such as hypertension, cardiovascular disease, diabetes, kidney disease, obesity, osteoarthritis and, medical histories of multiple drug hypersensitivities and diverse environmental allergies. The combination of advanced disease progression, important co-morbidities requiring polypharmacy, and multiple allergic histories makes this population exceptionally difficult to treat in clinical practice today.

"Our initial impression of the pegloticase Phase 3 top line data is very favorable," said Zeb Horowitz, MD., Sr. Vice President and Chief Medical Officer. "We believe that the Savient GOUT studies are very important in two regards. We believe that the Phase 3 data show that pegloticase has the potential to be the first effective therapeutic option to control uric acid in treatment-failure gout patients. Second, we believe that our assessment of tophi in GOUT 1 and GOUT 2 by digital photography and image analysis uniquely demonstrates the attainment of a statistically significant and medically relevant clinical outcome, in this most difficult to treat gout patient population."

The Phase 3 results confirm that the pre-specified primary efficacy endpoint for both pegloticase treatment arms was met in each placebo-controlled study in the ITT analysis. In the ITT analysis of the primary endpoint all discontinued patients were imputed as non-responders, making this a very conservative assessment of therapeutic response. The mean responder rate for the every two week dose group pooled across both studies was 42% (p is less than 0.001) and the mean responder rate for the every four week dose group was 35% (p is less than 0.001). In the Per Protocol analysis the responder rates were higher: every two week was 61% (p is less than 0.001), and every four week was 50% (p is less than 0.001). The placebo responder rate was zero in both trials for both the ITT and Per Protocol analyses.

We believe that the most clinically important of the secondary efficacy outcomes assessed in these studies was the effect of pegloticase on gout tophi. The every two week dose arm attained statistical significance in the pre-specified pooled analysis

(p equal to 0.005) for the elimination of gout tophi (complete elimination of at least one tophus and no new tophi), whereas the every four week dose group did not attain statistical significance.

Although many secondary efficacy endpoints were explored in this Phase 3 program, we have not yet finished analyzing this aspect of the data base, and thus cannot include these in the top line results. It appears that in some statistical analyses significance was observed and in others, favorable numerical trends were noted.

As anticipated, patients in both dose arms showed an increase in gout flares as compared to placebo only in the early study period. However, in the last three months of the study period both pegloticase dose arms showed reduced gout flare frequency compared to the first three months, but not attaining statistical significance relative to placebo. The numerical trend toward reduction of gout flare frequency below the placebo rate is considered favorable. Despite the pre-study history of frequent severe gout flares and the evidence that pegloticase treatment, as any other uric acid lowering treatment, initially induces gout flares in susceptible patients, unlike other uric acid lowering therapies the increase in gout flares induced by pegloticase appears to persist only during the early portion of the treatment period.

"We believe that achieving positive results for controlling uric acid level and elimination of gout tophi in this difficult to treat gout population indicates that pegloticase provides a clinically important advancement in managing hyperuricemia in patients with treatment-failure gout," commented Christopher Clement, President and Chief Executive Officer of Savient. "New approaches are long over due for patients who suffer from this painful and potentially crippling disease. We estimate that there are 25,000 to 100,000 treatment failure patients in the United States and currently these patients have no alternative therapeutic options other than symptomatic relief. If approved by the FDA, pegloticase would be the first new therapy for treating this disease in over forty years, and the only treatment to demonstrate control of plasma uric acid in the treatment-failure patients."

Throughout the study period patient safety was assessed by frequent review of adverse events and laboratory findings, and real-time assessment of serious adverse events (SAEs). No signal for adverse safety findings has appeared in preliminary analysis of the unblinded data set, except for the occurrence of infusion-related adverse events.

Three deaths occurred in the treatment phase of the pooled ITT population, including death in one patient who voluntarily withdrew consent for renal dialysis. (A fourth patient, not included in the ITT population, died after completing the study when she elected to withdraw from antibiotic treatment of MRSA sepsis.) None of the patient deaths appear to be causally related to pegloticase treatment, as judged by the clinical investigators and Savient medical monitors.

In the pooled ITT population, infusion reactions occurred at some time during the studies in 56 pegloticase treated patients (33%): 22 were in the every two week dose group and 34 were in the every four week dose group. Two placebo patients (5%) experienced an infusion reaction. Typically, an infusion reaction involved back or chest pain, muscle cramps, sweating, and flushing. Infusion reactions were most often mild or moderate in severity and usually controlled by slowing the infusion rate and/or giving diphenhydramine. However, infusion reactions could be severe, especially in terms of chest or back pain. Nineteen patients (11% of pegloticase treated patients) experienced an infusion reaction termed serious or severe: 6 in the every two week group and 13 in the every four week group. Sixteen patients (9%) reported infusion reaction as the reason for withdrawal from the studies, 8 patients in each of the every two week and every four week dose groups.

The occurrence of infusion reactions as a proportion of total infusions administered in the pooled ITT population is another way to view this adverse event representing lack of tolerability. The number of infusion reactions as a proportion of all

infusions administered was 5% (43/851) for the every two week dose group, 8% (70/846) for the every four week dose group, and 0.8 % (4/502) for the placebo group.

Infusion reactions that involved symptoms of transient lingual swelling, peri-oral edema, wheezing, or hypotension occurred in two patients in each treatment group, or 2.4% of patients who were exposed to pegloticase. Only one of the four patients was administered epinephrine and two were administered corticosteroids. All patients recovered fully, some very rapidly and others within approximately 60 minutes. None of the four were re-challenged and all withdrew. Although we continue to have uncertainty as to whether some or all of these patients actually experienced an anaphylactic reaction to the drug, these symptoms have been interpreted to represent anaphylaxis in other drug programs and may be interpreted so in the GOUT trials as well.

In one circumstance, a multiply allergic patient developed urticaria five days after pegloticase dose administration. Although suggestive of delayed type hypersensitivity, the multiply allergic condition of this patient and other factors makes assigning causality to any level of certainty difficult.

"We believe that the statistically sound and clinically meaningful results of the Phase 3 program in this difficult to treat gout population, most of whom have severe, progressive disease, are tremendously encouraging," said Dr. Horowitz. "We embarked on these gout trials using new methods and new endpoints in a population for whom no therapy is currently available. Both dose arms met the test of statistical significance for the normalization of plasma uric acid in both trials in the ITT and Per Protocol analyses. Moreover, we believe that the success of the pre-specified pooled analysis for the every two week dose group for the effect on gout tophi is of great importance, because the presence of gout tophi is considered to be a hallmark of advanced disease progression.

"Our early analysis of safety results appears to be favorable, with recognition that some patients may not be able to tolerate pegloticase infusions due to unacceptably severe infusion reactions," continued Dr. Horowitz. "We believe that this safety risk is manageable in the clinical practice setting, as it is for other biologics, because it is anticipated that only qualified specialists and trained infusion nurses will be involved in the administration of pegloticase. Still pending are the extensive and complex analyses of immunological assessments. In summary, we believe that the preliminary top line results indicate a favorable risk-benefit ratio justifying the use of pegloticase to control hyperuricemia and potentially to control the clinical consequences of hyperuricemia in the treatment-failure gout population."

The company plans to file a Biologics Licenses Applications (BLA) with the FDA in 2008 based on the positive results from its Phase 3 trials, following a pre-BLA meeting with the reviewing Division.

ABOUT PURICASE (pegloticase)

Puricase (pegloticase) is a pegylated recombinant mammalian urate oxidase, in development to control hyperuricemia and its clinical consequences in patients for whom conventional therapy is contraindicated or has been ineffective. The two Phase 3 pivotal trials assessed the safety and efficacy of a six-month course of pegloticase therapy in patients with treatment-failure gout, under the auspices of a Special Protocol Assessment from the U.S. Food and Drug Administration. **Savient has licensed worldwide rights to the technology related to Puricase (pegloticase) from Duke University and Mountain View Pharmaceuticals, Inc. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

ABOUT THE TREATMENT-FAILURE GOUT POPULATION

Approximately three to five-million Americans suffer from gout, many of whom experience only limited success in the long term management of their painful symptoms. Within this group, we estimate that allopurinol, the mainstay of therapy for control of uric acid, is contraindicated or has failed to achieve therapeutic success at appropriate dosages in approximately 25,000 to 100,000 patients, meaning that today tens of thousands of gout patients have no effective treatment option. It is for these treatment-failure patients that pegloticase potentially offers a unique benefit and for which the product has been granted Orphan drug designation.

CONFERENCE CALL

Savient Pharmaceuticals, Inc. Senior Management will hold a one-hour conference call to answer questions related to this announcement on December 13th, 2007 at 8:00 a.m. Eastern Time. Those interested in listening to the conference call live via the Internet may do so by visiting the Investor Relations section of Savient Pharmaceuticals' website at www.savientpharma.com. The webcast will be available for 14 days on the Company website beginning approximately one hour after the conclusion of the conference call.

A telephone replay will be available from 11:00 a.m. Eastern time on December 13th through December 23rd at 11:59 p.m. Eastern time by dialing (800) 642-1687 (domestic) or (706) 645-9291 (international) and entering conference ID number 27984783.

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 product development candidate, Puricase (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

It is important to note that in reporting these preliminary results the Company is reporting its views and opinions regarding the preliminary data and that the Company cannot forecast how the FDA or other regulatory authorities will view or consider the data upon review, or how any of the data set will be translated into label language, if approved. FDA typically conducts its own analyses from the original data sets and possibly may come to different conclusions than Savient has reached. Furthermore, the data reported here are preliminary data in as much as these are initial results, still to be extensively analyzed for possible inconsistencies and errors.

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 important 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. Forward-looking statements in this news release include, without limitation, statements regarding the results of Savient's two pivotal six month Phase 3 clinical trials for Puricase(R) (pegloticase), the filing of a Biologics License Application with the FDA and the absence of other therapies to treat gout. Important factors that may affect Savient's ability to achieve the matters addressed in these forward-looking statements include, but are not limited to, Savient's stock price and market conditions, delay or failure in developing Puricase (pegloticase) delay in achieving or failure to achieve FDA approval of Puricase (pegloticase), difficulties of expanding Savient's product portfolio through in-licensing, fluctuations in buying patterns of Oxandrin(R), 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 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, risks associated with stringent government regulation of the biopharmaceutical industry and the other risks discussed or referenced in our most recent annual report on Form 10-K, quarterly report on Form 10-Q and other current reports, each filed by Savient with the SEC. 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. Savient does not assume any obligation to update any forward-looking statements.

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