Savient Reports Favorable Interim Data from Puricase(R) (pegloticase) Open Label Extension Study

Continued Positive Data for Control of Hyperuricemia, Clinical Outcomes and Safety

EAST BRUNSWICK, N.J., May 07, 2008 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ: SVNT), today announced positive interim data from the ongoing pegloticase open label extension (OLE) to the Phase 3 pivotal trials in patients with treatment-failure gout. The interim results are based on the OLE data cut at the end of September 2007.

The OLE has 82 patients; 41 who elected to receive treatment with open-label pegloticase (8 mg) every two weeks and 41 patients who elected treatment every four weeks. The data set includes a small cohort of patients who have been treated with pegloticase continuously for at least 12 months since the beginning of the Phase 3 Study. The OLE utilizes the efficacy assessments and safety measures used in the Phase 3 and continues the practice of gout flare and infusion reaction prophylaxis.

The interim OLE analyses show that:

-- 100% of the patients who were responders for the control of plasma uric acid (PUA) in Phase 3 and who remained on or joined the every two week dosing group maintained normalization of plasma uric acid (PUA) throughout the OLE.

-- Approximately 70% of the patients who were responders for the control of PUA in Phase 3 and who were on or joined the every four week dosing group also maintained normalization of PUA throughout the OLE.

-- Approximately 25% of the patients who were non-responders for the control of PUA in Phase 3 attained PUA normalization in the OLE with nine months or more of continuous pegloticase treatment either every two or four weeks.

-- 31% of the patients who were non-responders for the resolution of gout tophi at the end of Phase 3 showed a complete response in the OLE, with additional patients showing a partial response for tophus resolution.

-- For patients in the OLE from Phase 3 pegloticase treated groups, a marked reduction in the occurrence of gout flares was observed in the OLE, such that only four gout flares were reported after month two in the every two week group and patients using pegloticase every two weeks for more than five months in the OLE no longer experienced any gout flares in subsequent months of participation.

-- Infusion reactions were experienced by 21% of patients and were similar to those of the Phase 3 in the kind of symptoms reported. The infusion reaction experience was largely benign, resulting in discontinuation in 8.5% of patients.

The interim OLE data supports the favorable safety experience observed across the two Phase 3 studies, and in the clinical development program taken as a whole. One patient death occurred in the interim OLE study period. This patient was a 54 year old woman with oxacillin resistant Staph aureus sepsis who was withdrawn from antibiotics by her family after suffering a massive cerebrovascular accident (or stroke) and brain death. Neither the clinical investigator, nor Savient medical monitors concluded that this patient's death was in anyway causally related to pegloticase treatment. As previously seen in the Phase 3 studies, we believe that the only adverse safety signal in the interim OLE data was the occurrence of infusion reactions, which resolved relatively quickly and have had no post-infusion adverse consequences.

"These interim OLE results provide valuable additional and strongly encouraging evidence of the safety and clinical benefit of pegloticase treatment for patients in the treatment failure gout population, patients for whom there is currently no effective treatment and who suffer from the most severe, debilitating and disabling aspects of this disease," stated Zeb Horowitz, M.D., Sr. VP and Chief Medical Officer. "The positive long term results shown with pegloticase treatment for normalization of uric acid, elimination of gout tophi, and evidence for the reduction or elimination of gout flares, we believe, can be termed a breakthrough for treatment failure gout patients. We believe that the strength and quality of this clinical evidence will be confirmed in the later more extensive cut of OLE data to be included in the BLA submission in September."

The data set to be used for the BLA submission later this year will include approximately 150 patients from the OLE, of which 80 to 90 patients will have been treated with pegloticase continuously for at least 12 months since the inception of Phase 3, with the balance of patients being treated for shorter durations in excess of 6 months.

"As we have stated before, we believe that pegloticase has the potential to change the paradigm of treatment available to the treatment-failure gout population," commented Christopher Clement, President and Chief Executive Officer of Savient. "Our successful pre-BLA meeting established a clear pathway for our BLA submission later this year. If approved by the FDA, we believe that pegloticase will be the first new therapy for treating this debilitating disease in over forty years and it may become the first therapy to control of the progression of the disease and potentially to induce a durable disease remission."

The company will host an investment community conference call beginning at 10:00 a.m. Eastern Time on May 8, 2008 regarding its financial results for the first quarter 2008, at which time a Company update regarding the interim OLE data and the Phase 3 immunogenicity results will also be presented.

ABOUT PURICASE(R) (pegloticase)

Puricase 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 exclusively licensed worldwide rights to the technology related to Puricase from Duke University and Mountain View Pharmaceuticals, Inc. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

The company previously reported that pegloticase had met the pre-specified primary efficacy endpoint of normalization of plasma uric acid for every two week and every four week dose administration, independently, in each of the two Phase 3 studies completed late last year. In addition, the 8 mg every two week dose arm attained statistical significance versus placebo in the pre-specified pooled analysis of the proportion of patients who had a "complete response" for the elimination of gout tophi, a secondary endpoint; and both the every two week and every four week treatment arms showed statistical significance versus placebo in the pre-specified pooled analysis for the reduction in the number of tender and swollen joints, reduction in the number of tender joints and improvement in Patient Reported Outcomes as measured by the Short Form-36 (SF-36) and the Health Assessment Questionnaire - Disability Index (HAQ-DI).

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.

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, 2 and 3 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. Pegloticase became the official generic name for Puricase assigned by the USAN Council replacing the previously used name of PEG-uricase. 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. 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 interim results from the ongoing pegloticase Open Label Extension (OLE) to the Phase 3 pivotal trials, 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, delay or failure in the further development of Puricase (pegloticase), delay in achieving or failure to achieve FDA approval of Puricase (pegloticase), Savient's stock price and market conditions, 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.

SVNT-G

SOURCE: Savient Pharmaceuticals, Inc.

Savient Pharmaceuticals, Inc.
Mary Coleman, Director, Investor Relations
732-418-9300
information@savient.com
or
Lippert/Heilshorn & Associates
Anne Marie Fields, 212-838-3777
afields@lhai.com