Savient Reports Additional Positive Trial Data for Secondary Endpoints from Puricase(R) (pegloticase) Phase 3 Studies

Achieved Statistical Significance in the Pre-Specified Pooled Analysis of Secondary Endpoints for the Treatment Effect on the Number of Tender and Swollen Joints and for Patient Reported Outcomes

EAST BRUNSWICK, N.J., Feb 04, 2008 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ:SVNT), today announced additional positive results for secondary efficacy endpoints in the two replicate Phase 3 studies for Puricase(R) (pegloticase) for treatment-failure gout. Results were favorable for the treatment effect on clinical outcomes assessed by the reduction in the number of tender and swollen joints, and in improvement in Patient Reported Outcomes (PRO) as measured by Short Form-36 (SF-36) and the Health Assessment Questionnaire - Disability Index (HAQ-DI). These endpoints were assessed in a pre-specified pooled analysis from the two replicate studies and are reported for the Intent-to-Treat population. The improvement reported in these outcomes was clinically meaningful as determined by the pre-specified definitions.

The company previously reported that pegloticase had met the pre-specified primary efficacy endpoint, i.e. normalization of plasma uric acid for every two week and every four week dose administration, independently, in each of the two Phase 3 studies. In addition, the 8 mg every two week dose arm attained statistical significance versus placebo in the pre-specified pooled analysis, a secondary endpoint, in the proportion of patients who had a "complete response" for the elimination of gout tophi. The treatment effect of pegloticase on gout flares, another secondary endpoint, was reported as a favorable numerical trend in both treatment arms versus placebo, but neither treatment arm attained significance. The assessment of safety across the two Phase 3 studies was reported to be favorable and to have shown that the only adverse safety signal was the occurrence of infusion reactions. Seven patients (2/85 in the Q2 week arms, 5/84 in the Q4 week arms) had a total of 11 severe infusion reactions (muscle cramps, back or chest pain). Approximately 25 percent of all patients in the Q2 and Q4 treatment arms experienced a mild or moderate infusion reaction.

Following on this previously reported data, additional analysis showed statistical significance for both the every two week and every four week treatment arms versus placebo was achieved for:

-- a reduction in the number of tender and swollen joints

-- a reduction in the number of tender joints

-- an improvement in the clinician's global assessment (a 10 cm Visual Analog Scale)

For both treatment groups, the degree of improvement was greater for patients defined as plasma uric acid responders than for non-responders, but uric acid non-responders appeared to show improvement versus placebo as well. Further analysis of this finding is ongoing.

Two Patient Reported Outcomes instruments were employed in the pegloticase program, Short Form-36 (SF-36) and the Health Assessment Questionnaire - Disability Index (HAQ-DI), which have been used extensively in Rheumatology studies to assess clinically meaningful change in various rheumatic diseases. The results of the Phase 3 trials show that in the pre-specified pooled analysis, both treatment arms attained statistical significance for improvement versus placebo for the SF-36 physical component scores. The Arthritis-Specific Health Index form SF-36 also demonstrated statistically significant

improvement versus placebo for both treatment arms and again showed that even the plasma uric acid non-responders had improvement versus placebo. The SF-36 bodily pain scale also demonstrated statistical significance for both treatment arms versus placebo and also showed that the plasma uric acid non-responders appeared to improve but only about half as well as the responders.

The results of the HAQ-DI assessment on arthritis pain showed statistically significant improvement versus placebo for the Q2 week dose group. The patient's own assessment of their overall functioning, a component of the HAQ-DI, showed that both treatment arms attained statistically significant improvement versus placebo.

"These results provide valuable evidence of clinical benefit in our upcoming regulatory submissions and are expected to be presented in full detail in future scientific forums and in peer-reviewed publications," stated Zeb Horowitz, M.D., Sr. VP and Chief Medical Officer. "The strength of the evidence from the two GOUT trials has the potential to change the way physicians and patients view treatment-failure gout, a view currently centered almost exclusively on the unsuccessful control of uric acid and the acute symptomatic relief of painful gout flares, gradually leading to increasingly advanced disease. In light of the pegloticase data, gout treatment-failure patients and their physicians have reason to hope for a better treatment option."

The company is scheduled to have a pre-BLA meeting with the reviewing division of the U.S. Food and Drug Administration (FDA) on April 17, 2008 and plans to file the BLA with the FDA as soon as practicable following the pre-BLA meeting based on the positive results from its Phase 3 trials.

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 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.**

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 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.

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