Savient's Pegloticase Data in Treatment-Failure Gout Patients Presented at 72nd Annual Meeting of the American College of Rheumatology Conference

EAST BRUNSWICK, N.J., Oct 27, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Phase 3 and Open Label Extension Results Support Efficacy and Safety of Pegloticase

Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced that data from its pegloticase pivotal clinical studies in treatment-failure gout (TFG) patients was presented at scientific sessions during the annual meeting of the American College of Rheumatology (ACR). Four presentations focused on results from the pegloticase double blind placebo controlled Phase 3 pivotal studies. Data from the interim results of the uncontrolled open label extension (OLE) study were included as well. The data presented at the sessions extended the positive clinical results previously reported by the Company and further demonstrated the safety and efficacy of this novel biological drug in treatment for up to one year or longer. The presentations included results and analyses in three areas not previously discussed that included the effect of pegloticase on gout tophi, gout flares, and the immune response to pegloticase in patients with long-term treatment.

The results from the OLE study were consistent with findings from the Phase 3 studies, both of which met the primary endpoint relating to the normalization of plasma uric acid, for pegloticase 8 mg intravenous infusion every 2 weeks or every 4 weeks. A substantial subset of patients who completed the Phase 3 clinical trials and enrolled in the OLE continued to show improvements in the resolution of their signs and symptoms of treatment-failure gout with continuing pegloticase treatment, extending the positive clinical results seen in Phase 3. The two clinical efficacy endpoints of most interest, gout flares and gout tophi, showed an increasing proportion of patients with favorable response over time. The results of the pivotal Phase 3 studies and the interim data set from the OLE with 101 patients with at least 12 months of continuous pegloticase treatment, will be included in the Biologics License Application (BLA) that the Company plans to file with the Food Drug Administration (FDA) by the end of the month.

"The results from these studies represent hope for treatment-failure gout patients, as defined by our clinical program," said Dr. Zeb Horowitz, Chief Medical Officer for Savient. "Many of these patients have suffered from debilitating, sometimes crippling gout symptoms for many years along with serious co-morbidities and are considered to be difficult to treat. Currently, there are no alternative treatment options available for these patients. The information presented this week from our pegloticase studies further demonstrate a compelling treatment effect not only for the control of uric acid, but more importantly for the amelioration of the signs and symptoms of disease. If approved, pegloticase would be an important new therapy for patients living with the debilitating effects of treatment-failure gout."

"Based on the positive results that were reported from our Phase 3 studies along with the continued clinical improvement and high rate of patient participation in our OLE program, we believe this is indicative of the need for a new treatment option," stated Christopher Clement, President and CEO of Savient. "We are optimistic about the potential opportunity ahead and we are honored that the American College of Rheumatology chose to feature these exciting results in a plenary session."

The two pegloticase Phase 3 studies are known as the GOUT 1 and GOUT 2 studies (Gout Outcomes and Uric Acid Treatment) and the OLE Study is known as GOUT 3. Four ACR presentations focused on the results of the GOUT 1, GOUT 2 and GOUT 3 studies. A fifth presentation defined TFG as a unique medical condition amounting to a severe gout syndrome, in a synthesis of data derived from five studies: the pegloticase Phase 2 study, GOUT 1, 2, and 3, and a 12-month non-interventional natural history study in treatment-failure gout patients. This was the first time that the data from these studies was presented in a scientific forum.

New Results presented at ACR:

-- The GOUT 3 study data demonstrated the continuing efficacy of pegloticase in normalizing PUA to less than 6 mg/dL. It also demonstrated the ability to maintain control of PUA for up to 18 months with continuous treatment in both the every 2 weeks and every 4 weeks treatment groups, in a proportion of patients similar to that demonstrated in GOUT 1 and 2.

-- Gout Tophi: As previously reported by the Company, the superiority of pegloticase administered every 2 weeks as compared to placebo in attaining a gout tophus Complete Response was statistically significant and clinically meaningful in the pegloticase 8mg every 2 weeks group within 6 months of therapy, in the pre-specified pooled analysis. Moreover, the tophus Complete Response was attained for the every 2 weeks group in both the GOUT 1 and GOUT 2 pivotal trials individually, as well as in the pooled analysis. The pegloticase every 4 weeks group attained statistical significance for tophus Complete Response in the pre-specified pooled analysis. The analyses of secondary efficacy endpoints for the individual studies as well as for the pooled data across the two studies, has been included in the BLA submission for FDA review.

The GOUT 3 data presented at ACR provided continued evidence of the increase in pegloticase's favorable effect on achieving a Complete Response for tophus resolution that was demonstrated in the initial 6 months of treatment. With continued pegloticase therapy beyond 6 months in the GOUT 3 study, the proportion of patients demonstrating a Complete Response for tophus resolution increased over time in both the every 2 weeks and every 4 weeks groups. While other clinical assessments also showed clinical improvements, such as a partial tophus response, it is only the tophus Complete Response that was pre-specified as a clinical criterion by which to measure success. It is very encouraging that many patients, who had a tophus partial response in the first six months of treatment, developed a Complete Response over a longer treatment period in GOUT 3.

-- Gout Flares: The GOUT 1 and GOUT 2 pivotal studies assessed the affect of pegloticase treatment on both an efficacy and safety secondary endpoints in gout flares. As with all urate-lowering therapies, the frequency of flares increased upon initiation of pegloticase treatment as expected. The treatment-failure gout patients in the Phase 3 program had a high frequency of gout flares prior to study entry, as shown by the approximately 1.7 flares per the initial 3-month period for the placebo group. In the pooled analyses, pegloticase-induced increase in gout flares occurred in both treatment groups during Months 1-3 to a frequency of about 2.3 and 2.7 respectively, whereas the placebo group showed no change in flare frequency during the same 3-month period.

New data presented at ACR demonstrates that in Months 4-6 patients administered pegloticase every 2 weeks had a statistically significant lower flare incidence and frequency compared to placebo patients in the pooled analysis. Additionally, in Months 4-6, the pegloticase every 4 weeks group had a frequency of gout flares similar

to placebo indicating that the early increase in flares was transient in this treatment arm before returning to the placebo level.

The reduction of gout flares, by approximately 40%, in the every two-week dosing arm of these randomized, controlled, clinical trials is believed to be the first time a urate lowering therapy has demon strated a reduction of gout flares versus a placebo.

New results presented from the GOUT 3 study show that for patients who have been treated with pegloticase continuously for at least 12 months, the frequency of gout flares was reduced to approximately 0.2 flares per three months in the pegloticase every two weeks group, and 0.4 flares per 3 months in the every four weeks group. This represents a 9-fold and 4-fold reduction in the frequency of gout flares after 12 months of continuous therapy for the every two and every four weeks groups compared to the flare frequency reported prior to study entry. Patients and their physicians participating in GOUT 3 study view this reduction in gout flare frequency as an important clinical benefit and the Company believes this benefit contributes to their joint decision to continue therapy.

-- Immunology: The Company previously reported on the immune response to pegloticase treatment in the GOUT 1 and GOUT 2 studies, showing a high rate of seroconversion. The presence of anti-pegloticase antibodies was predictive of a loss of uric acid control and a greater increase in the risk of infusion reactions, but not a greater severity of infusion reactions, particularly in the subset of patients with the highest one-third of antibody titer.

Results of the GOUT 3 study reported confirm that for patients treated with pegloticase for up to 12 months showed that:

- The overwhelming majority of subjects who develop a high titer of anti-pegloticase antibody, with subsequent loss of uric acid control, have done so by the fourth month of treatment in the double blind studies. The proportion of patients who had lost uric acid control remained relatively constant during extended therapy with pegloticase.

- Neutralizing antibodies and clinically relevant titers of anti pegloticase IgE were not present in any of the patients with continued use of pegloticase out to as long as 18 months.

These results are consistent with those previously reported for the GOUT 1 and GOUT 2 studies. Further, the Company believes that the immunology results are consistent with the continuing and increasing clinical benefits that appear to be accruing to patients with continuing longer-term pegloticase treatment, e.g. control of hyperuricemia, elimination of gout tophi, and the reduction in gout flare frequency.

-- Safety: As previously reported, the pegloticase clinical development program (GOUT 1, GOUT 2, and GOUT 3) identified two adverse safety signals: the transient increase in gout flares in Months 1-3 and the occurrence of infusion reactions. As mentioned above, new data presented at ACR demonstrated that in Months 4-6 of the GOUT 1 and

GOUT 2 studies, the incidence of gout flares in the every 2 weeks dosing group was significantly below that of placebo patients in the pooled analysis and at the same level as placebo patients in the every 4 weeks dosing group.

Additional new results presented from the GOUT 3 study extended this improvement noting a 9-fold and 4-fold reduction in the frequency of gout flares against initial study entry baseline for the every 2 weeks and every 4 weeks dosing groups respectively. The infusion reaction experience in the GOUT 3 study was consistent and similar in nature and pattern to that observed in the GOUT 1 and GOUT 2 studies and was easily managed utilizing the methods specified in the study protocols.

As previously reported in GOUT 1, GOUT 2 and GOUT 3, there were a total of seven patient deaths in the clinical program: 5 (5/169 or 3%) in pegloticase treatment groups and two (2/44 or 4.5%) in the placebo groups.

- Of these seven deaths, 3 were attributed to cardiac events. Two of the events occurred in the pegloticase arms and one in the placebo group as previously reported by the Company and not believed to be drug related.

Cardiovascular Serious Adverse Events (SAEs) in patients on pegloticase GOUT 1 and GOUT 2 were as follows:

- There were two reported cardiac SAEs which were included among the seven deaths indicated above.

- A third patient who was on pegloticase every 4 weeks, following a placebo dose had an SAE relating to congestive heart failure which was resolved after hospitalization. However, as previously reported, this patient died of renal failure after voluntarily withdrawing from renal dialysis.

- The remaining five patients with cardiac SAEs continued to receive pegloticase in the trials. It is important to note that all five patients continued treatment successfully despite their cardiovascular event.

None of these cardiovascular events, including the patient deaths were thought to be causally related to pegloticase treatment by the Investigators and Sponsor.

We believe the overall safety profile of pegloticase in the clinical program indicates that long-term administration of 8 mg pegloticase in the treatment-failure gout population is safe by 2-hour i.v. infusion either every 2 weeks or every 4 weeks. The pegloticase 8 mg every 2 weeks dose regimen appears to be better tolerated with respect to infusion reactions than the pegloticase 8 mg/4 weeks dose regimen.

The Company believes that both dose regimens have an acceptable safety and tolerability profile. The emerging safety profile of long-term pegloticase therapy is consistent with that observed in the six-month double-blind studies, with no apparent new safety concerns related to long-term exposure.

Savient's Chief Medical Officer, Dr. Zeb Horowitz, will host a conference call and webcast on Wednesday, October 29, 2008 at 9:00 AM PT/12:00 PM ET to discuss the pegloticase presentations given at the American College of Rheumatology's 72nd Annual Scientific Meeting in San Francisco. A question and answer period will follow Dr. Horowitz's prepared remarks. Both the live and archived web cast can be accessed from the Investor Relations page of Savient's website at http://www.savient.com. A digital recording of the web cast will be available within one hour following the conclusion of the call and will be available for 14 days. To access the recording, use the Dial-In Number and the Conference ID listed below.

Dial: (888) 802-8577 (U.S. participants) or (973) 935-8754 (International participants).

Conf ID: 68878067

[For further information on the findings, please visit the ACR website at www.rheumatology.org.]

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(R) (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. **Savient has exclusively licensed worldwide rights to the technology related to Puricase from Duke University and Mountain View Pharmaceuticals, Inc.** 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

We may from time to time make written or oral forward-looking statements, including statements contained herein, in our filings with the Securities and Exchange Commission, in our press releases and in our reports to stockholders within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts included in this press release regarding our strategy, strategic alliances, competitive position, plans and objectives of management 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 help identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding the clinical results of the Phase 3 (GOUT 1 and GOUT 2) clinical trials and the interim results from the ongoing Open Label Extension (OLE) (GOUT 3) study for Puricase(R) (pegloticase), the filing, based on those results, of a BLA with the FDA, the filing of a Marketing Authorization Application with the EMEA, the results of the pre-BLA meeting with the FDA and its potential impacts on the BLA submission, the timing of approval of the BLA and launch of pegloticase, the market for pegloticase, and the absence of other therapies for treatment-failure gout patients, are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our current assessment of the Phase 3 clinical data and on 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, the delay or failure in completing development of pegloticase and developing other product candidates; our stock price and market conditions, varying interpretations of our clinical and CMC data by the FDA, delay achieving or failure to achieve FDA approval of pegloticase, difficulties of expanding our product portfolio through in-licensing or acquisition; inability to manufacture commercial quantities of our products; inability to gain market acceptance sufficient to justify development and commercialization

costs if our products are approved for marketing; our 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 our products; economic, political and other risks associated with foreign operations; risks of maintaining protection for our 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 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 to shareholders. 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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