Savient Provides Update on KRYSTEXXA(TM) BLA Resubmission Activities

Company Completes Reversion to Phase 3 Manufacturing Process and Reaffirms 1Q 2010 Target for KRYSTEXXA BLA Resubmission

EAST BRUNSWICK, N.J., Jan 08, 2010 /PRNewswire via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today provided an update on its activities directed toward the resubmission of its Biologics License Application (BLA) for KRYSTEXXA(TM) (pegloticase) as a treatment for chronic gout in patients refractory to conventional therapy and reaffirmed its belief that it continues to be on track for the filing of the BLA resubmission for KRYSTEXXA in the first quarter of 2010.

The Company announced that:

- It has completed the reversion to the manufacturing processes used to manufacture its pegloticase active pharmaceutical ingredient (API) drug substance for the pivotal Phase 3 clinical trials which the Company had committed to pursue during the September 2009 Type "A" meeting as its plan to address the concerns raised by the Food and Drug Administration (FDA) in the July 31, 2009 complete response letter. Three consecutive batches of pegloticase API drug substance were manufactured in late October 2009 at the Company's third party contract manufacturer (CMO) and were then manufactured into final KRYSTEXXA drug product in November 2009. All batches were placed on stability testing by early December 2009. This manufacturing process reversion included the successful return to the PEGylation concentration utilized in the manufacture of pegloticase API for the pivotal replicate Phase 3 clinical trials.

- The Company has received from its third party testing laboratories the majority of the in-process and final release analytical test results performed on the three consecutive batches of pegloticase API drug substance and final drug product. These analytical tests are necessary to validate these batches as being comparable to the drug product used in the Phase 3 clinical trials to establish the safety and efficacy of the drug product for the treatment of gout in patients refractory to conventional therapy. The Company believes that the analytical results to date demonstrate that the manufacturing process is consistent and that the drug substance and drug product produced in this validation campaign is comparable to the material used in the KRYSTEXXA Phase 3 clinical trials. The Company does not believe that the remaining pending analytical tests will alter their current view with respect to the success of the validation campaign and expects to receive these remaining analytical test results from its third party testing laboratories well in advance of its planned resubmission filing.

- The Company's CMO has submitted to the FDA in late December 2009 comprehensive reports and documentation of the steps that they have completed to date with the goal of addressing deficiencies and other observations that have been identified by the FDA. In addition, although not required by the FDA, the submissions by the Company's CMO included their plans and framework for implementing a broad continuous quality improvement plan.

- The safety update data to be included in the BLA resubmission demonstrates a continuing safety profile similar to that seen in the Phase 3 clinical trials. This safety update includes data from the Open Label Extension Study of KRYSTEXXA through the end of September 2009. Ninety five patients were exposed to KRYSTEXXA for at least 18 months and 63 patients were exposed for between 24 and 30 months. In particular, the Company observed no new safety concern signals and there was no evidence of any adverse change in the cardiovascular safety profile or evidence of cumulative toxicity when compared to the data provided in the original BLA or subsequent 120-day safety update to the BLA.

The Company conducted the manufacturing validation campaign following a Type "A" meeting held with the FDA in September 2009 at which the FDA indicated that, in its view, Savient's plan to revert to and validate the original manufacturing process used to produce KRYSTEXXA drug product for the Phase 3 clinical trials, together with certain process revisions such as the inclusion of additional 0.22 micron filters in the manufacturing process, was a reasonable approach that is expected to produce pegloticase API drug substance that is representative of that used to establish safety and efficacy in the pivotal Phase 3 clinical trials. The Company does not expect further clinical trials to be required provided that when the BLA resubmission is reviewed, the FDA does not observe any significant differences in their assessment of comparability results.

The complete response letter also required correction of deficiencies and observations cited by the FDA during its June 2009 pre-approval inspection of the facilities of the Company's CMO. While remediation of the deficiencies and observations arising from the FDA pre-approval inspection had been underway since the June 2009 inspection in accordance with two work plans submitted to the FDA by the CMO in June and July 2009, in October 2009 the FDA provided notification that these original work plans were not adequate and identified additional corrective actions that would be required to successfully remediate the deficiencies and observations noted in their facility, and since October 2009, the CMO has been addressing additional chemistry and manufacturing controls issues with their facility. The reports submitted to the FDA by the Company's CMO in December 2009 detail the remediation steps they have taken to date, additional actions that are currently underway and the plans and programs designed with the goal of remediating the deficiencies and observations cited by the FDA and providing the FDA appropriate comfort with the facility's compliance with current good manufacturing practices, though the FDA may not agree. The FDA may require a reinspection of the manufacturing facility of the Company's CMO as part of its consideration of the KRYSTEXXA BLA resubmission, and that reinspection could result in additional concerns being raised by the FDA. It is also possible that the FDA could require the Company to repeat its manufacturing validation campaign once the FDA determines that the Company's CMO has resolved all of these issues to the satisfaction of the FDA, though Savient does not expect the FDA to take this step.

Based on the progress made to date, the Company believes that it continues to be on track for the filing of the BLA resubmission for KRYSTEXXA within the first quarter of 2010. The resubmission will include all data requested by the FDA with respect to the manufacturing issues identified in the complete response letter and the integrated safety update, as well as drafts of prescribing information and product labeling, REMS program materials and a Medication Guide, which the Company believes are all consistent with the comments provided by the FDA in the complete response letter received by the Company on July 31, 2009 or during the September Type "A" meeting. When resubmitted, Savient expects the BLA to be subject to a Class 2 resubmission review cycle meaning an FDA decision on an action with respect to all components of the BLA resubmission would be expected within six months of the date of the resubmission.

WEBCAST INFORMATION FOR COMPANY PRESENTATION AT THE 28TH ANNUAL J.P. MORGAN HEALTHCARE CONFERENCE

Savient's management team will be presenting at the J.P. Morgan Healthcare Conference on Monday, January 11, 2010 at 2:30 p.m. Pacific Time. A live broadcast of the presentation and question and answer session following the presentation will be available on the company's website. Individuals can access a live webcast through the investor relations section of the company's website www.savient.com. Following the live presentation, a replay of the webcast will be made available on the Company's website for 60 days. Please log on to Savient's website 15 minutes prior to the start of the webcast to ensure adequate time for any downloads that may be necessary.

ABOUT KRYSTEXXA(TM)

KRYSTEXXA(TM) (pegloticase) is a PEGylated uricase enzyme intended for the treatment of chronic gout in patients refractory to conventional therapy. Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing KRYSTEXXA(TM) (pegloticase) for the treatment of chronic gout in patients refractory to conventional therapy. **Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA, formerly referred to as Puricase(R), from Duke University and Mountain View Pharmaceuticals, Inc.** 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.**

FORWARD-LOOKING LANGUAGE

All statements other than statements of historical facts included in this press release 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 identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding the results of Savient's actions and efforts in support of its planned resubmission of the KRYSTEXXA(TM) (pegloticase) BLA, the results of the reversion to and revalidation of the Phase 3 manufacturing process, whether the Company's third party contract manufacturing organization will successfully address the deficiencies and observations cited by the FDA at their facility, the timing of a resubmission to the FDA in response to the complete response letter, the efficacy and safety of KRYSTEXXA, potential FDA marketing approval for KRYSTEXXA and whether any further clinical trials will be required are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, our Phase 3 clinical data, our current understanding of the complete response letter 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 possibility that the FDA may raise further issues regarding the BLA for KRYSTEXXA or require that we conduct additional clinical trials; reliance on third parties to manufacture, market and distribute many of our products; our ability to commercialize and market acceptance of KRYSTEXXA; difficulties in obtaining financing; potential development of alternative or more effective products by competitors; economic, political and other risks associated with foreign operations; risks of maintaining protection for our intellectual property; risks of an adverse determination in 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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