Savient Provides Update On Puricase(R) (pegloticase) Biologics License Application

EAST BRUNSWICK, N.J., Apr 21, 2008 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ:SVNT) today announced an update on plans for filing its Biologics License Application (BLA) for Puricase(R) (pegloticase) for treatment-failure gout based on the results of its pre-BLA meeting with the U.S. Food and Drug Administration (FDA) reviewing division (Office of Drug Evaluation II) on April 17, 2008.

Key results of this meeting were:

-- The Company believes, based upon pre-BLA meeting correspondence from the division, that the pegloticase program will meet the criteria for a priority review, but a formal decision as to a priority review will not be made by the FDA until the BLA is filed.

-- No new clinical data is required for pegloticase submission and agreement was reached with the FDA on the content and structure of the planned BLA filing in the treatment-failure gout orphan population.

-- Agreement with the FDA was reached on BLA requirements for Chemistry, Manufacturing and Controls (CMC) data and for release testing of the commercial drug supply.

-- No decision has been made on the use of an Advisory Panel, but if FDA decides that pegloticase must go before an Advisory Panel, it would not extend a six-month priority review timeline.

In order to meet the FDA priority review timelines, all available twelve-month pegloticase data must be included in the initial BLA submission. The Company had originally planned to submit safety and efficacy data, including clinical outcomes data from its Open Label Extension (OLE) study after the filing of the BLA, as part of a typical post-submission safety update. However, since almost all patients in the OLE who were in pegloticase treatment groups in the Phase 3 studies have already completed twelve months of continuous dosing, the Company is able to meet this additional requirement. The Company believes that the compilation and analysis of this additional data from the OLE will take approximately three months beyond its original target of the end of June for the submission. This OLE data will now be included in the Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) together with data from the Phase 3 pivotal trials in the initial BLA submission. While the inclusion of this data will result in the Company's filing the BLA approximately three months later than previously planned, this scenario will result in a submission that includes substantially more data related to long-term safety and clinical outcomes efficacy and, assuming grant of a priority review, expected approval of the BLA within the early 2009 timeframe previously projected by the Company.

"We are very pleased with the outcomes from the meeting with the FDA and we remain very excited about the prospect of pegloticase approval," said Christopher Clement, President and CEO of Savient. "We believe that the addition of the OLE efficacy and safety data in the BLA, as opposed to filing the OLE as an update, will strengthen and streamline the overall submission. While the inclusion of OLE efficacy and safety data in the initial BLA will result in a slightly longer timeframe for filing, we believe these modifications to our submission strengthens the filing. We also believe that despite this minor delay, we will remain on track to launch pegloticase as planned for early 2009. Finally, we are encouraged that inclusion of this safety and efficacy data in the BLA submission will aid in obtaining a strong indication for pegloticase."

As previously announced in its two replicate, six-month Phase 3 clinical trials, the Company had achieved statistically significant positive results for pegloticase treatment-failure gout patients, which was conducted under the auspices of a Special Protocol Assessment (SPA) with the FDA. The Company also established an Open Label Extension protocol in which all patients who completed the Phase 3 program had the opportunity to elect to participate. This protocol allowed those patients the opportunity to receive pegloticase in a carefully monitored environment until marketing authorization is attained.

ABOUT PURICASE(R) (pegloticase)

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 an SPA from the FDA. **Savient has licensed exclusive worldwide rights to the technology related to pegloticase from Duke University and Mountain View Pharmaceuticals, Inc. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

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, pegloticase for treatment-failure gout, has achieved 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'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

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 clinical trials for Puricase(R) (pegloticase), the filing, based on those results, of a BLA and Marketing Authorization Application with the FDA, 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, our stock price and market conditions, the delay or failure in completing development of pegloticase and developing other product candidates; 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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