Savient Submits Biologics License Application (BLA) for pegloticase

EAST BRUNSWICK, N.J., Oct 31, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced the submission of its BLA to the U.S. Food and Drug Administration (FDA) seeking approval to market pegloticase in the United States along with its request for a priority review. Savient's filing includes data from both the six-month placebo controlled Phase 3 pivotal trials, as well as data from the Open Label Extension (OLE) study. The data set includes 101 patients with at least twelve months continuous treatment.

"Filing the BLA for pegloticase is a major milestone for Savient," said Christopher Clement, President and Chief Executive Officer. "This filing reflects our commitment to changing the paradigm of therapy available to the treatment-failure gout population and brings us one step closer to commercializing this drug and offering a solution to patients who suffer from this debilitating disease."

The two replicate, six-month, Phase 3 clinical trials for pegloticase were performed under the auspices of a Special Protocol Assessment (SPA) and pegloticase was granted Orphan Drug designation by the FDA. The OLE study was established to allow patients who completed the Phase 3 program the opportunity to continue to receive pegloticase for an extended period of time.

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 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 and the BLA was filed with the FDA in October 2008.

Savient has exclusively licensed worldwide rights to the technology related to pegloticase, formerly referred to as Puricase(R), 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 pegloticase BLA filing, request for priority review, clinical results of the Phase 3 pivotal clinical trials and the ongoing Open Label Extension (OLE) program for pegloticase, the timing of approval of the BLA, and the market for pegloticase, 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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