



## Pegloticase BLA Filing Accepted for Priority Review by FDA

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Application for Treatment-Failure Gout Granted Priority Review

Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's Biologics License Application (BLA) for pegloticase, a novel biological drug for treatment-failure gout (TFG) patients. The FDA also granted the Company's BLA with a priority review status which accelerates the review period to six months. A priority review designation is assigned to drugs that are deemed by the FDA to have the potential to provide an important advancement in treatment or provide a treatment for which there is no adequate therapy available. Under priority review, the target date for an FDA decision on the pegloticase BLA is April 30, 2009.

The BLA submission is based on the two replicate, six-month Phase 3 clinical trials, performed under the auspices of a special protocol assessment. Additionally, the Company's BLA includes data from the open label extension (OLE) study for pegloticase, per the request of the FDA. The OLE study allowed those patients who completed the Phase 3 trials to continue or begin receiving pegloticase for an extended period of time. The data set includes 101 patients with at least twelve months of continuous treatment. Pegloticase was previously granted orphan drug designation by the FDA.

Treatment-failure gout occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with allopurinol at the maximum medically appropriate dose or for whom allopurinol is contraindicated.

### ABOUT PEGLOTICASE

Pegloticase (formerly referred to as Puricase(R)) 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(R) is a registered trademark of Mountain View Pharmaceuticals, Inc.**

### ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. 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. Further information on Savient can be accessed by visiting: <http://www.savient.com>.

## 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 help identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding our BLA filing with the FDA, a potential Advisory Committee, approval of the BLA, preparation for commercialization of pegloticase, the efficacy and safety of pegloticase 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; 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 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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