

Savient Announces Completion of Patient Enrollment in Phase 3 Trials of Puricase® for Treatment-Failure Gout

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Company Expects To Announce Top Line Data by Year-End

EAST BRUNSWICK, N.J.--(BUSINESS WIRE)--Savient Pharmaceuticals, Inc. (NASDAQ:[SVNT - News](#)) announced today that it has reached its Phase 3 enrollment target of 200 patients total, in the two replicate placebo-controlled six-month clinical trials. The trials assess the safety and efficacy of Puricase in patients with treatment-failure gout, under the auspices of a Special Protocol Assessment from the U.S. Food and Drug Administration. Completion of the in-life portion of the Phase 3 trials is expected during the fourth quarter of this year, with release of top line results by year-end.

"We are extremely pleased with the progress of the clinical development program for Puricase and now, having successfully reached our Phase 3 enrollment timeline, we remain on target for a Biologics License Application filing in early 2008," commented Christopher Clement, President and Chief Executive Officer of Savient. "We believe Puricase represents an important innovation in the care of gout patients, potentially delivering the first and only effective therapy for patients with treatment-failure gout."

Puricase, a PEGylated recombinant porcine urate oxidase, is being developed to control hyperuricemia and its clinical consequences in patients for whom conventional therapy is contraindicated or has been ineffective. The Phase 3 study design designates the normalization of uric acid during months 3 and 6 of the six-month trials as the primary endpoint. Secondary efficacy endpoints that define clinical outcomes such as the reduction in the burden of gout tophi, the occurrence of gout flares, and the reduction in the count of tender and swollen joints will be analyzed in a data set pooled from the two replicate studies numbers.

"The Phase 3 program is progressing with a high degree of commitment shown by study participants and our clinical investigators," stated Zeb Horowitz, MD, Senior Vice President and Chief Medical Officer of Savient. "Up to this point, the tolerability of intravenous dosing has been good, with a low rate of infusion reactions across all placebo and Puricase infusions. Even more importantly, physicians appear to be highly successful in treating through infusion reactions when they do occur, just as in clinical practice with other infused biologicals. Patients and physicians continue to demonstrate satisfaction and confidence in the treatment, as evidenced by their participation in our Open Label Extension protocol in which patients can choose to receive Puricase or go on observation only after completion of their Phase 3 participation. **Thus far, 100% of completed patients have chosen to enroll in the Open Label Extension protocol in order to receive Puricase treatment for 12 months beyond the six-month core Phase 3 trials.**"

The company intends to allow patients currently in the screening process at the clinical sites to complete the screening and enroll in the Phase 3 clinical trials if they qualify, going somewhat beyond the 200 patient target of randomization. "The patients currently in screening have no alternative therapeutic option and should not be turned away," said Dr. Horowitz. "Allowing them to complete the screening process will translate into an extension of patient randomization for about two additional weeks, but it should not jeopardize subsequent key milestone dates. These patients and their physicians are truly anxious for a new therapy."

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals is a biopharmaceutical company engaged in developing and marketing pharmaceutical products that target unmet medical needs in both niche and broader markets. The Company's product development candidate, Puricase® for treatment-failure gout, has reported positive Phase 1 and 2 clinical data; patient dosing in Phase 3 clinical studies began in May 2006, with patient enrollment completed in March 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 markets Oxandrin®, oxandrolone tablets, (USP) C III 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

This news release contains 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 Savient's 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. These forward-looking statements involve substantial risks and uncertainties and are based on current expectations, assumptions, estimates and projections about Savient's business and the biopharmaceutical and specialty pharmaceutical industries in which Savient operates. Such risks and uncertainties include, but are not limited to, Savient's stock price and market conditions, delay or failure in developing Puricase® (PEG-uricase) and other product candidates, difficulties of expanding Savient's product portfolio through in-licensing, introduction of generic competition for Oxandrin®, fluctuations in buying patterns of wholesalers, potential future returns of Oxandrin or other products, Savient's 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 Savient's products, economic, political and other risks associated with foreign operations, risks of maintaining protection for Savient's 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. Savient may not actually achieve the plans, intentions or expectations disclosed in Savient's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that Savient makes. Stockholders should not place undue reliance on the forward-looking statements, which speak only as to the date of this press release. Savient's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that Savient may make. Except as required by law, Savient does not assume any obligation to update any forward-looking statements.

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