

Savient Pharmaceuticals, Inc. Completes Patient Dosing in Phase 2 Clinical Trial of Puricase for Severe Gout

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EAST BRUNSWICK, N.J.—(BUSINESS WIRE)—Jan. 10, 2005—Savient Pharmaceuticals, Inc. (NASDAQ: SVNT - News), an emerging specialty pharmaceutical company engaged in developing, manufacturing and marketing pharmaceutical products that address unmet medical needs today announced the completion of patient dosing in a Phase 2 clinical trial of Puricase®, a poly(ethylene glycol) ("PEG") conjugate of recombinant porcine uricase (urate oxidase), for the treatment of severe, refractory gout.

The Phase 2 clinical study, an open-label, randomized, multi-center dose-ranging trial involving 41 patients, appears to have reproduced the dramatic, rapid and sustained reduction in plasma uric acid that was seen in the Phase 1 intravenous study. Preliminary data suggest that i.v. administration of Puricase every two weeks or every four weeks rapidly achieves and maintains a level of plasma uric acid within the normal range in the majority of patients. The safety profile emerging from the open label Phase 2 study appears to be acceptable for proceeding to more extensive patient exposure in a Phase 3 development program. This study compared three dosage levels and two dosage regimens over a twelve-week period.

"We are pleased with our progress and with what we have seen throughout the Phase 2 study. We are confident that we will have favorable Phase 2 data to provide to the FDA," said Zeb Horowitz, M.D., Savient's Senior V.P. and Chief Medical Officer.

Analysis of the Phase 2 data is expected to be completed in the first quarter of 2005. Following the data analysis, the Company plans to request an end-of-Phase 2 meeting with the FDA to obtain concurrence on the design of the Phase 3 program and the requirements for registration within the FDA designated Orphan Drug indication, "...to control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective." The targeted orphan patient population is estimated at 30,000-50,000 patients in the United States.

Savient licensed worldwide rights to the technologies related to Puricase from Duke University ("Duke") of North Carolina and Mountain View Pharmaceuticals, Inc. ("MVP"), a California corporation. Duke developed the recombinant porcine uricase enzyme and MVP developed the PEGylation technology to prolong its duration of action and enhance its safety by reducing the potential for immune responses. MVP and Duke were granted U.S. and foreign patents covering the licensed technology.

About Savient Pharmaceuticals, Inc.

Savient Pharmaceuticals, Inc. is engaged in developing, manufacturing, and marketing pharmaceutical products that address unmet medical needs in both niche and wider markets. Products marketed by Savient in the United States are Oxandrin® (oxandrolone, USP) and Delatestryl® (testosterone enanthate). Savient's subsidiary, Rosemont Pharmaceuticals Limited, develops, manufactures, and markets through its own sales force oral liquid formulations of prescription products for the UK pharmaceutical market. Savient's Israeli subsidiary, Bio-Technology General (Israel) Ltd., manufactures and markets in Israel Bio-Tropin(TM) (recombinant human growth hormone), BioLon® (sodium hyaluronate for ophthalmic surgery), Bio-Hep-B® (hepatitis B vaccine), and Arthrease(TM) (sodium hyaluronate for osteoarthritis). Products marketed by Savient's licensees are Mircette® (oral contraceptive), and BioLon® in the United States, and Bio-Tropin(TM), BioLon®, Bio-Hep-B®, Silkis® (a vitamin D derivative), and recombinant human insulin, in international markets. Savient's news releases and other information are available on Savient's website at www.savientpharma.com.

Arthrease is a trademark of DePuy Orthopaedics, Inc., except in Israel, where it is owned by Bio-Technology General (Israel) Ltd., Savient's wholly owned subsidiary; Mircette is a registered trademark of Organon, Inc.; **Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**; Silkis is a registered trademark of Galderma S.A.

This news release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. All statements, other than statements of historical facts, included in this report regarding Savient's expected timing of revenues and results of operations are forward-looking statements. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions help to 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, delay or failure in developing Prosaptide, Puricase and other product candidates; difficulties of expanding Savient's product portfolio through in-licensing; disruption of management and costs associated with the divestiture of Savient's operations in Israel; introduction of generic competition for Oxandrin; fluctuations in buying patterns of wholesalers; potential future returns of Oxandrin or other products; 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 on-going or future intellectual property or other litigation; and risks associated with stringent government regulation of the biopharmaceutical and specialty pharmaceutical industries. Savient may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on Savient's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements made by Savient. 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. Savient does not assume any obligation to update any forward-looking statements.

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