Savient's Puricase(R) (PEG-uricase) Substantially Reduces and Sustains Lower Plasma Urate Levels in Patients with Treatment-Resistant Gout

Anecdotal Evidence Shows Resolution of Tophi - Phase 2 Data Presented at the 2005 Annual Meeting of the American College of Rheumatology

SAN DIEGO, Calif., Nov. 14 /PRNewswire-FirstCall/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNTE) announced today that patients with elevated blood uric acid levels and treatment-resistant gout who were treated with its investigational drug Puricase(R) (PEG-uricase) had substantial and sustained reduction in plasma urate levels, according to study results that will be presented on Wednesday, November 16 at the American College of Rheumatology 2005 Annual Meeting. In addition, two case studies from the Phase 2 open-label trial that will be presented today show anecdotal photographic evidence that treatment with PEG-uricase unexpectedly resolved tophi, the nodular deposits of urate that can cause pain, local ulceration, disfigurement and joint destruction. It is unknown whether tophi were resolved in patients at other investigational sites as clinical outcome measures were not part of the phase 2 protocol design.

"Lowering urate levels is an important goal in treating gout because urate deposits in joint spaces provoke attacks of this painful and often disabling disease," said John S. Sundy, MD, PhD, Division of Rheumatology at Duke University Medical Center and lead investigator. "These encouraging results support further studies to determine the efficacy of PEG-uricase as a therapeutic option for lowering uric acid levels in patients with treatment-resistant gout."

PEG-uricase is a poly(ethylene glycol) conjugate of recombinant porcine uricase (urate oxidase) for the treatment of patients with severe gout for whom conventional therapy is contraindicated or has been ineffective. Duke University developed the recombinant porcine uricase enzyme. In February 2001, Savient received FDA Orphan Drug designation from the U.S. Food and Drug Administration for PEG-uricase, and the Company expects to initiate its Phase 3 clinical testing program during the first quarter of 2006.

About Gout

According to the National Institutes of Health, gout accounts for approximately 5 percent of all cases of arthritis and is one of the most painful rheumatic diseases. There are an estimated 5 million Americans with gout, including 50,000-70,000 patients for whom conventional therapy is contraindicated or has been ineffective. Gout results from deposits of needle-like crystals of uric acid in connective tissue and in the joints. These deposits lead to inflammatory arthritis, which causes joint swelling, redness, heat, pain, and stiffness and damage to the affected joints. In patients for whom conventional therapy is contraindicated or has been ineffective, the disease can become chronic, progressively worsen and cause debilitating flares of pain and swelling, development of tophi, loss of joint functionality, renal disease and kidney stones.

About the Phase 2 Study Oral Presentation

This Phase 2, randomized, open-label, multicenter, parallel group study assessed the urate response, and pharmacokinetic and safety profiles of PEG-uricase in patients with hyperuricemia and severe gout who are unresponsive to or intolerant of conventional therapy. The mean duration of disease was 14 years and 70 percent of the study population had one or more tophi.

In the study, 41 patients (mean age of 58.1 years) were randomized to 12 weeks of treatment with intravenous PEG-uricase at one of four dose regimens: 4 mg every two weeks (7 patients); 8 mg every two weeks (8 patients); 8 mg every four weeks (13 patients); or 12 mg every four weeks (13 patients). Plasma uricase activity and urate levels were measured at defined intervals. Pharmacokinetic parameters, mean plasma urate concentration and the percentage of time that plasma urate was less than or equal to 6 mg/dL were derived from analyses of the uricase activities and urate levels.

Patients who received 8 mg of PEG-uricase every two weeks had the greatest reduction in plasma urate with levels below 6mg/dL 92 percent of the treatment time (pre-treatment plasma urate of 9.1mg/dL vs. mean plasma urate of 1.4mg/dL over 12 weeks).

Substantial and sustained lower plasma urate levels were observed in the other PEG-uricase treatment dosing groups:

- 86 percent of the treatment time in the 8 mg every four weeks group (pre-treatment plasma urate of 9.1 mg/dL vs. mean plasma urate of 2.6 mg/dL over 12 weeks);
- 84 percent of the treatment time in the 12 mg every four weeks group (pre-treatment plasma urate of 8.5mg/dL vs. mean plasma urate of 2.6 mg/dL over 12 weeks); and
- 73 percent of the treatment time in the 4 mg every two weeks group (pre-treatment plasma urate of 7.6 mg/dL vs. mean plasma urate of 4.2 mg/dL over 12 weeks).

About the Two Case Studies Poster Presentation

At one clinical investigation site, two patients out of six were asked to be photographed pre- and post PEG-uricase therapy while participating in a randomized, phase 2 open-label, multi center study to determine safety, pharmacokinetics and changes in uric acid (UA) levels with PEG-uricase. Photography was not required by the original protocol because a clinical outcome such as regression of tophi was not anticipated during the relatively brief treatment period of only three months.

"For patients with tophaceous deposits caused by gout, treatment with currently available therapies takes a period of years to achieve tophus resolution," said Herbert S.B. Baraf, MD, FACP, FACR, Clinical Professor of Medicine at George Washington University, and a participating investigator at the Center for Rheumatology and Bone Research, Wheaton, Md. "Our findings, while anecdotal, support further investigation of the potential benefits of PEG-uricase treatment in patients with chronic tophaceous gout."

While scientifically intriguing, anecdotal observations are not indicative of efficacy. The safety and efficacy of PEG-uricase will be determined in the Phase 3 clinical trial.

A total of 27 study patients received all intended doses of PEG-uricase. Thirty-eight patients experienced an adverse event that was possibly treatment-related, most commonly gout flare (36 patients). As expected with biological administration, there was a high rate of infusion reaction: 23 patients (150 infusions) experienced 34 events that occurred within 24 hours of infusion; 21 of these events in 18 subjects were considered possible infusion reactions, and 14 of these subjects were withdrawn without repeated administration. During the study, the rate of administration was adjusted and infusion reactions subsequently declined. There were no anaphylactic reactions. Of the nine serious adverse events reported, five were described as possibly treatment-related: gout flare (3), hypersensitivity reaction (1), and anemia (1).

About Savient Pharmaceuticals, Inc.

Based in East Brunswick, New Jersey, Savient Pharmaceuticals, Inc. is a specialty pharmaceutical company dedicated to developing, manufacturing and marketing novel therapeutic products that address unmet medical needs. Positive Phase 1 and 2 clinical data have been reported for the Company's lead product development candidate, Puricase(R) (PEG-uricase), for the treatment of refractory gout. 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 initial focus in rheumatology. The Company's operations also include a wholly-owned U.K. subsidiary, Rosemont Pharmaceuticals Ltd., which develops, manufactures and markets liquid formulations of prescription pharmaceutical products. Rosemont's product portfolio includes over 90 liquid formulations primarily targeting the geriatric population. Further information on the Company can be accessed by visiting http://www.savientpharma.com. **Savient licensed exclusive, 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. MVP and Duke were granted U.S. and foreign patents covering the licensed technology. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

Safe Harbor Statement

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 the Company's strategy, expected future financial position, discovery and development of products, strategic alliances, competitive position, plans and objectives of management are forward-looking statements. 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, statements as to the commencement of Phase 3 trials for PEG-uricase and the timing of such trial are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on current expectations, assumptions, estimates and projections about the Company's business and the biopharmaceutical and specialty pharmaceutical industries in which the Company operates. Such risks and uncertainties include, but are not limited to, delisting of the Company's common stock from The NASDAQ Stock Market, delay or failure in developing Prosaptide, Puricase and other product candidates; difficulties of expanding the Company'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; 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 the Company's products; economic, political and other risks associated with foreign operations; risks of maintaining protection for the Company'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 and specialty pharmaceutical industries. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the Company's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes. The Company's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that the Company may make. The Company does not assume any obligation to update any forward-looking statements.

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