Savient Pharmaceuticals Reports Positive Top-Line Results for Puricase Phase 2 Trial

EAST BRUNSWICK, N.J.--(BUSINESS WIRE)--May 12, 2005--Savient Pharmaceuticals, Inc. (NASDAQ:SVNT), an emerging specialty pharmaceuticals company focused on addressing the unmet medical needs in both niche and broader markets, announced today the positive top-line results of its completed Phase 2 trial for its lead drug candidate, Puricase(R). This trial was designed to test the safety and efficacy of Puricase in patients with symptomatic gout who are intolerant of or unresponsive to conventional therapy. The Company estimates approximately 35,000 to 50,000 patients in the United States. The U.S. Food and Drug Administration (FDA) granted the Company an Orphan designation to study Puricase in this patient population.

Puricase is a polyethylene glycol ("PEG") conjugate of recombinant porcine uricase (urate oxidase) which was studied in a recently completed Phase 2 trial initiated in early 2004. The primary objective of the study was to determine the most appropriate dosing for a pivotal Phase 3 clinical trial, upon which the registration will be based. The Company believes that this objective has been achieved.

The Phase 2 study was a randomized, open label, parallel design trial. Forty-one patients were randomized to receive Puricase as an intravenous infusion administered once every two weeks (4 mg or 8 mg), or once every four weeks (8 mg or 12 mg), for a three-month treatment period. At entry, the mean age of the patients was 58.1 years. Eighty-five percent of the patients were male and 83% were Caucasian. The mean duration of the disease history was 14 years and one or more gout tophi were present in 70% of the patients.

The following data are reported as within group comparisons to baseline, group means, in the "intent-to-treat" population shown by dosing group.

The maximum percent decrease in plasma uric acid from baseline within the first 24 hours of Puricase dosing:

- 4 mg / 2 weeks - 72% (p equals .0002)
- 8 mg / 2 weeks - 94% (p less than .0001)
- 8 mg / 4 weeks - 87% (p less than .0001)
- 12 mg / 4 weeks - 93% (p less than .0001)

The percent decrease in plasma uric acid from baseline over the 12-week treatment period:

- 4 mg / 2 weeks - 38% (p equals .0002)
- 8 mg / 2 weeks - 86% (p less than .0001)
- 8 mg / 4 weeks - 58% (p equals .0003)
- 12 mg / 4 weeks - 67% (p less than .0001)

All dose groups maintained for the twelve-week treatment period the mean plasma uric acid levels below the prospectively planned success criterion of 6mg/dL. The 4 mg dose showed the least decrease in uric acid, and 12 mg was not meaningfully better than 8 mg. A dose of 8 mg every two weeks and every four weeks will be recommended for Phase 3.

Dr. Zeb Horowitz, Chief Medical Officer, Savient Pharmaceuticals said, "The efficacy of Puricase in reducing uric acid is in line with our expectations. Interestingly, anecdotal reports by study patients of clinical outcomes such as eradication of gout tophi, improvements in joint functioning and general improvements in the sense of well being were unexpected and remarkable. These potentially important and novel benefits of Puricase treatment will be studied formally in Phase 3. If confirmed in a Phase 3 trial, we believe Puricase could evolve into the first disease-modifying treatment for severe, refractory gout."

During the trial, patients in all dose groups exhibited adverse events typically associated with severe gout, e.g., gout flares, breakdown of gout tophi, or symptoms of gouty arthritis. This finding is not surprising considering that eligibility for the trial required a medical history of symptomatic gout. Additionally, adverse events associated with the intravenous infusion of Puricase occurred, which is not unusual for biological agents. For most of the study, Puricase had been administered as a 30-minute infusion. The duration of the infusion was later extended to 60 minutes. Thereafter, patients experienced fewer infusion reactions. Although manifestations of reactive antibody generation were not observed in Phase 2, the potential for development of anti-Puricase antibodies will be studied in Phase 3 as part of a comprehensive assessment of safety and efficacy.

Horowitz stated, "These results lead us to believe that Puricase may become the first effective therapy for this population of previously untreatable patients. We believe the rapid, dramatic, and sustained reduction in uric acid we have seen in this trial and in our Phase 1 program, together with the emerging safety profile, provides a solid foundation for moving into Phase 3."

Abstracts detailing the safety and efficacy data from this trial have been submitted for consideration for presentation at the November 2005 Annual Meeting of the American College of Rheumatology. In addition, the FDA has granted a late July 2005 date for an end-of-Phase 2 meeting to define the critical components of the Phase 3 program and data requirements for drug registration. The Company plans to initiate a Phase 3 clinical program by November 2005, contingent upon the outcome of the meeting with the FDA.

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., an emerging specialty pharmaceuticals company, 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(R) (oxandrolone, USP) and Delatestryl(R) (testosterone enanthate). The Company'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 product Mircette(R), an oral contraceptive, is marketed by its licensee, Organon, Inc. Savient's news releases and other information are available on the Company's website at www.savientpharma.com. **Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

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, results of operations, cash flows, financing plans, 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, the statements regarding the divestiture of the Company's global biologics manufacturing business and the potential for

commercializing the Company's Puricase drug product candidate 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, the possibility that the divestiture of our global biologics manufacturing business will fail to close, due to failure to achieve regulatory approval or otherwise; delay or failure in developing Prosaptide, Puricase and other product candidates; difficulties of expanding the Company's product portfolio through in-licensing; disruption of management and costs associated with the divestiture of the Company's operations in Israel; 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 on-going 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.

CONTACT: Savient Pharmaceuticals, Inc.
Jenene Thomas, 732-565-4716
jdthomas@savientpharma.com
or
The Ruth Group
Investors/Media:
Stephanie Carrington/Gregory Tiberend
646-536-7017/7005
scarrington@theruthgroup.com
gtiberend@theruthgroup.com

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