Savient and FDA Agree on Phase 3 Protocol SPA
Puricase® (PEG-uricase) on Track to Enter Phase 3

EAST BRUNSWICK, N.J.--(BUSINESS WIRE)--March 21, 2006--Savient Pharmaceuticals Inc. (NASDAQ: SVNT), an emerging specialty pharmaceuticals company focused on developing, manufacturing and marketing novel therapeutic products for unmet medical needs, announced today that the Company has received written response from the U.S. Food and Drug Administration (FDA) that the Agency is in agreement with the Company's proposed Phase 3 protocol(s), submitted as a Special Protocol Assessment (SPA) for its lead drug candidate Puricase (PEG-uricase). The Company plans to implement the protocols in support of a marketing application for the orphan drug indication of the control of hyperuricemia in patients with symptomatic gout in whom conventional therapy is contraindicated or has been ineffective. The Company has scheduled the Phase 3 Investigators meeting for March 31 - April 2, 2006, with patient recruitment expected to be completed toward the end of 2006 or early 2007. An NDA filing with the FDA is anticipated in late 2007.

The FDA asked for minor changes in the proposed statistical analysis of the secondary efficacy endpoints, and then re-submission of the Special Protocol Assessment for final approval prior to enrollment of patients in the clinical program. Savient believes it has complied with FDA requests and has filed its SPA re-submission on March 17. These steps are part of the formal process delineated in FDA regulations (Guidance for Industry: Special Protocol Assessment) and will mean that patient dosing could start in May.

Christopher G. Clement, President and Chief Executive Officer of Savient commented, "The written FDA response is a key development for Savient and means that we are on track with our stated strategy to achieve a NDA submission by late 2007. As previously announced, the Company is devoting its efforts and resources towards the clinical development program and commercialization for Puricase (PEG-uricase). We are excited about the prospect of beginning our Phase 3 trials and advancing this drug toward registration for the orphan gout population that today has no safe and effective therapy. If we are able to demonstrate adequate safety and efficacy in the initial, we believe we will be able to explore other gout-related indications, and to determine whether Puricase has the potential to be a disease modifying therapy for patients who suffer from gout."

The Phase 3 program is designed to compare the safety and efficacy of Puricase (PEG-uricase) administered by two-hour intravenous infusion every two weeks or every four weeks versus placebo infusion, over a six month period. The program design consists of two replicate six-month placebo-controlled trials of approximately 100 randomized patients each. All patients who complete the placebo controlled trials will be invited to participate in a long-term open label extension, which the FDA suggested to continue for two years. Therefore, patients who are randomized to the placebo arms will be eligible to receive Puricase (PEG-uricase) treatment in an open label extension trial following completion of the six-month controlled registration trial.

Each of the two trials is independently powered for the primary efficacy (or key registration) endpoint, a responder analysis assessing the proportion of patients who have normalized plasma uric acid at month 3 and month 6. Secondary efficacy endpoints will be assessed in a population pooled from the two trials. These endpoints will include an assessment of the reduction in burden of gout tophi using digital photography, reduction in the frequency of gout flares, improvement in the count of swollen and tender joints, and improvements in patient reported outcomes using the Short Form 36 (SF-36) and the Health Assessment Questionnaire-Disability Index (HAQ-DI).

Zeb Horowitz, MD, Chief Medical Officer said, "The SPA process has afforded Savient the opportunity to interact extensively with the reviewing Division of the FDA. We believe this process has been invaluable and may facilitate the FDA review of our Phase 3 data after we submit our NDA. The FDA response to our SPA submission is of tremendous importance to Savient, as it indicates agreement with the FDA on the key safety and efficacy endpoints, methodologies, and the statistical analysis plan in this innovative clinical program which explores new territory for the treatment of gout patients. The normalization of plasma uric acid remains the key registration endpoint, as it has been for all other drugs indicated to treat gout. However, the Savient program will also determine the effect of Puricase (PEG-uricase) on clinical outcomes of vital importance to symptomatic gout patients, not successfully achieved in any other gout drug development program. Since the Savient study population is one for which conventional therapy has already failed or is contraindicated, the potential benefit of Puricase treatment for these patients is uniquely important. We look forward with enthusiasm to implementation of the Phase 3 clinical program in the near future, with patient recruitment pending finalization of the formal SPA process."

Savient licensed exclusive, worldwide rights to the technologies related to Puricase (PEG-uricase) 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.

ABOUT SAVIENT

Based in East Brunswick, New Jersey, Savient Pharmaceuticals, Inc., is an emerging specialty pharmaceuticals company and is engaged in developing, manufacturing and marketing pharmaceutical products that address unmet medical needs in both niche and broader markets. The Company's lead product development candidate, Puricase(R) (PEG-uricase), for the treatment of refractory gout has reported positive Phase 1 and 2 clinical data. 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. Savient markets its product Oxandrin(R) (oxandrolone, USP) in the United States. The Company's subsidiary, Rosemont Pharmaceuticals Ltd., develops, manufactures, and markets through its own sales force oral liquid formulations of prescription products for the UK pharmaceutical market. Rosemont's product portfolio includes over 100 liquid formulations primarily targeting the geriatric population. Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc. Further information on the Company can be accessed by visiting: www.savientpharma.com

FORWARD LOOKING LANGUAGE

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 clinical development of Puricase (PEG-uricase), commencement of the Phase 3 clinical trial for Puricase (PEG-uricase), time for completion of patient recruitment and timing for the filing of an NDA for Puricase (PEG-uricase) 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 Company's ability to find a buyer for Rosemont Pharmaceuticals and to negotiate and consummate a sale of Rosemont at an attractive price; delay or failure in developing 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; the Company'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 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.
Jack Domeischel, 732-565-4716 or 516-480-8813 (cell)
jdomeischel@savientpharma.com

SOURCE: Savient Pharmaceuticals Inc.