Savient Receives FDA Final Approval for Puricase (PEG-uricase) Phase 3 Special Protocol Assessment (SPA); Patient Dosing to Begin in May

EAST BRUNSWICK, N.J., May 03, 2006 (BUSINESS WIRE) -- Savient Pharmaceuticals, Inc. (NASDAQ:SVNT) a specialty pharmaceutical company focused on developing, manufacturing and marketing novel therapeutic products for unmet medical needs, announced today that the Company has received written notification from the U.S. Food and Drug Administration (FDA) that the Agency has approved a Special Protocol Assessment (SPA) for the two replicate Phase 3 clinical trials for its lead drug, Puricase® (PEG-uricase). As previously announced the Company held its Phase 3 clinical investigators meeting at the end of March and plans to begin patient dosing in May.

Christopher G. Clement, President and Chief Executive Officer of Savient commented, "This final step in the formal process to receive approval from the FDA on our Special Protocol Assessment for the Phase 3 trials for Puricase is a major milestone for the Company. It allows us to remain on track for commercialization of Puricase with a BLA filing with the FDA targeted for late 2007. As previously stated, the Company's full efforts and resources are being devoted towards the clinical development program and commercialization of this product for treatment-failure gout."

Zeb Horowitz, MD, Savient Chief Medical Officer said, "The finalization of the SPA is very important to us, because it is a formal, written agreement with the FDA Review Division on the design, execution, and analysis of the Phase 3 pivotal studies in the Orphan gout (treatment-failure) population. Because our approach to the treatment of gout is novel, upfront agreement with FDA on the registration studies became a crucial component of our development strategy. The SPA process was a bit slower than we would have liked, but we have been able to use the time productively to progress Institutional Review Board reviews and approvals, complete training and pre-study preparations of clinical site staff and central laboratories, and generally to limber up for a successful study start and race to complete patient recruitment."

About Puricase® Phase 3 Clinical Study

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).

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® (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® (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.

SOURCE: Savient Pharmaceuticals, Inc.

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