



## **Savient Announces KRYSTEXXA(TM) Resubmitted BLA Accepted for Review by the FDA**

### **September 14, 2010 PDUFA Action Date Assigned**

EAST BRUNSWICK, N.J., March 30, 2010 /PRNewswire via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) announced today that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of and accepted for review the March 15, 2010 resubmission of the Biologics License Application (BLA) for KRYSTEXXA(TM) (pegloticase), a treatment for chronic gout in patients refractory to conventional therapy.

The FDA has deemed the resubmission a complete, class 2 response and has established September 14, 2010 as the PDUFA action date. The FDA also acknowledged that the BLA resubmission contains additional chemistry, manufacturing and controls (CMC), Safety Update, Labeling, Risk Evaluation and Mitigation Strategy (REMS) and Medication Guide submitted in response to the FDA's July 31, 2009 complete response letter.

"As expected, the FDA has determined our resubmission to be a class 2 review matter and thus the PDUFA action date is September 14th, 2010," stated Paul Hamelin, R.Ph., President of Savient. "We look forward to working with the FDA in moving KRYSTEXXA through the regulatory review process over the next few months."

### **ABOUT KRYSTEXXA(TM)**

KRYSTEXXA(TM) is a PEGylated uricase enzyme intended for the treatment of chronic gout in patients refractory to conventional therapy. Chronic gout that is refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

### **ABOUT SAVIENT PHARMACEUTICALS, INC.**

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing KRYSTEXXA(TM) (pegloticase) for the treatment of chronic gout in patients refractory to conventional therapy. **Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA, formerly referred to as Puricase(R), from Duke University and Mountain View Pharmaceuticals, Inc.** Savient also manufactures and supplies Oxandrin(R) (oxandrolone tablets, USP) CIII in the U.S. **Puricase is a registered trademark of Mountain View Pharmaceuticals, Inc.**

### **FORWARD-LOOKING LANGUAGE**

All statements other than statements of historical facts included in this press release are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding whether our BLA resubmission, combined with the submissions made and planned by our third party

contract manufacturer, fully addresses the deficiencies and observations raised and provides the additional materials requested in the Complete Response Letter that we received from the FDA on July 31, 2009, which were further clarified in our meeting with the FDA on September 14, 2009, the timing of FDA action with respect to the resubmission and potential FDA marketing approval for KRYSTEXXA are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, our Phase 3 clinical data, our current understanding of the complete response letter and on current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate. Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to, the possibility that the FDA may raise further issues regarding the BLA for KRYSTEXXA or require that we conduct additional clinical trials; reliance on third parties to manufacture, market and distribute many of our products; our ability to commercialize and market acceptance of KRYSTEXXA; difficulties in obtaining financing; potential development of alternative or more effective products by competitors; economic, political and other risks associated with foreign operations; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry and other important factors set forth more fully in our reports filed with the Securities and Exchange Commission, to which investors are referred for further information. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date of publication of this press release to shareholders. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.

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