



Savient Pharmaceuticals Receives Complete Response Letter from U.S. Food and Drug Administration for KRYSTEXXA(TM)

Savient to Host Conference Call on Monday, August 3, 2009 at 8:00am

EAST BRUNSWICK, N.J., Aug 02, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced that the Company has received a complete response letter from the U.S. Food and Drug Administration (FDA) stating that the FDA can not at this time approve the Company's Biologics License Application (BLA) for KRYSTEXXA(TM) (pegloticase) as a treatment for chronic gout in patients refractory to conventional therapy.

The complete response letter from the FDA cites deficiencies with the chemistry, manufacturing and controls (CMC) section of the BLA and also provided the current draft of the proposed labeling and further guidance regarding a Risk Evaluation and Mitigation Strategy (REMS) (Medication Guide and Communication Plan). The Company intends to immediately request a meeting with the FDA to discuss and clarify the issues raised in the complete response letter. Under FDA regulations, the Company believes that this meeting is deemed a "Type A" meeting, meaning that the FDA would meet with the Company within 30 days of its receipt of the meeting request.

One of the issues raised by the FDA in the complete response letter addresses a change made by the Company in the proposed process for manufacturing KRYSTEXXA for commercial use. The FDA has concluded that the comparability data submitted for the material manufactured using the proposed commercial manufacturing process was not adequate to demonstrate that it was representative of the material used to establish the safety and efficacy of KRYSTEXXA in its Phase 3 clinical trials. The FDA stated that the Company has the option of either reverting to and validating the manufacturing process used to produce KRYSTEXXA for the Phase 3 clinical trials or conducting additional comparability clinical trials to support the use of KRYSTEXXA manufactured using the proposed commercial manufacturing process. The Company currently expects that it will seek to address this issue by reverting to and revalidating the manufacturing process used to produce KRYSTEXXA for the Phase 3 clinical trials.

The complete response letter also stated that the FDA has determined that a REMS is necessary for KRYSTEXXA consisting of:

- A Medication Guide to ensure the safe and effective use of KRYSTEXXA by patients,
- A Communication Plan directed to healthcare providers likely to prescribe KRYSTEXXA to support the dissemination of information about the risks of severe infusion reactions and possible anaphylaxis, the risk of severe adverse reactions in administering KRYSTEXXA to patients with glucose-6-phosphatase dehydrogenase (G6PD) deficiency and major cardiovascular events, and
- An Assessment Plan to monitor and assess the effectiveness of the Medication Guide and Communication Plan in communicating to patients and physicians an understanding of the risks of KRYSTEXXA treatment.

The complete response letter included additional CMC comments focused on tightening manufacturing parameters and narrowing analytical specifications associated with commercial production. The Company was also informed that its resubmission to the FDA in response to the complete response letter must include an update of safety data from all on-going studies. Additionally, the Company's drug substance manufacturer BTG-Israel has already provided a work plan to remediate observations arising from the FDA pre-approval inspection of BTG-Israel's manufacturing facility and a satisfactory inspection report is required prior to the approval of KRYSTEXXA.

"While our timeline for resubmission to the FDA is subject to a number of uncertainties, we currently believe that we can target completion of our resubmission for early 2010. We hope to have more clarity on the expected timeline after we meet with the FDA to discuss the complete response letter," stated Paul Hamelin, President of Savient Pharmaceuticals. "While we believe we have made substantial progress toward the potential final approval of KRYSTEXXA, we also have more work to do with the FDA to resolve these open issues. We are committed to work diligently to address these issues with a goal of obtaining final approval for KRYSTEXXA so we can provide this therapy to those chronic gout patients who are suffering from this crippling, debilitating disease and have no other treatment options."

The Company believes that its resubmission will respond to all of the deficiencies cited in the complete response letter and would lead to a new Prescription Drug User Fee Act expected action date of either two or six months after the date of the Company's resubmission, depending on the FDA's classification of the resubmission.

ABOUT KRYSTEXXA(TM)

KRYSTEXXA(TM) (pegloticase) is a PEGylated uricase enzyme intended for the treatment of chronic gout in patients refractory to conventional therapy. Gout 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.

Conference Call Information

Savient will host a live webcast to discuss the approval of KRYSTEXXA on August 3, 2009 at 8:00 a.m. Eastern Time. Both the live and archived webcast can be accessed from the Investor Relations page of Savient's Website at <http://www.savient.com>. A digital recording of the webcast will be available within one hour following the conclusion of the call and will be available for 14 days. To access the recording, use the dial-in number and the Conference ID listed below.

Dial: 888-203-1112 (domestic) or 719-457-0820 (international)

Conf ID: 9640146

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and marketing pharmaceutical products that target unmet medical needs in both niche and broader specialty markets. Savient has developed one product: KRYSTEXXA(TM) (pegloticase) which is a PEGylated uricase enzyme intended 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. Further information on Savient can be accessed by visiting: <http://www.savient.com>. **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 potential FDA marketing approval for KRYSTEXXA(TM) (pegloticase), a meeting with the FDA to discuss the complete response letter, the reversion to and revalidation of the Phase 3 manufacturing process, the terms of a REMS program, the timing of a resubmission to the FDA in response to the complete response letter and the efficacy and safety of 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, our ability to commercialize and market acceptance of KRYSTEXXA; difficulties in obtaining financing; potential development of alternative or more effective products by competitors; reliance on third parties to manufacture, market and distribute many of our products; 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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