Savient Provides Update on Meeting with U.S. Food and Drug Administration for KRYSTEXXA(TM)

Company Confirms Early 2010 Target for KRYSTEXXA Resubmission

EAST BRUNSWICK, N.J., Sept 16, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Savient Pharmaceuticals, Inc. (Nasdaq: SVNT) today announced that on September 14, 2009, the Company completed a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) received by Savient on July 31, 2009 regarding the Company's Biologics License Application (BLA) for KRYSTEXXA(TM) (pegloticase) as a treatment for chronic gout in patients refractory to conventional therapy.

Based on the results of this meeting with the FDA, Savient believes that the FDA supports its approach to resolve all issues cited in the CRL. The meeting also confirmed that the FDA does not expect further clinical trials to be required as a result of Savient's reversion to the original manufacturing process to produce the Phase 3 clinical trial material for KRYSTEXXA, provided that no significant differences are observed between the material produced with the validated Phase 3 process and the Phase 3 clinical trial material. Savient, therefore, continues to believe that it can meet its previously discussed timeline of filing the resubmission in response to the CRL in early 2010.

"We are encouraged by the FDA's continuing collegial and collaborative dialogue in providing guidance to assist us in establishing the path forward to our resubmission for KRYSTEXXA," stated Paul Hamelin, President of Savient Pharmaceuticals. "We are grateful to the FDA for granting us this meeting so quickly and appreciate the considerable time and effort devoted by the FDA reviewers in evaluating our pre-meeting package and in providing very valuable feedback and guidance."

In response to the CRL, Savient requested and was granted the Type A meeting with the FDA to discuss, clarify and reach alignment on a resubmission plan to fully address all deficiencies and issues identified in the CRL. The FDA indicated that, in its view, Savient's plan to revert to and validate the original manufacturing process used to produce the Phase 3 clinical trials material, together with the inclusion of additional 0.22 micron filters in the manufacturing process, is a reasonable approach that the FDA expects will produce drug substance that is representative of that used in the pivotal Phase 3 clinical trials. The FDA stated that it also expects that the comparability between material produced with the validated Phase 3 process and the Phase 3 clinical trial material used in the replicate clinical trials to establish safety and efficacy can be sufficiently established by quality criteria alone without the need to conduct additional clinical studies, provided no significant differences between products are observed.

The FDA also agreed at this meeting with the methods and criteria proposed by Savient to tighten manufacturing analytical methods and acceptance criteria for all manufacturing steps in the final commercial production process. However, some of these final analytical methods and acceptance criteria are subject to being set based upon the data from historical manufacturing and validation batches that will be included in the resubmission. The meeting

outcomes confirm Savient's belief that it is on track to meet its previously discussed timeline of filing the resubmission in response to the CRL in early 2010.

The FDA also provided additional clarity relating to the steps necessary for Savient's drug substance manufacturer, Bio-Technology General (Israel) Ltd (BTG), a subsidiary of Ferring Pharmaceuticals, to satisfactorily correct the observations cited by the FDA during its pre-approval inspection of the BTG manufacturing facility. Savient believes that BTG's remediation of these observations can be corrected ahead of its resubmission to the FDA in response to the CRL.

The FDA also stated that the format and content of Savient's proposed safety update, which will include additional data collected from the KRYSTEXXA Open Label Extension study, is acceptable to the FDA.

During the meeting, the Company was informed that the review cycle for the resubmission would include the review of all data to fully address all issues identified in the CRL, including the final product labeling and the REMS materials. Since the resubmission will include REMS materials, this is subject to a Class 2 review cycle, meaning simultaneous approval of all components of our filing within six months of the date of our resubmission.

"We look forward to continuing to work with the FDA and executing on our resubmission strategy to the Complete Response Letter so that we can move forward with delivering this important therapy to treat chronic gout patients who are suffering from this crippling, debilitating disease and who have no other treatment options," commented Mr. Hamelin.

Savient also stated that the official minutes of this Type A meeting with the FDA will be made available to the Company within approximately 30 days from the date of the meeting.

Conference Call Information

Savient's management team will host a live conference call and Webcast today at 9:00 a.m. Eastern Time/6:00 a.m. Pacific Time to further discuss the results of the Type A meeting with the FDA. To participate by telephone, please dial 888-349-9587 from the U.S. or 719-457-2640 for international callers. The conference identification number is 8540659. The live and archived Webcast can be accessed on the investor relations section of the Savient Website at www.savient.com. Please log on to Savient's website 15 minutes prior to the start of the call to ensure adequate time for any downloads that may be necessary.

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.

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), whether any further clinical trials will be required, the actions that may be required of Savient by the FDA in connection with the BLA, the reversion to and revalidation of the Phase 3 manufacturing process, 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.

SVNT-G

SOURCE Savient Pharmaceuticals, Inc.

http://www.savient.com