



Savient Pharmaceuticals Announces New Data Surrounding KRYSTEXXA® and the Impact of Refractory Chronic Gout at the American College of Rheumatology Meeting

- Data from Phase III and open-label extension studies further explained and characterized infusion reactions and related management strategies with KRYSTEXXA, the first and only FDA-approved treatment for refractory chronic gout (RCG)**
- Retrospective study showed disconnect between EU gout treatment guidelines and practice patterns in the U.S.**
- Surveys of gout patients in the U.S. and select EU countries found that gout flares and tophi are directly correlated to lower health-related quality of life, reduced work productivity and increased use of healthcare resources**
- Analysis of U.S. managed care health plans revealed that patients with inadequately- controlled gout symptoms incurred significant economic burden directly related to the severity of their condition**

EAST BRUNSWICK, N.J., Nov. 5, 2011 /PRNewswire/ -- Savient Pharmaceuticals, Inc. (NASDAQ: SVNT) today announced that data providing further clarity and context surrounding the risk for and management of infusion reactions that may occur with KRYSTEXXA® (pegloticase) in the treatment of refractory chronic gout (RCG) patients will be presented at the American College of Rheumatology (ACR) Annual Scientific Meeting in Chicago. Additionally, the results from several Savient-sponsored studies highlighting the health-related quality of life and economic impact of inadequately-controlled gout and RCG will also be presented at the meeting.

A post-hoc analysis of data from the pivotal Phase III KRYSTEXXA clinical trials and an open-label extension study further characterized the signs and symptoms of infusion reactions and anaphylaxis and their management in the context of the clinical studies. While all patients studied were pre-medicated to decrease the potential risk of these events, the data also confirmed that risk of infusion reactions and anaphylaxis could be mitigated by the monitoring of serum uric acid (SUA) prior to each infusion and discontinuing of KRYSTEXXA treatment when SUA rises to above 6 mg/dL.

"These data contribute to the growing body of evidence supporting the profile and clinical utility of KRYSTEXXA," said John H. Johnson, Chief Executive Officer and President of Savient Pharmaceuticals. "Savient remains focused on educating healthcare professionals about KRYSTEXXA and its role in helping patients who have not found success with available conventional therapies to gain control of their RCG."

Data from health-related quality-of-life studies provided further insights surrounding the management of gout and RCG, and the relationship between symptom severity and patients' work productivity, healthcare resource utilization and medical costs:

- A retrospective examination of real-world practice habits indicated that there is a disconnect between EU gout treatment guidelines and current practice patterns among rheumatologists and primary care physicians in the United States (U.S.). The analysis found that with the availability of oral conventional urate-lowering therapies (ULTs), 64 percent of rheumatologists' patients and 70 percent of primary care physicians' patients had uric acid levels greater than 6 mg/dL; an indicator that their gout was not adequately controlled. In addition, 37.5 percent of patients in rheumatology practices and 14.2 percent of patients in primary care practices had tophi. These data suggest that patients under the care of rheumatologists had higher disease burden than those under the care of primary care physicians.
- Results from a survey of 620 gout patients in the U.S. and select EU countries, including France, Germany, Italy, Spain and the United Kingdom, showed that patients with higher uric acid levels also reported the presence of tophi and experienced an increased number of gout flares. Patients with tophi endured a greater disease burden compared to those without the deposits, including: greater overall work productivity loss (40.2 percent vs. 21.2 percent), activity impairment (48.7 percent vs. 37.2 percent), and more physician visits (9.0 vs. 6.5) ($p < 0.05$ for all). Further, gout flares also impacted patients' mental and physical well-being. Patients reported a greater deterioration in their quality of life in correlation with the number of gout flares they experienced, as well as work- and social-related impairment.
- Information from a U.S. database analysis of 24,503 gout patients underscored the link between gout symptom severity and the physical and economic cost to the patient. According to the analysis, patients with tophi who experienced greater than or equal to 3 gout flares during the study had significantly more physician office visits, laboratory services,

and ancillary services than patients in the control group without tophi or gout flares ($p < 0.001$). A comparison of patient records revealed that total 12-month costs averaged \$21,059 among patients with tophi and greater than or equal to 3 gout flares compared to \$10,657 for patients in the control group ($p < 0.001$). In addition, patients with tophi and greater than or equal to 6 gout flares had even higher resource utilization and overall healthcare costs totaling \$32,178 compared to the control group ($p < 0.01$).

"The gout epidemiology data presented at the ACR meeting underscore the importance of initiating early treatment with the appropriate medication to minimize the mental, physical and economic impact of gout and refractory chronic gout," commented Herbert S. B. Baraf, M.D., Clinical Professor of Medicine at The George Washington University School of Medicine and an investigator who conducted clinical trials with KRYSTEXXA. "Recently published data demonstrated that treatment with KRYSTEXXA resulted in significant and sustained reductions in uric acid levels and clinical improvements in RCG patients. The data from the post-hoc analysis of the KRYSTEXXA pivotal and extension studies will add to physicians' knowledge of the treatment and provide them with a straightforward approach for managing the risk of potential infusion reactions."

ABOUT THE STUDIES

Complete abstracts can be found online via the following links:

[Characterization and Management of Infusion Reactions in Refractory Chronic Gout \(RCG\) Treated with Pegloticase \(KRYSTEXXA\)](#)

Presentation Number: 2582

Wednesday, November 9, 2011: 9:45 AM

Oral presentation W 474 A (McCormick Place Convention Center)

[Patient Management/Treatment and Outcomes of Gout Between Primary Care Physicians and Rheumatologists: A Chart Review of 1,039 Patients with Gout In the United States](#)

Presentation Number: 1035

Monday, November 7, 2011: 9:00 AM-6:00 PM

Poster Hall (McCormick Place Convention Center)

[Gout Patient Burden Associated with Flares, Tophi, and Awareness of Uric Acid Levels In U.S. and E.U.](#)

Presentation Number: 216

Sunday, November 6, 2011: 9:00 AM-6:00 PM

Poster Hall (McCormick Place Convention Center)

[Economic Burden of Gout Patients Treated with Urate Lowering Therapy](#)

Presentation Number: 2583

Wednesday, November 9, 2011: 10:00 AM

Oral presentation W 474 A (McCormick Place Convention Center)

ABOUT KRYSTEXXA®

KRYSTEXXA® (pegloticase) is a PEGylated uric acid specific enzyme for administration by intravenous infusion for the treatment of refractory chronic gout (RCG) in adult patients. KRYSTEXXA became commercially available in the U.S. by prescription on December 1, 2010, and is the only U.S. Food and Drug Administration approved product specifically indicated for the treatment of RCG. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia. For more information about KRYSTEXXA, please visit: <http://www.krystexxa.com/>.

IMPORTANT SAFETY INFORMATION ABOUT TREATMENT WITH KRYSTEXXA®

KRYSTEXXA is not indicated for the treatment of asymptomatic hyperuricemia. Patients who are at risk of having a condition known as G6PD deficiency should be screened by their physician prior to starting therapy with KRYSTEXXA.

Possible side effects of KRYSTEXXA include:

- Anaphylaxis which occurred in some patients treated with KRYSTEXXA. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis. Patients should be pre-medicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA.
- Infusion reactions which occurred in some patients treated with KRYSTEXXA. The risk of an infusion reaction is higher in

patients who have lost therapeutic response. Because the risk of infusion reactions is higher in patients who lose therapeutic response to KRYSTEXXA, monitor serum uric acid before each infusion and consider discontinuing treatment if levels rise above 6 mg/dL, particularly when two consecutive levels above 6 mg/dL are observed.

- As with other urate-lowering therapies, an increase in gout flares was seen in some patients treated with KRYSTEXXA. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion. Patients receiving re-treatment may be at increased risk for anaphylaxis and infusion reactions and should be monitored carefully.

ADVERSE REACTIONS

The most commonly reported serious adverse reactions are anaphylaxis, infusion reactions and gout flares. Most common adverse reactions: gout flares (77%), infusion reactions (26%), nausea (12%), contusion or ecchymosis (11%), nasopharyngitis (7%), constipation (6%), chest pain (6%), anaphylaxis (5%), and vomiting (5%).

Please see the Full Prescribing Information and Medication Guide at <http://www.krystexxa.com/>.

ABOUT REFRACTORY CHRONIC GOUT

Gout is a painful, debilitating form of arthritis and affects approximately eight million people in the U.S. alone. A significant sub-population of gout patients, approximately 120,000, are burdened with a difficult-to-treat form of the condition, known as refractory chronic gout (RCG). Symptoms of gout are caused by the body's response to the presence of uric acid crystals in the joints and surrounding tissue, which form when uric acid levels in the blood are elevated (a condition called hyperuricemia). The longer hyperuricemia persists, the higher the risk of developing gout. Symptoms of gout may include painful flares, pain or swelling in the joints (known as "gouty arthritis") or deposits of uric acid crystals under the skin, called "tophi." In cases of RCG, these symptoms may have a major influence on patient health-related quality of life due to the frequency and severity of episodes, the recurrent pain and the disfigurement associated with this condition. Although most cases of gout can be controlled with conventional urate-lowering therapy, when uric acid levels remain high, and signs and symptoms persist despite treatment efforts, chronic gout may be defined as refractory.

ABOUT SAVIENT PHARMACEUTICALS, INC.

Savient Pharmaceuticals, Inc. is a specialty biopharmaceutical company focused on developing and commercializing KRYSTEXXA® (pegloticase) for the treatment of chronic gout in adult patients refractory to conventional therapy. Savient has exclusively licensed worldwide rights to the technology related to KRYSTEXXA and its uses from Duke University ("Duke") and Mountain View Pharmaceuticals, Inc. ("MVP"). Duke developed the recombinant uricase enzyme and MVP developed the PEGylation technology used in the manufacture of KRYSTEXXA. MVP and Duke have been granted U.S. and foreign patents disclosing and claiming the licensed technology and, in addition, Savient owns or co-owns U.S. and foreign patents and patent applications, which collectively form a broad portfolio of patents covering the composition, manufacture and methods of use and administration of KRYSTEXXA. Savient also manufactures and supplies Oxandrin® (oxandrolone tablets, USP) CIII in the U.S. For more information, please visit the Company's website at www.savient.com.

FORWARD-LOOKING STATEMENTS

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 the safety and efficacy of KRYSTEXXA, status of our KRYSTEXXA marketing efforts and additional plans related thereto, market demand and reimbursement for KRYSTEXXA, our view of the refractory chronic gout (RCG) market size, and our market expansion plans including our MAA filing before the EMA 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, 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, our ability to commercialize KRYSTEXXA; the risk that the market for KRYSTEXXA is smaller than we have anticipated; our ability to retain the personnel; our reliance on third

parties to manufacture KRYSTEXXA; competition from existing therapies and therapies that are currently under development, including therapies that are significantly less expensive than KRYSTEXXA; our ability to gain market acceptance for KRYSTEXXA among physicians, patients, health care payers and others in the medical community; whether we are able to obtain financing, if needed; 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. 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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