



Savient Announces Named Patient Programme for KRYSTEXXA® in the European Union for Patients with Refractory Chronic Gout

EAST BRUNSWICK, New Jersey, March 5, 2012 /PRNewswire/ --

Savient Pharmaceuticals, Inc. today announced that KRYSTEXXA(R)(pegloticase) is now available in the European Union to healthcare professionals and their patients suffering from refractory chronic gout (RCG) through a Named Patient Programme, which is sponsored by its wholly-owned subsidiary, Savient Pharma Ireland Limited, and managed by Idis Limited (Idis). RCG is a difficult-to-treat form of gout and currently there are no other available therapies approved in the European Union for the treatment of RCG. KRYSTEXXA is currently available in the U.S. and is the only U.S. Food and Drug Administration approved treatment for RCG.

"In responding to prescriber and patient requests for access to KRYSTEXXA in the European Union, we are pleased to have established this Named Patient Programme in collaboration with Idis as we continue to advance our efforts to ensure that patients suffering from RCG have access to KRYSTEXXA. We believe that KRYSTEXXA can address a significant unmet medical need globally and we remain committed to provide this therapy to those patients who suffer from this crippling, debilitating disease and have no other treatment options available to them," said Kenneth Bahrt, M.D., Senior Vice President and Chief Medical Officer of Savient Pharmaceuticals, Inc.

"We are pleased to be working with Savient to ensure that those patients with RCG have access to KRYSTEXXA through this Named Patient Programme," said Natalie Douglas, Chief Executive Officer, Idis. "We remain deeply committed to working in partnership with companies like Savient to give physicians and their patients access to new and innovative medicines through fully compliant channels."

Idis develops and implements Managed Access Programmes that allow patients with unmet medical needs to access medicines that are not available through the traditional clinical trial or commercial framework. For this programme, Idis will facilitate access to KRYSTEXXA on a named patient basis to European hospitals, pharmacies, physicians on behalf of their patients. Under a Named Patient Programme, treatments that are pending approval by the European Medicines Agency (EMA) can be legally administered to patients who are suffering from serious diseases until they are commercially available in each market. Savient is seeking approval for KRYSTEXXA in Europe and filed its regulatory application with the EMA in May 2011.

Healthcare professionals licensed in the European Union treating patients with RCG interested in KRYSTEXXA should contact Idis at:

Telephone: +44-(0)-1932824123

Fax: +44-(0)-1932824323

Email to: global@idispharma.com

ABOUT KRYSTEXXA(R)

KRYSTEXXA(R)(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(R)

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.

Discontinue oral urate-lowering therapies before instituting KRYSTEXXA and do not institute oral urate-lowering therapy while the patient is on KRYSTEXXA therapy.

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 6mg/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 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(R)(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(R)(oxandrolone tablets, USP) CIII in the U.S. For more information, please visit the Company's website at <http://www.savient.com>.

ABOUT Idis

Around the world, patients with unmet medical needs are frequently driven to seek access to medicines outside the clinical trial and commercial setting. Idis is the leading expert in developing, implementing and managing global Managed Access Programs by which pharmaceutical and biotechnology companies and healthcare providers can respond to the needs of these patients. "Managed Access" is an umbrella term encompassing a variety of different regulatory approaches, including Named Patient Programs that enable access to medicines that are not available to patients via the traditional clinical or commercial route.

Idis has 25 years experience of partnering with pharmaceutical and biotechnology companies to create regulatory-compliant, ethical access to medicines for healthcare professionals and their patients with unmet medical needs.

Since 1987, Idis has developed and managed access to thousands of medicines from virtually every therapeutic category, impacting the lives of hundreds of thousands of patients in countries around the world. For more information please visit: <http://www.idispharma.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(R), 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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