Crealta Pharmaceuticals LLC Announces Completion of the Acquisition of Substantially All of the Assets of Savient Pharmaceuticals, Inc.

Acquisition is highlighted by KRYSTEXXA® (pegloticase), the only product approved for the treatment of refractory chronic gout

Glendale, WI, January 10, 2014 (PR Newswire) -- Crealta Pharmaceuticals LLC (“Crealta”), a new specialty pharmaceutical company, announced today the completion of the acquisition of substantially all of the assets of Savient Pharmaceuticals, Inc. (“Savient”). Crealta previously announced the winning of an auction for these assets, the signing of a definitive acquisition agreement with Savient, and the subsequent approval of the transaction by the U.S. Bankruptcy Court for the District of Delaware.

The key asset acquired by Crealta is KRYSTEXXA (pegloticase), a novel biologic product that was approved by the FDA in 2010. KRYSTEXXA is a PEGylated uric acid specific enzyme, or uricase, that has been shown to statistically significantly reduce uric acid levels for many patients with refractory chronic gout.

"We are tremendously excited to have completed the transaction, and more importantly, to ensure the continued availability of this critical product," commented Ed Fiorentino, Chairman and CEO of Crealta. "Crealta is committed to providing outstanding support and service to healthcare professionals and the patients that they serve with refractory chronic gout."

Crealta was established in August 2013 in partnership with GTCR, one of the nation's leading private equity firms.

KRYSTEXXA IMPORTANT SAFETY INFORMATION

The following information is provided in both the U.S. and European prescribing information.

KRYSTEXXA is not indicated for the treatment of asymptomatic hyperuricemia. KRYSTEXXA is indicated for adults who have tried or cannot take oral gout medications and still have high uric acid levels and signs and symptoms of gout. Patients who have a genetic condition known as G6PD deficiency should not use KRYSTEXXA.

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

Warnings and Precautions:

- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. 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 discontinue treatment if levels rise above 6mg/dL, particularly when two consecutive levels above 6 mg/dL are observed.
- 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.

In addition, the European Summary of Product Characteristics (SmPC) includes two other special warnings and precautions for use.

- If hemolysis and/or methemoglobinemia occur in patients receiving KRYSTEXXA, treatment should be immediately and permanently discontinued and appropriate measures initiated.
- Patients over 100 kg body weight may have higher titers of anti-pegloticase antibodies and infusion-related reactions showed a tendency to occur in a greater proportion of patients in this weight group.

The most commonly reported serious adverse reactions were anaphylaxis, infusion reactions and gout flares. The SmPC includes the following very common adverse reactions: gout flares, infusion reactions, nausea, dermatitis, urticaria, pruritus, skin irritation and dry skin. In the U.S. prescribing information, the most common adverse reactions (5% or greater) reported were gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

Please see full prescribing information for KRYSTEXXA.

About Refractory Chronic Gout (RCG)
Symptoms of gout are caused by the body's response to the presence of high uric acid (urate) levels which can lead to the formation of urate 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 urate crystals under the skin, called "tophi." Although most cases of gout can be controlled with conventional urate-lowering therapy, uric acid levels may remain high and symptoms persist despite treatment efforts, even at maximum medically appropriate doses of conventional therapies.

RCG is a chronic disease that, if left untreated, can lead to chronic pain, tophi-induced joint destruction and disfigurement, and significant mobility restrictions for patients. RCG has been granted orphan drug status by the FDA due to the relatively small patient population afflicted with this debilitating condition.

About Crealta
Crealta is a specialty pharmaceutical company focused on innovative therapeutics designed to improve patient outcomes. The company was formed to acquire, develop, and market specialty pharmaceutical products with a focus on select physician specialties. For more information about Crealta, please visit www.crealtapharma.com, call 1-781-639-1910, or email kaplan@kogspr.com.

About GTCR
Founded in 1980, GTCR is a leading private equity firm focused on investing in growth companies in the Financial Services & Technology, Healthcare and Information Services & Technology industries. The Chicago-based firm pioneered The Leaders Strategy™ – finding and partnering with management leaders in core domains to identify, acquire and build market-leading companies through transformational acquisitions and organic growth. Since its inception, GTCR has invested more than $10 billion in over 200 companies. For more information, please visit www.gtcr.com.