Coherus and Baxalta Announce CHS-0214 (Investigational Etanercept Biosimilar) Met Primary Efficacy Endpoints in Phase 3 Psoriasis Clinical Study (RaPsODY)

REDWOOD CITY, Calif. and BANNOCKBURN, Ill., Nov. 09, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS) and Baxalta Incorporated (NYSE:BXLT) today announced that CHS-0214, a proposed biosimilar of Enbrel® (etanercept), met its primary endpoints in a confirmatory, double-blind, randomized, controlled, two-part Phase 3 study. This on-going 52-week study is evaluating the efficacy and safety of CHS-0214 compared to Enbrel® in patients with moderate-to-severe chronic plaque psoriasis.

“We are pleased with this positive clinical outcome,” said Barbara Finck, M.D., Chief Medical Officer of Coherus. “CHS-0214 is an important option for patients requiring treatment with etanercept. If approved by regulatory agencies, CHS-0214 has the potential to offer patients a high-quality treatment option for conditions for which etanercept is indicated.”

“Achievement of this late-stage clinical milestone further validates the capabilities of our development platform in advancing biosimilar compounds toward approvals within regulated markets,” said Denny Lanfear, President and Chief Executive Officer of Coherus.

The efficacy endpoints were based on a Week 12 assessment of Psoriasis Activity Severity Index (PASI) scores. At Week 12, the primary endpoints, the mean percent change in PASI from baseline and the proportion of subjects achieving 75% improvement in PASI from baseline, were within the pre-specified margins for demonstrating equivalence of CHS-0214 compared to Enbrel®. There were no clinically meaningful differences in the safety profiles of the products.

“We are encouraged by the data from this confirmatory study,” said Dagmar Rosa-Björkeson, Executive Vice President and President, Biosimilars, Baxalta. “Plaque psoriasis has a significant impact on a patient’s quality of life and self-perception, so early access to treatment is imperative. If approved, CHS-0214 would expand access of treatment options for patients with moderate-to-severe chronic plaque psoriasis.”

The study continues as planned until Week 52. The psoriasis study is one of two, large, Phase 3 confirmatory trials intended for inclusion in global marketing applications for CHS-0214. Results for the second Phase 3 study in patients with rheumatoid arthritis are expected in the first quarter of 2016.

Coherus and Baxalta initiated a collaboration to develop and commercialize CHS-0214 in September of 2013.

About CHS-0214, a proposed biosimilar of Enbrel® (etanercept)

CHS-0214 was evaluated in two comprehensive single-dose, cross-over pharmacokinetic / bioequivalence (PK / BE) studies in healthy volunteers. In both trials, CHS-0214 met PK similarity to Enbrel® based on pre-specified pharmacokinetic criteria. The safety profiles of CHS-0214 and Enbrel® were similar in these studies.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play global biosimilar platform company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products. For additional information, please visit www.coherus.com.

Forward Looking Statement For Coherus

To the extent that statements contained in this press release are not descriptions of historical facts regarding Coherus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the ability of Coherus to obtain regulatory approval from the FDA for CHS-0214, its ability to submit a 351(k) (biosimilar) license application for CHS-0214 on its desired timeline and the potential benefits of CHS-0214. Such forward-looking statements involve substantial risks and uncertainties that relate to future events and the actual results could differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the biosimilar development process, including the regulatory approval process, the timing of the actions of regulatory bodies and other governmental authorities, clinical results, changes in laws and regulations, product quality or supply for CHS-0214 and Enbrel®, patient safety and patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see the company's current and future reports filed with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015.

About Baxalta

Baxalta Incorporated (NYSE:BXLT) is a $6 billion global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology. Driven by passion to make a meaningful impact on patients’ lives, Baxalta’s broad and diverse pipeline includes biologics with novel mechanisms and advanced technology platforms such as gene therapy. The Baxalta Global Innovation and R&D Center is located in Cambridge, Massachusetts. Launched in 2015 following separation from Baxter International, Baxalta’s heritage in biopharmaceuticals spans decades. Baxalta’s therapies are available in more than 100 countries and it has advanced biological manufacturing operations across 12 facilities, including state-of-the-art recombinant production and plasma fractionation. Headquartered in Northern Illinois, Baxalta employs 16,000 employees worldwide.

Forward Looking Statement For Baxalta

This release includes forward-looking statements concerning Baxalta's collaboration with Coherus on CHS-0214, including expectations with regard to future regulatory actions and potential impact on patients. Such statements are made of the date that they were first issued and are based on current expectations, beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Baxalta's control and which could cause actual results to differ materially from those in the forward-looking statements, including the following: clinical trial results; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality, manufacturing or supply issues; patient safety issues; and other risks identified in Baxalta's Registration Statement on Form 10 and other Securities and Exchange Commission filings, all of which are available on Baxalta's website. Baxalta expressly disclaims any intent or obligation to update these forward-looking statements except as required by law.

Enbrel® is a registered trademark of Amgen Inc.

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