



## Coherus Announces Positive Phase 2b Efficacy Data on Novel Oral Therapy in Relapsing Remitting Multiple Sclerosis

Jun 28, 2016

*Six Month Study Demonstrates Significant Reduction in Contrast-Enhancing Lesions Meeting Primary Endpoint*

*Safety and Tolerability Support Differentiated Product Profile*

REDWOOD CITY, Calif., June 28, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading global biosimilars company with late-stage clinical products, today announced that a study with CHS-131 in treatment-naïve, relapsing remitting multiple sclerosis (RRMS) subjects demonstrated approximately a 50% decrease in the incidence of new contrast-enhancing (CE) lesions over six months when compared to placebo. CHS-131 was generally well-tolerated and without evidence of immune suppression or the side-effects commonly seen in other oral multiple sclerosis (MS) therapies. CHS-131 is a novel, first-in-class, well-tolerated, once-daily, oral drug candidate for MS patients which has anti-inflammatory activity in the central nervous system (CNS) and crosses the blood-brain barrier.

"These are exciting results for a new drug with non-immunosuppressive activity that is well-tolerated by patients," said Patricia G. Coyle, M.D., Vice Chair at State University of New York (SUNY) Stony Brook Neurosciences Institute. "This clearly warrants further clinical investigation." Dr. Coyle is a well-known MS expert and was not a study investigator or a consultant to the company.

This Phase 2b trial was a randomized, double-blind, placebo-controlled clinical study that evaluated the efficacy, safety and tolerability of two orally administered doses (3 mg and 1 mg daily) of CHS-131 against placebo for six months in 227 subjects with RRMS. The primary endpoint of the trial was the reduction in the cumulative number of total CE lesions determined by magnetic resonance imaging (MRI) from baseline to week 24 of study treatment, a standard endpoint for Phase 2 trials in RRMS. Subjects were assessed clinically and by MRI monthly for six months. All MRIs were read in a blinded fashion at a U.S. imaging center. Patients on CHS-131 experienced a statistically significant reduction in CE lesions that was dose dependent, with the 3 mg dose resulting in a 46.3% reduction in CE lesions with a p-value of 0.01 compared to placebo.

The detailed results of the study are expected to be presented at a scientific conference later in 2016.

Safety and tolerability data from the trial provide support for a differentiated, potential best-in-class profile. The overall adverse event profile appeared relatively similar between the CHS-131 dose groups and placebo with no new safety signals for patients receiving CHS-131. The study is ongoing and part 2 is an open label safety extension in which clinical response, CE lesions on MRI, and safety will continue to be evaluated.

"We believe these results are consistent with a well-differentiated profile with strong commercial potential in the \$20 billion MS market. CHS-131 is strategically synergistic with our biosimilar MS therapeutic area franchise and we see this asset as the cornerstone of our MS strategy. It is expected to be complementary with existing CNS therapies and the injectable protein product candidates in the Coherus MS biosimilar program. The product candidate is substantially Phase 3 ready in terms of preclinical toxicology. We will now be moving forward with our various MS biosimilar candidates," said Denny Lanfear, President & Chief Executive Officer Coherus. "We are excited about these positive results as we continue to focus on execution in a transformative year for Coherus."

### **About CHS-131**

CHS-131 is an anti-inflammatory molecule without immunosuppressive activity and has been studied in over 600 patients in other indications, as well as MS, and has been demonstrated to be generally well tolerated. Therefore, CHS-131 may be a candidate for first-line therapy alone or in combination with other MS disease modifying therapies, many of which are immunosuppressive.

Unlike CHS-131, many MS disease modifying therapies are designed to function by suppressing the immune response, both in the nervous system and throughout the body. This renders patients susceptible to certain opportunistic infections, malignancies and other side effects. In contrast, CHS-131 has potent anti-inflammatory effects without evidence of immunosuppression.

Coherus will hold a conference call on Tuesday, June 28, 2016 at 12:00 noon ET.

### **Conference Call Information**

Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)

Conference ID: 41704816

Please join the conference call at least 10 minutes early to register.

### **A replay of this conference call will be available through July 4, 2016:**

Dial-in: (404) 537-3406 (domestic) or (855) 859-2056 (international)

Conference ID: 41704816

### **About Coherus BioSciences, Inc.**

Coherus is a leading global biosimilar 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 in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit [www.coherus.com](http://www.coherus.com).

### **Forward-Looking Statements**

*Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities including market opportunities, expectations, goals, objectives, strategies, product pipeline, clinical studies, product*

*development, release of data and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to further the clinical development and obtain marketing approval for and commercialization of CHS-131 and Coherus' biosimilar candidates. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible 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 Coherus' business in general, see Coherus' Annual Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 9, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.*

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INVESTOR RELATIONS

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