



## **CELTIC THERAPEUTICS AND BELLUS HEALTH INITIATE CONFIRMATORY PHASE III CLINICAL STUDY FOR KIACTA™, A DRUG CANDIDATE FOR THE TREATMENT OF AA AMYLOIDOSIS**

LAVAL, Canada, and NEW YORK, USA. December 15, 2010 – BELLUS Health Inc. (TSX: BLU) and Celtic Therapeutics announced today that a global confirmatory phase III clinical study was initiated on December 14, 2010 for KIACTA™ (eprodysate). KIACTA™ is a drug candidate being developed for the treatment of AA amyloidosis, a life-threatening orphan disease that occurs in patients with long-lasting inflammatory conditions, most commonly due to rheumatoid arthritis. The study is designed to confirm the safety and efficacy of KIACTA™ in preventing renal function decline in patients with AA amyloidosis.

"KIACTA™ has the potential to offer a much awaited treatment to patients with AA amyloidosis, a devastating disease affecting an estimated 50,000 patients in the United States, Europe and Japan, for which there is currently no specific treatment available," said Dr. Peter B. Corr, Co-Founder and General Partner of Celtic Therapeutics. "In its initial phase III clinical study, KIACTA™ reduced the risk of renal decline or mortality by 42% (Cox proportional hazards regression model,  $p=0.025$ ) as compared to placebo over a two-year period, and showed an excellent safety profile. KIACTA™ also continues to be safe and well tolerated upon chronic administration, with some patients exposed to the compound for more than eight years in the compassionate use program. These past findings make us confident regarding the outcome of the confirmatory phase III study," Dr. Corr added.

"We are pleased to see KIACTA™ advancing to a confirmatory phase III clinical study so quickly and are delighted that leading investigators throughout the world are eager to participate in this important trial", said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "As agreed upon with the US Food and Drug Administration (FDA) in a Special Protocol Assessment (SPA) and the European Medicines Agency (EMA), this confirmatory study represents the last key step before applications for regulatory approval for KIACTA™ can be filed. The initiation of this registration trial is positive news for patients with AA amyloidosis and represents an important milestone for BELLUS Health and its shareholders," Mr. Bellini concluded.

### **Details of the confirmatory phase III clinical study**

The international, randomized, double-blind, placebo-controlled, event-driven study will involve approximately 230 patients diagnosed with AA amyloidosis enrolled from approximately 90 sites in 30 countries worldwide. The primary efficacy composite endpoint of the study is based on patients reaching an event linked to the deterioration of their renal function, defined as a persistent decrease in creatinine clearance (CrCl) of 40% or more, a persistent increase in serum creatinine (SCr) of 80% or more, or progression to end-stage renal disease (ESRD). The primary efficacy analysis will be the time from baseline to the first renal deterioration event of the primary composite endpoint.

The study is tentatively planned to end when approximately 104 renal events have occurred. The number of events and enrollment target for the study will be reviewed and may be refined following an interim analysis which will be conducted following the occurrence of at least 20 events and 15 months after the enrollment of the first patient. It is currently estimated that the study will be completed in 2014.

### **About KIIACTA™**

KIIACTA™ is an investigational product candidate for the treatment of AA amyloidosis. KIIACTA™ has received Orphan Drug Status designation in the United States and Orphan Medicinal Product designation in Europe and began a Phase III confirmatory clinical trial in December of 2010.

KIIACTA™ was investigated in a landmark international, randomized, double-blind, placebo-controlled, and parallel-designed clinical trial in which 183 AA amyloidosis patients were enrolled at 27 sites around the world. The results of the Phase II/III clinical trial for KIIACTA™ demonstrated that this product candidate offers important clinical benefits to patients by reducing the progression of AA amyloidosis-associated renal disease. These results were published in the June 7, 2007 issue of the New England Journal of Medicine.

### **About AA Amyloidosis**

AA amyloidosis is a progressive and fatal condition that affects approximately 50,000 people in the United States, Europe and Japan with chronic inflammatory diseases, including rheumatoid arthritis, ankylosing spondylitis, juvenile rheumatoid arthritis, and Crohn's disease. The disease also occurs in patients suffering from many other conditions ranging from chronic infections to inherited inflammatory diseases such as Familial Mediterranean Fever. The most common clinical presentation of AA amyloidosis is renal dysfunction. Involvement of the gastrointestinal system is also frequent and is usually manifested as chronic diarrhea, gastrointestinal bleeding, abdominal pain and malabsorption. Enlargement of the liver and the spleen may also occur in some patients. End-stage renal failure is the main cause of death in 40-60% of cases. The median survival time from diagnosis varies from two to 10 years depending on the stage of the disease at the time of diagnosis.

No specific treatment is currently available for this orphan disease. The goal of the existing therapies is limited to the control of the underlying chronic inflammatory disease. Current therapeutic approaches are non-specific, and often toxic, invasive or ineffective.

### **About BELLUS Health**

BELLUS Health is a development-focused health company concentrating on research and development of products that provide innovative health solutions and address critical unmet medical needs. For further information, please visit [www.bellushealth.com](http://www.bellushealth.com).

### **About Celtic Therapeutics**

Founded in 2007 by Stephen Evans-Freke and Dr. Peter B. Corr, Celtic Therapeutics is a successor firm to Celtic Pharma Management L.P., pursuing the same pharmaceutical product-focused strategy on a larger scale. As a global private equity firm, it identifies, acquires and develops therapeutic products and related diagnostics in mid- and late-stage clinical development, in order to build one of the most valued portfolios of late-stage drug development programs in the global biopharmaceutical industry. Based in the US Virgin Islands, Celtic Therapeutics maintains origination and drug development operations in New York City and Switzerland. The Celtic Therapeutics team comprises extensive experience in all aspects of pharmaceutical investment management as well as a world class clinical and commercial development experience in the pharmaceutical industry. For further information, please visit [www.celtictherapeutics.com](http://www.celtictherapeutics.com).

## Forward Looking Statements

*Certain statements contained in this news release, other than statements of fact that are independently verifiable at the date hereof, may constitute forward-looking statements. Such statements, based as they are on the current expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond BELLUS Health Inc.'s control. Such risks include but are not limited to: the impact of general economic conditions, general conditions in the pharmaceutical and/or nutraceutical industry, changes in the regulatory environment in the jurisdictions in which the BELLUS Health Group does business, stock market volatility, fluctuations in costs, and changes to the competitive environment due to consolidation, that actual results may vary once the final and quality-controlled verification of data and analyses has been completed, as well as other risks disclosed in public filings of BELLUS Health Inc. Consequently, actual future results may differ materially from the anticipated results expressed in the forward-looking statements. The reader should not place undue reliance, if any, on any forward-looking statements included in this news release. These statements speak only as of the date made and BELLUS Health Inc. is under no obligation and disavows any intention to update or revise such statements as a result of any event, circumstances or otherwise, unless required by applicable legislation or regulation. Please see the Annual Information Form of BELLUS Health Inc. for further risk factors that might affect the BELLUS Health Group and its business.*

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