Auven Therapeutics and Bellus Health Announce Completion of Pivotal Phase 3 Confirmatory Trial of KIACTA™ for the Treatment of Orphan Disease AA Amyloidosis

Study Reached 120 Qualifying Events, Top-Line Results Expected in Q2 2016

ST. THOMAS, U.S. Virgin Islands, LAUSANNE, Switzerland, HAMILTON, Bermuda and LAVAL, Quebec, Jan. 21, 2016 (GLOBE NEWSWIRE) -- Auven Therapeutics, a global private equity company focused on accelerated development of breakthrough therapeutic drugs, and BELLUS Health Inc. (TSX:BLU), a drug development company focused on rare diseases, today announced the completion of the KIACTA™ (eprodisate) Phase 3 confirmatory study for the treatment of AA amyloidosis. Top-line results are expected to be announced in Q2 2016 after all remaining patients have completed final study visits, all queries have been resolved based on input from study sites and the database has been locked.

AA amyloidosis is a rare disease secondary to severe chronic inflammation or infection leading to the formation and deposition of amyloid fibrils in organs, often resulting in end-stage renal disease and death. Currently there are no therapies available that target the disease directly. In prior clinical studies, KIACTA™ has been shown to slow the decline of renal function in AA amyloidosis patients by its ability to interfere with the formation of amyloid fibrils A and the deposition of these fibrils in tissues.

“We designed this trial to confirm the results of the prior Phase 2/3 study in which KIACTA™ demonstrated significant delays in AA amyloidosis disease progression, in some cases for a number of years,” said Dr. Peter B. Corr, Co-Founder and Managing General Partner of Auven. “We are very pleased to complete this step in our pivotal study and look forward to reviewing and announcing the top-line results during the second quarter of 2016.”

The five-year Phase 3 study completed enrollment in January 2015 with a total of 261 patients. In January 2016, the event-driven study met its completion target of 120 patient events linked to the deterioration of kidney function. As all remaining patients have a final study visit in the coming weeks, the final number of events could increase.

Assuming that this Phase 3 study achieves its primary endpoint, it will support global regulatory approvals for KIACTA™ for the treatment of AA amyloidosis. Preclinical data also suggests KIACTA™ has potential to treat other diseases, including sarcoidosis. In vitro study test results in sarcoidosis indicate KIACTA™ may reduce SAA-induced inflammatory cytokine expression and the initiation of a Phase 2b/3 study in this second orphan indication is expected in 2016.

“The KIACTA™ Phase 3 confirmatory study is the most comprehensive study ever conducted in AA amyloidosis patients,” said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. “We are excited that a key portion of the study is complete and look forward to receiving the top-line data.”

“We anticipate this trial will demonstrate conclusively KIACTA™’s potential to make a major impact in the lives of those who currently have no other treatment options available to them, and we look forward to commencing a formal sale process for KIACTA™ later this year,” said Stephen Evans-Freke, Co-Founder

and Managing General Partner of Auven.

About KIACTA™ for AA Amyloidosis

KIACTA™ is an oral therapy in development for the treatment of AA amyloidosis, an orphan disease for which there is no currently approved therapy available. AA amyloidosis is a progressive, severe and potentially fatal condition that affects people with chronic inflammatory diseases. Chronic inflammation and/or infection cause amyloid deposits accumulating within internal organs resulting in potential organ failure over time. KIACTA™ has been studied for its ability to slow the decline of renal function in AA amyloidosis patients by interfering with the formation of amyloid fibrils and the deposition of these fibrils in tissues. KIACTA™ has received Orphan Drug Status in the United States for AA amyloidosis and Orphan Medicinal Product designation for AA amyloidosis in Europe and Japan.

KIACTA™ was originally developed by BELLUS Health. Auven Therapeutics acquired worldwide rights related to KIACTA™ from BELLUS Health in 2010 and is responsible for conducting and financing the KIACTA™ development program. Auven Therapeutics and BELLUS Health expect to share overall proceeds from a KIACTA™ divestiture equally, assuming that total divestment transaction proceeds reach a pre-determined threshold. Proceeds will be shared between Auven Therapeutics and BELLUS Health based on a formula that provides for Auven Therapeutics to have certain preference rights on exit proceeds related to their investment costs in KIACTA™.

About Auven Therapeutics (www.auventx.com)

Auven Therapeutics is a global private equity firm that acquires and pursues accelerated development of breakthrough therapeutic drugs prior to licensing them to commercial partners. Auven's in-house team of senior pharmaceutical development executives establishes the clinical, regulatory, manufacturing and commercial strategies for all its products and oversees their execution. Auven was founded in 2007 by Stephen Evans-Freke and Dr. Peter B. Corr and maintains operations in Lausanne, London, Ft. Lauderdale, Bermuda, and the U.S. Virgin Islands.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a drug development company focused on rare diseases. It has a portfolio of rare disease projects including KIACTA™ in Phase III for AA amyloidosis, KIACTA™ for sarcoidosis, clinical stage Shigamab™ for STEC-related Hemolytic Uremic Syndrome (sHUS) and a research-stage project for AL amyloidosis.

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 important risks, uncertainties and assumptions, known and unknown, many of which are beyond BELLUS Health Inc.'s and Auven Therapeutics' control. Such risks include but are not limited to: the ability to obtain financing, the impact of general economic conditions, general conditions in the pharmaceutical industry, changes in the regulatory environment in the jurisdictions in which BELLUS Health Inc. and Auven Therapeutics do business, stock market volatility, fluctuations in costs, changes to the competitive environment due to consolidation, achievement of forecasted burn rate, potential payments/outcomes in relation to indemnity agreements and contingent value rights, achievement of forecasted pre-clinical and clinical trial milestones, and that actual

results may vary once the final and quality-controlled verification of data and analyses has been completed. In addition, the length of the KIACTA™ Phase III Confirmatory Study and the sharing of proceeds between Auven Therapeutics and BELLUS Health Inc. from potential future revenue of KIACTA™ is dependent upon a number of factors including the quantum of proceeds. Consequently, actual future results may differ materially from the anticipated results expressed in the forward-looking statements. Auven Therapeutics and BELLUS Health Inc. believe that expectations represented by forward-looking statements are reasonable, yet there can be no assurance that such expectations will prove to be correct. The reader should not place undue reliance, if any, on any forward-looking statements included in this news release. These forward-looking statements speak only as of the date made and BELLUS Health Inc. and Auven Therapeutics are under no obligation and disavow any intention to update publicly or revise such statements as a result of any new information, future event, circumstances or otherwise, unless required by applicable legislation or regulation. Please see BELLUS Health Inc.'s public filings including the Annual Information Form for further risk factors that might affect BELLUS Health and its business.

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