



# Auven Therapeutics and BELLUS Health Announce Licence Agreement with Mount Sinai for KIACTA<sup>TM</sup> in Sarcoidosis

**NEW YORK, USA and LAVAL, CANADA May 2, 2014** – Auven Therapeutics, the 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 that Auven has entered into a license agreement with the Icahn School of Medicine at Mount Sinai in New York, under which Auven obtains rights to develop KIACTA™ (eprodisate) as a treatment for chronic sarcoidosis.

Auven intends to conduct a Phase II (proof-of-concept) clinical trial to evaluate KIACTA™'s effectiveness and safety to treat certain medical manifestations of sarcoidosis. KIACTA™ is aimed at addressing the disease process (i.e. pathophysiology) in sarcoidosis patients. Auven expects to finalize a study protocol by mid-year and anticipates that the trial will start dosing patients in the fourth quarter of 2014. The Phase II trial is expected to be completed within approximately 18 months of the time the first patient is enrolled.

The idea to use KIACTA™ as a treatment for chronic sarcoidosis was developed by Adam S. Morgenthau, MD, Assistant Professor of Medicine at the Icahn School of Medicine at Mount Sinai. Dr. Morgenthau is the director of the Sarcoidosis Clinic at Mount Sinai, one of the largest centers of its kind in the U.S., and which specializes in treating patients with complex cases of sarcoidosis. "KIACTA™'s mechanism of action, and its benign safety profile demonstrated to date, make it an attractive clinical candidate for a proof-of-concept study in patients with chronic sarcoidosis, a disease whose current treatments may cause debilitating long-term side effects," said Dr. Morgenthau.

Sarcoidosis is a rare condition that causes small patches of red and swollen tissue - called granulomas - that can develop in multiple organs in the body, but mostly in the lungs and skin. The disease affects approximately 120,000 patients in the US alone and identification of an effective treatment is a major unmet medical need. While acute sarcoidosis can improve on its own, chronic sarcoidosis can cause scarring to the lungs and decreased lung function over time, potentially affecting other areas of the body, including the liver.

"There is no cure for sarcoidosis, and treatment options are limited and can have serious adverse effects" said Dr. Peter B. Corr, Co-Founder and Managing General Partner of Auven Therapeutics. "Obtaining the rights to move KIACTA™ into a second indication further expands its commercial potential and may help patients with this sometimes debilitating chronic disease" he added.

KIACTA™ is an orally bioavailable small molecule, currently being investigated in a Phase III pivotal study in patients with AA Amyloidosis, an orphan indication that results from long-standing inflammatory conditions. Auven Therapeutics acquired worldwide rights related to KIACTA™ from Bellus Health in 2010 and assumed control of the KIACTA™ development program and related activities, including the Phase III clinical study in AA Amyloidosis.

The agreement was negotiated through Mount Sinai Innovation Partners which facilitates the real-world application and commercialization of Mount Sinai discoveries and the development of research partnerships with industry.

#### **Notes to Editors**

## **About Auven Therapeutics (<u>www.auventx.com</u>)**

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 establish 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, New York, 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<sup>TM</sup> in phase III for AA amyloidosis, clinical stage Shigamab<sup>TM</sup> for STEC-related Hemolytic Uremic Syndrome (sHUS) and a research-stage project for AL amyloidosis. The lead program KIACTA<sup>TM</sup> is currently in a Phase III Confirmatory Study for the treatment of AA amyloidosis, an orphan indication resulting in renal dysfunction that often rapidly leads to dialysis and death.

# About the Sarcoidosis Program at Mount Sinai (<u>www.mountsinai.org/patient-care/service-areas/lung-diseases-and-surgery/areas-of-care/sarcoidosis-program</u>)

Since its establishment by Louis Siltzbach, MD, in 1948, Mt. Sinai's Sarcoidosis Program has grown to become the largest in the world, with more than 18,000 patients enrolled to date, and approximately 40 more coming to the Sarcoidosis Clinic each week. Because sarcoidosis is a multi-organ disease, the Sarcoidosis Clinic offers expertise in all aspects of the condition with the help of a multidisciplinary team. Sarcoidosis is a challenging disease in which patients can struggle for years with ineffective treatments and unanswered questions. To meet the need for treatment, Mount Sinai has brought a team of experts together to form an unparalleled sarcoidosis service that combines all the medical skills and resources patients need to manage every aspect of this condition.

#### **About Sarcoidosis**

Sarcoidosis is a systemic granulomatous disease of uncertain etiology that affects men and women of all races and ages worldwide. Sarcoidosis is characterized by abnormal masses or lumps (called granulomas) consisting of inflamed tissues that can develop in any part of the body, but are most commonly found in the lymph glands, lungs and skin. These granulomas may alter the normal structure and the function of the affected organ(s) and can also affect the heart, nervous system, liver, spleen, muscles, nose, sinuses or eyes Sarcoidosis has a variable clinical presentation and course. Most patients with sarcoidosis recover, but approximately 30% develop

chronic, debilitating disease. Mortality occurs in 1-5% of patients. Lung fibrosis is the most common cause of death. Evidence suggests that chronic granulomatous inflammation leads to fibrosis. Corticosteroids, the mainstay of therapy in sarcoidosis, nonspecifically suppress chronic granulomatous inflammation, often causing debilitating adverse effects but do not correct the underlying disease. Specific therapies for the treatment of chronic granulomatous inflammation are needed.

### **About KIACTA for AA Amyloidosis**

KIACTA™(eprodisate) is an orally bioavailable small molecule intended for the treatment of AA amyloidosis, an orphan indication that often rapidly leads to dialysis and death due to end stage renal disease. Auven Therapeutics and BELLUS Health are partners in the development of KIACTA™. Auven Therapeutics is responsible for conducting and paying for the currently ongoing Phase III Confirmatory Study. Patient recruitment is ongoing and is expected to be completed in the second quarter of 2014. The Phase III Confirmatory Study is an event driven trial that is expected to conclude in 2016. The study will be used to confirm the positive safety and efficacy results shown in the Phase II/III study previously conducted by BELLUS Health.

## **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 and Auven Therapeutics' control. Such risks include but are not limited to: the ability to obtain financing immediately in current markets, 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 BELLUS Health Inc. and Auven Therapeutics do business, stock market volatility, fluctuations in costs, and changes to the competitive environment due to consolidation, achievement of forecasted burn rate, achievement of forecasted clinical trial milestones, and that actual results may vary once the final and qualitycontrolled verification of data and analyses has been completed. The length of KIACTA™ Phase III Confirmatory Study is dependent upon many factors including clinical sites activation, patients enrollment rate, patients drop-out rate and occurrence of worsening events. 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. and Auven Therapeutics are under no obligation and disavow 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 BELLUS" public fillings including the Annual Information Form of BELLUS Health Inc. for further risk factors that might affect the BELLUS and its business.

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