BELLUS Health Presents Phase 1 Data for BLU-5937, its Lead Product Candidate for the Treatment of Refractory Chronic Cough, at the American Thoracic Society International Conference

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- Clinical results conclusively demonstrate that BLU-5937, a highly selective P2X3 antagonist, is a differentiated product candidate that has little to no impact on taste perception -

- Clinical Phase 2 study to assess the efficacy, safety and tolerability of BLU-5937 in chronic cough patients is expected to begin in mid-2019 -

LAVAL, Quebec--(BUSINESS WIRE)-- BELLUS Health Inc. (TSX: BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders, today presented results from the clinical Phase 1 study of BLU-5937, an orally-administered P2X3 antagonist, being developed for the treatment of refractory chronic cough. Clinical data presented at the American Thoracic Society International Conference in Dallas, Texas showed that BLU-5937 is well-tolerated and importantly, provide the first clinical evidence that a highly selective P2X3 antagonist is associated with little to no impact on taste.

Data presented, in the form of a poster presentation entitled “BLU-5937 a Highly Selective P2X3 Homotrimeric Receptor Antagonist with Improved Taste Safety Profile in Healthy Subjects,” may be accessed on the Events and Presentations page under the Investors & News section of the Company's website at www.bellushealth.com.

“The results of this study represent a significant advancement in the field of anti-tussive research and further validate the hypothesis that a highly selective P2X3 antagonist does not lead to taste disturbance side effects,” commented Dr. Denis Garceau, Senior Vice-President, Drug Development of BELLUS Health. “This ability to maintain taste function represents a significant competitive advantage since it will translate to improved tolerability and therefore a higher compliance rate in a patient population that is in great need of a safe and effective therapy.”

The Phase 1 study was a randomized, double-blind, placebo-controlled study of 90 healthy adult subjects. Participants were divided into 6 single ascending dose (SAD; n=60) and 3 multiple ascending dose (MAD; n=30) cohorts. The primary objectives were to assess the safety, tolerability (including taste perception), and pharmacokinetic profile. BLU-5937 was found to be safe and well-tolerated at all doses, with very low incidence of transient and sporadic taste adverse events. Specific results showed:

- Based on human pharmacokinetic profile seen in the Phase 1 study and achieving dose levels required to reach optimal efficacy in the preclinical cough models, the anticipated therapeutic doses of BLU-5937 are expected to be 50mg - 100mg BID;
- At the anticipated therapeutic doses of 50mg – 100mg BID, BLU-5937 did not cause any loss of taste perception and only one subject out of 24 (4.2%) reported transient taste alteration. No subject reported total loss of taste at any dose;
- There were no cases of taste alteration or taste loss at 200mg BID;
- Incidence of taste alteration was higher at supra-therapeutic doses (≥ 400mg) and analysis of drug blood levels suggests it may correlate with drug exposure that partially inhibits P2X2/3 receptors;
- In the MAD cohorts, five subjects (4 at 400mg BID; 1 at 100mg BID) experienced taste alteration events: all 5 subjects reported a taste event on the first dose; 3 of them experienced a second episode during the 7-day dosing period and 2 had no further event;
- There were no serious adverse events (SAE) reported, and no subjects withdrew prematurely due to an adverse event (AE). Overall incidence of AEs was comparable between placebo (50%) and BLU-5937 (44%). The other most frequent AEs (>5%) were: taste alteration (19.4%), headache (11.1%), numbness (11.1%), nausea (8.3%), dizziness (5.6%) and heartburn (5.6%);
- No significant trends of mean changes in vital signs, electrocardiogram (ECG), and clinical laboratory values were observed.

Results from the Phase 1 study support the advancement to a Phase 2 study, which is expected to be initiated in mid-2019, with top-line results anticipated in mid-2020. This will be a dose-escalation, crossover design study to assess the efficacy, safety, and tolerability of BLU-5937 at four doses: 25, 50, 100, and 200mg BID. In the Phase 1 study, 2.5% of subjects tested at these doses had a taste alteration event. Approximately fifty patients with refractory unexplained chronic cough are expected to be enrolled at 12 clinical sites in the United Kingdom and United States.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) for human P2X3 receptors versus P2X2/3 receptors - has the potential to be a best-in-class therapeutic for refractory chronic cough patients.

The P2X3 receptor in the cough reflex pathway is a rational target for treating refractory chronic cough, and it has been validated in multiple clinical studies. With a modestly-selective P2X3 antagonist therapy for chronic cough, an adverse effect on taste perception is a well-known and widely-documented tolerability issue. The Company believes that a highly selective P2X3 antagonist can reduce coughing in patients with refractory chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors.

In addition to chronic cough, BLU-5937 may potentially have clinical benefit in other afferent hypersensitization-related disorders, such as visceral pain, hypertension, and migraine, among others. BELLUS Health is exploring how P2X3 activation can contribute to irritation and pain, and how inhibition of P2X3 receptors may be able to help treat these afferent hypersensitization-related disorders.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders. The Company's lead product candidate, BLU-5937, is being developed for the treatment of chronic cough.

Chronic cough is a cough lasting more than eight weeks and is associated with significant adverse physical, social and psychosocial effects on health and quality of life. It is estimated that approximately 26 million adults in the United States suffer from chronic cough with more than 2.6 million having unexplained or refractory chronic cough lasting for more than a year. There are limited treatment options for refractory chronic cough and no currently approved therapeutics.

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” within the meaning of Canadian securities legislation and regulations. 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 control. Such risks factors include but are not limited to: the ability to expand and develop its project pipeline, 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. does 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 BELLUS Health Inc.’s product candidates’ development process, their market size and commercial value, as well as the sharing of proceeds between BELLUS Health Inc. and its potential partners from potential future revenues, if any, are dependent upon a number of factors. Consequently, actual future results and events may differ materially from the anticipated results and events expressed in the forward-looking statements. BELLUS Health Inc. believes 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. is under no obligation and disavows 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 with the Canadian securities regulatory authorities, including the Annual Information Form, for further risk factors that might affect BELLUS Health Inc. and its business.

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