



BELLUS Health Announces Completion of Dosing in Phase 2 RELIEF Trial with BLU-5937 for the Treatment of Refractory Chronic Cough

April 6, 2020

- Topline data on track for mid-year 2020 -

LAVAL, Quebec--(BUSINESS WIRE)--Apr. 6, 2020-- BELLUS Health Inc. (Nasdaq: BLU; TSX: BLU) (the "Company" or "BELLUS Health") , a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of chronic cough and other hypersensitization-related disorders, today announced that it has completed patient dosing in its Phase 2 RELIEF clinical trial of BLU-5937 for the treatment of refractory chronic cough, with 52 patients completing treatment. The Company decided to close the trial early due to the impact of the COVID-19 pandemic on the RELIEF clinical trial activities. The Company continues to expect topline data from the trial mid-year 2020.

A total of 68 patients with refractory chronic cough were enrolled into the trial, with 52 completing treatment. Sixteen patients dropped out in total, including 13 as a result of difficulties with conducting follow-up visits related to the COVID-19 pandemic or early termination of the trial.

"With 52 patients completing dosing, the RELIEF trial is the largest crossover study conducted in refractory chronic cough, providing the powering needed to evaluate efficacy and safety of BLU-5937," said Roberto Bellini, President and CEO of BELLUS Health. "Given the robust number of patients and the impact of the Covid-19 pandemic, we concluded that it was prudent to close the trial as our primary focus is the safety and well-being of our trial participants, clinical investigators and their site staffs."

The RELIEF trial is a 2-arm dose-escalation, placebo-controlled, and crossover design to assess the efficacy, safety, and tolerability of BLU-5937, a highly selective P2X3 antagonist, in refractory chronic cough at four doses: 25, 50, 100 and 200 mg, administered orally, twice-daily (BID). With 52 patients having completed dosing, the RELIEF trial is powered at more than 80% to see a 30% difference between BLU-5937 and placebo in awake cough frequency.

Further details on BELLUS Health's RELIEF trial for BLU-5937 can be found at <https://clinicaltrials.gov/ct2/show/NCT03979638>.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) for human P2X3 receptors, which are implicated in chronic cough, versus P2X2/3 receptors, which play a major role in taste - has the potential to be an important treatment option for chronic cough, chronic pruritus and other hypersensitization-related disorders.

The P2X3 receptor in the cough reflex pathway is a rational target for treating chronic cough, and it has been validated in multiple clinical trials with different P2X3 antagonists. With a low-selectivity 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 its highly selective P2X3 antagonist can also reduce coughing in patients with chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors. This hypothesis has been validated in a recent clinical trial with a more selective antagonist of P2X3; however, BLU-5937 is the most selective of the P2X3 antagonists currently being studied.

In addition to chronic cough and chronic pruritus, BLU-5937 may also have broad applicability across other afferent hypersensitization-related disorders, potentially enabling the Company to build a pipeline of therapies using its P2X3 platform. BELLUS Health is exploring how P2X3 activation can contribute to irritation and pain, and whether inhibition of P2X3 receptors can help treat these afferent hypersensitization-related disorders.

About BELLUS Health

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 product candidate, BLU-5937, is being developed for the treatment of chronic cough and chronic pruritus.

Chronic cough, the lead indication for BLU-5937, 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 refractory chronic cough lasting for more than a year. There is no specific therapy approved for refractory chronic cough and treatment options are limited.

Chronic pruritus, commonly known as chronic itch, is an irritating sensation that leads to scratching, and persists for longer than six weeks, which can be debilitating and has a significant impact on quality-of-life. It is a hallmark of many conditions, including atopic dermatitis ("AD"). It is estimated that chronic pruritus associated with AD affects more than 16.9 million adults in the United States.

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 and other applicable securities laws. 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's control. Such statements include, but are not limited to, the potential of BLU-5937 to successfully treat chronic cough, chronic pruritus and other hypersensitization-related disorders, BELLUS Health's expectations related to its preclinical studies and clinical trials, including the timing and results for the BLU-5937 Phase 2 RELIEF trial and its chronic pruritus program, the potential patient tolerance of BLU-5937 as compared to other competitor candidates and the potential applicability of BLU-5937 and

BELLUS Health's P2X3 platform to treat other disorders. Risk factors that may affect BELLUS Health's future results include but are not limited to: the ability to expand and develop its project pipeline, the ability to obtain adequate financing, the impact of general economic conditions, general conditions in the pharmaceutical industry, the impact of the COVID-19 pandemic on the Company's operations, plans and prospects, changes in the regulatory environment in the jurisdictions in which BELLUS Health 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 preclinical study and clinical trial milestones, reliance on third parties to conduct preclinical studies and clinical trials for BLU-5937 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's product candidate's development process and its market size and commercial value are dependent upon a number of factors. Moreover, its growth and future prospects are mainly dependent on the successful development, patient tolerability, regulatory approval, commercialization and market acceptance of its product candidate BLU-5937 and other products. Consequently, actual future results and events may differ materially from the anticipated results and events expressed in the forward-looking statements. BELLUS Health 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 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's public filings with the Canadian securities regulatory authorities, including, but not limited to, its Annual Information Form, and the United States Securities and Exchange Commission for further risk factors that might affect BELLUS Health and its business.

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