BELLUS Health Announces Topline Results from its Phase 2 RELIEF Trial of BLU-5937 for the Treatment of Refractory Chronic Cough

July 6, 2020

- Primary endpoint of placebo-adjusted reduction in awake cough frequency did not reach statistical significance -

- Highly statistically significant and clinically meaningful reductions in placebo adjusted awake cough frequency achieved in pre-specified analysis of high cough count patients (baseline cough frequency at or above the median) -

- BLU-5937 was well tolerated with low impact on taste perception; safety profile comparable to placebo -

- Patient enrichment strategy with higher cough count patients to be pursued in adaptive Phase 2b trial expected to start in Q4 2020 -

- Company to host conference call and webcast at 8:00 a.m. ET -

LAVAL, Quebec--(BUSINESS WIRE)--Jul. 6, 2020-- BELLUS Health Inc. (Nasdaq: BLU; 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 announced topline results from its Phase 2 RELIEF trial of BLU-5937 in patients with refractory chronic cough.

The Phase 2 RELIEF trial of BLU-5937 did not achieve statistical significance for the primary endpoint of reduction in placebo-adjusted cough frequency at any dose tested. A clinically meaningful and highly statistically significant placebo-adjusted reduction in cough frequency was achieved in a pre-specified sub-group of high cough count patients (all patients at or above the baseline median average of 32.4 coughs per hour).

All patients (n=62)

Dose	Placebo-adjusted reduction in awake cough frequency	P-value
25mg BID	-11%	p=0.14
50mg BID	-6%	p=0.46
100mg BID	-8%	p=0.41
200mg BID	-17%	p=0.09

Patients with awake cough frequency at or above baseline median (≥32.4 cough/hr; n=31)

Dose	Placebo-adjusted reduction in awake cough frequency	P-value
25mg BID	-28%	p=0.0005
50mg BID	-28%	p=0.0003
100mg BID	-30%	p=0.0014
200mg BID	-32%	p=0.0006

BLU-5937 was also observed to be well tolerated with no serious adverse events reported and no withdrawals due to treatment-related adverse events at any dose. Taste effects, including taste alteration and partial taste loss, were infrequent at all dose levels (6.5%, 9.8%, 10% and 8.6% at 25mg BID, 50mg BID, 100mg BID and 200mg BID, respectively, versus 4.9% on placebo) and mostly mild in nature. No patients reported complete taste loss. There were no clinically meaningful changes in vital signs, electrocardiogram or clinical laboratory values.

"In the RELIEF trial, we observed data that we believe is competitive within the P2X3 class, including the reduction in cough frequency shown in patients with higher cough counts and a low taste effect. While we had hoped to see more response in the lower cough patients, BLU-5937 and other P2X3 antagonists may have the most benefit in patients with a greater disease burden," said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "We believe the Phase 2 data support moving BLU-5937 forward into an adaptive Phase 2b trial enriched for higher cough count patients. We expect to begin this trial in the fourth quarter of 2020."

"Currently, there are no approved treatments for refractory chronic cough, a condition that affects the quality of life of millions of patients globally. BELLUS Health was able to show clinically and statistically meaningful reductions in cough count in patients with higher baseline cough count, which may be the best available clinical indicator of cough hypersensitization via the P2X3 pathway. In addition, BLU-5937's high selectivity resulted in a favorable tolerability profile with little reported taste disturbance," said Dr. Jaclyn Smith, Professor of Respiratory Medicine at the University of Manchester in the United Kingdom and an Honorary Consultant at the University Hospital of South Manchester NHS Foundation Trust, and Chair of BELLUS Health's Clinical Advisory Board. "The RELIEF Phase 2 data set the stage for the further development of BLU-5937 and I look forward to continuing to work on the program."

About the Clinical Phase 2 RELIEF Trial

The RELIEF trial is a dose-escalation, placebo-controlled, and crossover design to assess the efficacy, safety and tolerability of BLU-5937, a highly selective P2X3 antagonist, at four doses: 25, 50, 100 and 200mg, administered orally, twice-daily. RELIEF enrolled a total of 68 refractory chronic cough patients from 16 sites in the United Kingdom and United States, with 52 completing both treatment periods. 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. There were three additional non-drug related discontinuations. Further details on the RELIEF trial can be found at https://clinicaltrials.gov/ct2/show/NCT03979638.

Conference Call & Webcast Information:

The Company will host a conference call and webcast to discuss the topline results from the RELIEF Phase 2 trial on July 6th, 2020 at 8:00 a.m. ET.

Individuals can participate in the conference call by dialing 877-407-9041 (domestic) or 201-389-0937 (international) and referring to the "BELLUS RELIEF Phase 2 Trial Topline Results." The live webcast of the event may be accessed through the Events and Presentations page of BELLUS Health's website, under the Investors & News section.

The archived webcast will be available for replay on the BELLUS Health website after the event.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) - is in development for chronic cough, chronic pruritus and other hypersensitization-related disorders.

The P2X3 receptor in the cough reflex pathway, which is implicated in chronic cough, is a rational target for treating chronic cough, and it has been evaluated in multiple clinical trials with different P2X3 antagonists. The Company believes that its highly selective P2X3 antagonist has the potential to reduce coughing in patients with chronic cough while maintaining taste function by not inhibiting P2X2/3 receptors, which play a major role in taste.

In addition to chronic cough and chronic pruritus, BLU-5937 may also have broad applicability across other afferent hypersensitization-related disorders, enabling the Company to consider developing 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 (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 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 approximately 3 million having refractory chronic cough lasting for more than a year and approximately 6 million having refractory chronic cough lasting more than 8 weeks and under one year. There is no specific therapy approved for refractory chronic cough and current 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, the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other applicable securities laws. Forward-looking statements are frequently, but not always, identified by words such as "expects," "anticipates," "believes," "intends," "estimates," "potential," "possible," "projects," "plans," and similar expressions. 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 its clinical development plan and timing and design of future trials for its chronic cough program, the potential tolerability profile, selectivity and other characteristics 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 ability of BELLUS Health to maintain its rights to intellectual property and obtain adequate protection of future products through such intellectual property, the impact of general economic conditions, general conditions in the pharmaceutical industry, the impact of the COVID-19 pandemic on BELLUS Health's operations, plans and prospects, including to the initiation and completion of clinical trials in a timely manner or at all, 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, 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, BELLUS Health's 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, including, but not limited to, its Annual Report on Form 40-F, for further risk factors that might affect BELLUS Health and its business.

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