Bellus Health Announces Positive End-of-Phase 2 Meeting with the FDA and its CALM Phase 3 Program for BLU-5937 in Refractory Chronic Cough

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- CALM Phase 3 program consists of two pivotal trials (CALM-1 and CALM-2), with primary efficacy endpoint of 24-hour cough frequency measured at 12- and 24-weeks, respectively -

- The Company has reached alignment with FDA on the primary efficacy endpoint of 24H cough frequency reduction being assessed using the VitaloJAK cough monitoring system in a patient population enriched for baseline cough frequency -

- First patient expected to be enrolled in the fourth quarter of 2022; Topline results from CALM-1 expected in 2H 2024 -

LAVAL, Quebec--(BUSINESS WIRE)--Jul. 12, 2022-- BELLUS Health Inc. (Nasdaq: BLU; TSX: BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of refractory chronic cough and other cough hypersensitivity indications, today announced a positive End-of-Phase 2 ("EOP2") meeting with the U.S. Food and Drug Administration ("FDA") and the details of the CALM Phase 3 program for BLU-5937, a highly selective, second generation P2X3 antagonist product candidate, for the treatment of refractory chronic cough ("RCC").

"The successful completion of our End-of-Phase 2 meeting with the FDA marks a significant milestone for BELLUS. We are appreciative of the FDA's support and guidance and are pleased to have identified a clear regulatory path to a potential approval for BLU-5937," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "Based on our SOOTHE Phase 2b data, we remain confident in BLU-5937's potential to be a best-in-class treatment option for RCC patients, if approved. We are well positioned to execute our CALM Phase 3 program, with cash resources sufficient to bring us through topline results with CALM-1, and we look forward to initiating this pivotal program in the fourth quarter."

Based on the FDA's feedback, the CALM Phase 3 program is composed of two pivotal trials, CALM-1 and CALM-2, each evaluating the efficacy, safety and tolerability of BLU-5937 in approximately 675 adults with RCC. CALM-1 and CALM-2 will be placebo-controlled, parallel-arm trials randomized 1:1:1 with expected treatment arms of 25 mg BID, 50 mg BID and placebo. The primary endpoint of 24H cough frequency will be measured at 12-weeks for CALM-1 and 24-weeks for CALM-2. The Company has reached alignment with the FDA that the CALM Phase 3 program's primary endpoint, similar to the successful SOOTHE Phase 2b trial, can be assessed using the VitaloJAK cough monitoring system in a patient population enriched for baseline 24H cough frequency of ≥20 coughs/hour (equivalent to awake cough frequency of ≥25 coughs/hour used in SOOTHE Phase 2b trial). Key secondary efficacy endpoints include Cough Severity using Visual Analogue Scale ("CS-VAS"), the Leicester Cough Questionnaire ("LCQ") and Chronic Cough Diary ("CCD"). The CALM Phase 3 trials will also enroll participants with baseline 24H cough frequency <20 coughs/hour. A key secondary efficacy endpoint will assess reduction in cough frequency in a broader population including the enriched population and additional participants with baseline 24H cough frequency below 20 coughs/hour. CALM-1 will have a 40-week randomized extension period and an additional 24-week open label extension. CALM-2 will have a 28-week open label extension. The trials are planned to run in parallel, and the Phase 3 CALM program is expected to enroll its first patient in the fourth quarter of 2022. Topline data from CALM-1 are expected in the second half of 2024.

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist, is in development for RCC and other cough hypersensitivity indications.

The P2X3 receptor, which is implicated in cough reflex hypersensitization, 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 cough frequency in patients with RCC and improve quality of life while limiting taste disturbance adverse events.

In addition to RCC, the mechanism of action of BLU-5937 may also have broad therapeutic applicability across other cough hypersensitivity indications. The Company is evaluating potential opportunities to study BLU-5937 in additional cough indications where cough hypersensitivity plays an important role.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of RCC and other cough hypersensitivity indications. The Company's product candidate, BLU-5937, has successfully completed a Phase 2b trial in RCC. BELLUS Health is planning a Phase 3 program, which is expected to begin enrollment in the fourth quarter of 2022.

Chronic cough is a cough lasting longer than eight weeks. When the cause of chronic cough cannot be identified or the cough persists despite treatment of all identified associated causes, the condition is referred to as RCC. It is estimated that there are approximately 9 million patients in the United States suffering from RCC. RCC is associated with significant adverse physical, social, and psychological effects on health and quality of life. Currently, there is no specific therapy approved for RCC and treatment options are limited.

The Company is exploring the potential use of BLU-5937 in other patient populations experiencing cough hypersensitivity as well as other P2X3-related hypersensitization conditions.

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 RCC and other hypersensitization-related disorders and benefit such patients, BELLUS Health's expectations related to its preclinical studies and clinical trials, including the timing of initiation of and the design of its Phase 3 clinical trials of BLU-5937 in RCC, the timing and outcome of interactions with regulatory agencies, the potential activity and tolerability profile, selectivity, potency and other characteristics of BLU-5937, including as compared to other competitor candidates, especially where head-to-head studies have not been conducted and cross-trial comparisons may not be directly comparable due to differences in study protocols, conditions and patient populations, the commercial potential of BLU-5937, including with respect to patient population, pricing and labeling, BELLUS Health's financial position and sufficiency of cash resources to bring through topline results with CALM-1, 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 benefits and impact on label of its enrichment strategy, estimates and projections regarding the size and opportunity of the addressable RCC market for BLU-5937, 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 ongoing 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, supply chain impacts, stock market volatility, fluctuations in costs, changes to the competitive environment due to consolidation, achievement of forecasted burn rate, 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 differ from topline results 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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