BELLUS Health Announces Positive Results from its Phase 1 Bioavailability Equivalence Study Evaluating Once-Daily Extended-Release Formulation of Camlipixant in Comparison to Twice-Daily Immediate Release Formulation

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Once-daily Extended-Release formulation demonstrated equivalent bioavailability to twice-daily Immediate Release formulation

Extended-Release formulation was well tolerated, with the safety profile consistent with previous camlipixant trials and no taste-related adverse events reported

Additional data to be presented at a future medical conference

LAVAL, Quebec--(BUSINESS WIRE)--Apr. 5, 2023-- BELLUS Health Inc. (Nasdaq:BLU; TSX:BLU) ("BELLUS Health" or the "Company"), a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough ("RCC"), today announced positive data from its Phase 1 bioavailability equivalence study evaluating a once-daily Extended-Release ("ER") formulation of camlipixant in comparison to a twice-daily Immediate Release ("IR") formulation. Camlipixant is the Company's twice-daily, oral P2X3 antagonist product candidate for the treatment of RCC currently being investigated in the CALM Phase 3 program.

The ER formulation demonstrated equivalent bioavailability to the IR formulation, with equivalent total systemic drug exposure (90% geometric mean AUC_{∞} and 82% geometric mean AUC_{24h}), as well as equivalent minimum drug concentration (88% geometric mean C_{24h}). The ER formulation was well tolerated, with the safety profile consistent with previous camlipixant trials and no taste-related adverse events reported. These results establish proof of concept for developing a once-daily ER formulation of camlipixant. To continue the development of the once-daily ER formulation, the Company intends to conduct a multiple dose study of the ER formulation. A patent application has been filed covering once-daily formulations of camlipixant.

"We are pleased with the outcome of the bioavailability equivalence study, which establishes the proof of concept for developing a once-daily formulation of camlipixant, our potentially best-in-class P2X3 inhibitor in Phase 3 development," commented Roberto Bellini, President and Chief Executive Officer of BELLUS Health. "At BELLUS Health, we are working to better the lives of individuals suffering from persistent cough, and these results reflect our continued progress to establish and differentiate camlipixant as the market leading option for RCC patients. We look forward to providing additional data from this study at an upcoming medical conference."

This Phase 1, open-label bioavailability equivalence study was designed to assess the safety, tolerability, and pharmacokinetic profile of a single dose, once-daily ER formulation of camlipixant versus a twice-daily IR reference formulation (two single doses of 25 mg, 12 hours apart) in 16 healthy adult subjects.

About BELLUS Health (www.bellushealth.com)

BELLUS Health is a clinical-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough, starting with the development of camlipixant (BLU-5937) for the treatment of refractory chronic cough (RCC). Camlipixant, the Company's lead asset, is an investigational P2X3 receptor antagonist for the treatment of RCC, which is currently being evaluated in the CALM Phase 3 clinical program. With no approved treatments in the U.S., camlipixant has the potential to be a breakthrough in the RCC treatment landscape.

Chronic cough is defined as a cough lasting longer than eight weeks. When the cause of chronic cough cannot be identified or the cough persists despite treatment of any associated condition, the condition is referred to as RCC. RCC is a frequent, yet often under-recognized, medical condition that has significant physical, social, and psychological consequences on one's quality of life. There are currently no approved treatments for this condition in the United States, European Union or the United Kingdom.

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 camlipixant (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 completion of its Phase 3 clinical trials of camlipixant in RCC and the expected timing of topline results from CALM-1 and CALM-2 Phase 3 clinical trials, the timing and outcome of interactions with regulatory agencies, the ability of BELLUS Health to validate its use of the VitaloJAK cough monitoring system to the satisfaction of relevant regulatory agencies, the potential activity and tolerability profile, selectivity, potency and other characteristics of camlipixant, 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 camlipixant, including with respect to patient population, pricing and labeling and potential treatment alternatives, BELLUS Health's financial position and sufficiency of cash resources to bring through topline results of CALM-1 and CALM-2 clinical trials, timely or at all, and the potential applicability of camlipixant and BELLUS Health's P2X3 receptor platform to treat other disorders. Risk factors that may affect BELLUS Health's future results include but are not limited to: the intended benefits, acceptability to regulatory agencies and impact of its enrichment strategy, continuing feedback and discussions with the FDA and other regulatory authorities regarding the design of the CALM Phase 3 program, estimates and projections regarding the size and opportunity of the addressable RCC market for camlipixant, 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 camlipixant, that final data from studies and clinical trials may differ from reported data from preliminary studies or clinical trials 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 camlipixant 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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