BELLUS Health Announces Completion of Patient Enrollment in SOOTHE Phase 2b Trial for Refractory Chronic Cough and BLUEPRINT Phase 2a Trial for Chronic Pruritus Associated with Atopic Dermatitis

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Topline results from both studies are expected in December 2021

LAVAL, Quebec--(BUSINESS WIRE)--Sep. 23, 2021-- 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 hypersensitization-related disorders, today announced that the Company has completed patient enrollment in the Phase 2b SOOTHE clinical trial of BLU-5937 in refractory chronic cough (“RCC”) and the Phase 2a BLUEPRINT clinical trial of BLU-5937 in chronic pruritus associated with atopic dermatitis (“AD”). Topline results from both trials are expected in December 2021.

“Completion of enrollment in our SOOTHE trial marks an important milestone, underscoring the progress we have made advancing BLU-5937 for the treatment of RCC. As recently reported, we are encouraged by the positive outcome of our recent administrative interim analysis from the SOOTHE trial, and look forward to sharing topline results from both SOOTHE and our Phase 2a BLUEPRINT trial in chronic pruritus in December 2021,” said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. “Chronic cough and chronic pruritis negatively impact individuals’ quality of life, and each indication represents a significant unmet medical need. We are grateful to the patients and clinical investigators who are participating in our trials.”

BELLUS Health previously announced on September 13, 2021 results from a planned administrative interim analysis of the Phase 2b SOOTHE trial in RCC. An independent statistical team reported that a predefined stringent probability threshold for clinical efficacy was met for at least one and up to all three doses of BLU-5937 tested. In addition, the analysis reported that limited taste-related adverse events were observed, consistent with previous trials of BLU-5937, and no serious adverse events were reported.

About SOOTHE

The SOOTHE trial is a multicenter, randomized, double-blind, four-week, parallel arm, placebo-controlled Phase 2b trial evaluating three doses of BLU-5937 (12.5 mg, 50 mg and 200 mg BID) in 310 participants with RCC. A total of 249 participants with a baseline awake cough frequency of ≥25 awake coughs per hour were randomized across four arms (1:1:1:1) evaluating the three active doses of BLU-5937 and placebo in the main study. Treatment arms were stratified to balance the number of participants with baseline awake cough frequency ≥45 coughs per hour across trial arms. The primary efficacy endpoint is the placebo-adjusted change in the 24-hour cough frequency from baseline to day 28 collected with a cough recorder. An exploratory group of an additional 61 participants with a baseline awake cough frequency of ≥10 and <25 coughs per hour were randomized across 2 arms (1:1) evaluating one active dose (200 mg BID) and placebo to further investigate the effect of BLU-5937 in patients with lower cough frequency. More information about the trial is available at www.clinicaltrials.gov: NCT04678206.

About BLUEPRINT

The BLUEPRINT trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-design Phase 2a trial evaluating the efficacy, safety and tolerability of BLU-5937 in 142 participants with moderate to severe chronic pruritus associated with mild to moderate AD. Participants were randomized into one of two treatment arms (1:1) and receive either 200 mg BID of BLU-5937 or placebo for a four-week treatment period. The primary efficacy endpoint is the change from baseline in weekly mean Worst Itch-Numeric Rating Scale (WI-NRS) score at week four. A key secondary endpoint is a responder-rate analysis of at least four-point WI-NRS improvement from baseline at week four. More information about the trial is available at www.clinicaltrials.gov: NCT04693195.

About BELLUS Health (www.bellushealth.com)

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

RCC is a cough lasting more than 8 weeks despite appropriate treatment for underlying condition(s). 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 psychosocial effects on health and quality of life. Currently, there is no specific therapy approved for RCC and treatment options are limited.

Chronic pruritus associated with AD is an irritating sensation that leads to scratching and persists for longer than 6 weeks in AD patients. It is estimated that up to 10% of adults in the United States suffer from AD – almost all report symptoms of pruritus with over 50% of patients attributing chronic pruritus as their most burdensome symptom. Despite currently available treatments targeting AD, there continues to be a lack of options specifically targeting the burden of pruritus in patients with AD.

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 the design and timing of its Phase 2b clinical trial of BLU-5937 in RCC and its Phase 2a clinical trial of BLU-5937 in chronic pruritus associated with AD, including 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, the commercial potential of BLU-5937, including with respect to patient population, pricing and labeling, BELLUS Health's financial position, 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 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 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, the ability of the interim analysis to predict the final results of the SOOTHE trial, 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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FOR MORE INFORMATION:
Ramzi Benamar
Chief Financial Officer
rbenamar@bellushealth.com

Media:
Julia Deutsch
Solebury Trout
jdeutsch@soleburytrout.com
Source: BELLUS Health Inc.

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