BELLUS Health Provides Update on Its Chronic Cough Drug Candidate BLU-5937 and Reports Financial and Operating Results for the First Quarter Ended March 31, 2019

May 8, 2019

LAVAL, Quebec--(BUSINESS WIRE)--BELLUS Health Inc. (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 provided an update on BLU-5937, its lead drug candidate for refractory chronic cough, and reported its financial and operating results for the first quarter ended March 31, 2019. All currency figures reported in this press release are in Canadian dollars, unless otherwise specified.

Key Updates:

- Two Abstracts Accepted for Presentation: Two abstracts, including data from the clinical Phase 1 study for BLU-5937, were accepted for presentation at the American Thoracic Society Conference on May 21 and at the American Cough Conference on June 7;
- CTA Accepted in the UK: The United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) accepted the Company’s Clinical Trial Authorisation (CTA) application, clearing the start of its clinical Phase 2 study for BLU-5937 in chronic cough patients in the United Kingdom;
- IND Accepted in the U.S.: In April 2019, the Company announced that the U.S. Food and Drug Administration (FDA) accepted its Investigational New Drug (IND) application, clearing the start of its Phase 2 study in the United States;
- Phase 2 Start on Track: The clinical Phase 2 study for BLU-5937 in chronic cough patients is scheduled to be initiated in mid-2019, with top-line results anticipated in mid-2020;
- Cash Runway to 2021: The Company concluded the quarter with cash, cash equivalents, and short-term investments totalling $45.4 million, expected to provide enough capital to fund its operations into Q1 2021.

“We are extremely pleased by the progress we’ve made in advancing the development of BLU-5937 including getting both the IND and CTA accepted, which clears the path for the initiation of the Phase 2 study, a critical milestone for the Company,” said Roberto Bellini, President and Chief Executive Officer of BELLUS Health. “The clinical data from our successful Phase 1 study positions BLU-5937 as a potential best in class P2X3 antagonist for chronic cough, and we look forward to sharing more data from that study at the American Thoracic Society Conference on May 21 and the American Cough Conference on June 7.”

Abstracts Accepted for Presentation

Event: American Thoracic Society Conference
Poster Presentation: BLU-5937 a Highly Selective P2X3 Homotrimeric Receptor Antagonist with Improved Taste Safety Profile in Healthy Subjects
Poster Board Number: P556
Session Title: C37 – Symptoms, Pleural Disease, Behavioral Science, and Other Topics
Date: May 21, 2019
Time: 11:15 am to 1:00 pm CT
Location: Dallas, Texas

Event: American Cough Conference
Oral Presentation: BLU-5937, a Highly Selective P2X3 Homotrimeric Receptor Antagonist, Exhibits Excellent Pharmacokinetic and Safety Profile Including Improved Taste Safety Profile in Healthy Subjects
Date: June 7, 2019
Time: 3:35 pm ET
Location: Reston, Virginia

BLU-5937 for Chronic Cough

The Company’s lead drug candidate is BLU-5937, a highly-selective P2X3 antagonist which has the potential to be a best-in-class therapeutic for refractory chronic cough patients.

Topline data from the Phase 1 study of orally administered BLU-5937, reported in November 2018, demonstrated that it is safe and well-tolerated, with a pharmacokinetic profile supporting twice-daily dosing. At the anticipated therapeutic doses of 50mg – 100mg, BLU-5937 did not cause any loss of taste perception, and only one subject out of 24 (4.2%) reported transient taste alteration. No subject reported total loss of taste at any dose levels.

The Company anticipates initiating a clinical Phase 2 study in mid-2019. This will be a dose-escalation, crossover design study to assess the efficacy, safety and tolerability of BLU-5937 at four doses: 25, 50, 100 and 200mg BID. Approximately fifty patients with refractory unexplained chronic cough are expected to be enrolled at 12 clinical sites in the United Kingdom and United States.

Summary of Financial Results
Three months ended March 31, 2019
Three months ended March 31, 2018
(in thousands of dollars, except per share data)

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2019</th>
<th>March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenues</td>
<td>$ 9</td>
<td>$ 9</td>
</tr>
<tr>
<td>Research and development expenses, net</td>
<td>(3,229)</td>
<td>(1,245)</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>(1,403)</td>
<td>(704)</td>
</tr>
<tr>
<td>Net finance (costs) income</td>
<td>(168)</td>
<td>97</td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>(4,791)</td>
<td>(1,843)</td>
</tr>
<tr>
<td>Basic and diluted loss per share</td>
<td>(0.03)</td>
<td>(0.02)</td>
</tr>
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- Research and development expenses, net of research tax credits, amounted to $3,229,000 for the three-month period ending March 31, 2019, compared to $1,245,000 for the corresponding period the previous year. The increase is primarily attributable to higher expenses incurred in relation to the development of BLU-5937.
- General and administrative expenses amounted to $1,403,000 for the three-month period ended March 31, 2019, compared to $704,000 for the corresponding period the previous year. The increase is mainly due to higher stock-based compensation expense in relation to the Company’s stock option plan and deferred share unit plans.
- Net finance costs amounted to $168,000 for the three-month period ended March 31, 2019, compared to net finance income of $97,000 for the corresponding period the previous year. The increase in net finance costs is primarily attributable to a foreign exchange loss that arose from the translation of the Company’s net monetary assets denominated in US dollars.

As at March 31, 2019, the Company had available cash, cash equivalents and short-term investments totalling $45,442,000, compared to $48,906,000 as at December 31, 2018.

The Company’s full unaudited condensed consolidated interim financial statements and accompanying management’s discussion and analysis for the three-month period ended March 31, 2019 will be available shortly on SEDAR at www.sedar.com.

BELLUS Health Announces Election of Directors at Annual and Special Meeting

At the Annual and Special Meeting of Shareholders held in Laval, Quebec, each director nominee listed in the Management Information Circular dated March 13, 2019 was elected as a Director of the Company.

The details of the election are as follows:

<table>
<thead>
<tr>
<th>Director Nominee</th>
<th>Outcome</th>
<th>Votes For</th>
<th>% For</th>
<th>Votes Withheld</th>
<th>% Withheld</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Francesco Bellini, O.C.</td>
<td>Elected</td>
<td>91,760,403</td>
<td>99.42%</td>
<td>531,254</td>
<td>0.58%</td>
</tr>
<tr>
<td>Roberto Bellini</td>
<td>Elected</td>
<td>92,165,217</td>
<td>99.86%</td>
<td>126,440</td>
<td>0.14%</td>
</tr>
<tr>
<td>Dr. Youssef L. Bennani</td>
<td>Elected</td>
<td>92,225,148</td>
<td>99.93%</td>
<td>66,509</td>
<td>0.07%</td>
</tr>
<tr>
<td>Franklin M. Berger</td>
<td>Elected</td>
<td>90,613,767</td>
<td>98.18%</td>
<td>1,677,890</td>
<td>1.82%</td>
</tr>
<tr>
<td>Dr. Clarissa Desjardins</td>
<td>Elected</td>
<td>92,252,093</td>
<td>99.96%</td>
<td>38,564</td>
<td>0.04%</td>
</tr>
<tr>
<td>Chau Q. Khuong</td>
<td>Elected</td>
<td>92,216,129</td>
<td>99.92%</td>
<td>75,528</td>
<td>0.08%</td>
</tr>
<tr>
<td>Pierre Larochelle</td>
<td>Elected</td>
<td>91,813,995</td>
<td>99.48%</td>
<td>477,662</td>
<td>0.52%</td>
</tr>
<tr>
<td>Joseph Rus</td>
<td>Elected</td>
<td>92,164,483</td>
<td>99.86%</td>
<td>127,174</td>
<td>0.14%</td>
</tr>
</tbody>
</table>

The results of the final votes regarding all matters subject to a vote during the Annual and Special Meeting that took place today will be made available on SEDAR’s website (www.sedar.com).

About BLU-5937

BLU-5937, a highly selective P2X3 antagonist - (>1500 fold) for human P2X3 receptors versus P2X2/3 receptors - has the potential to be a best-in-class therapeutic for refractory chronic cough patients.

The P2X3 receptor in the cough reflex pathway is a rational target for treating refractory chronic cough, and it has been validated in multiple clinical studies. With a modestly-selective 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 a highly selective P2X3 antagonist can reduce coughing in patients with refractory chronic cough, while maintaining taste function, by not inhibiting P2X2/3 receptors.

In addition to chronic cough, BLU-5937 may potentially have clinical benefit in other afferent hypersensitization-related disorders, such as visceral pain, hypertension, and migraine, among others. BELLUS Health is exploring how P2X3 activation can contribute to irritation and pain, and that inhibition of P2X3 receptors may be able to 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 lead drug candidate, BLU-5937, is being developed for the treatment of chronic cough.

Chronic cough 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 unexplained or refractory chronic cough lasting for more than a year. There are limited treatment options for refractory chronic cough, including no currently approved therapeutics.

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. 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 Inc.’s control. Such risks factors include but are not limited to: the ability to expand and develop its project pipeline, the ability to obtain financing, the impact of general economic conditions, general conditions in the pharmaceutical industry, changes in the regulatory environment in the jurisdictions in which BELLUS Health Inc. 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 pre-clinical and clinical trial milestones 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 Inc.’s drug candidates’ development process, their market size and commercial value, as well as the sharing of proceeds between BELLUS Health Inc. and its potential partners from potential future revenues, if any, are dependent upon a number of factors. Consequently, actual future results and events may differ materially from the anticipated results and events expressed in the forward-looking statements. BELLUS Health Inc. 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 Inc. 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 Inc.’s public filings with the Canadian securities regulatory authorities, including the Annual Information Form, for further risk factors that might affect BELLUS Health Inc. and its business.

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