

GSK reaches agreement to acquire late-stage biopharmaceutical company BELLUS Health



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- Acquisition further strengthens specialty medicines and respiratory pipeline with camlipixant, a highly selective P2X3 antagonist and potential best-in-class treatment for refractory chronic cough
- Currently in phase III clinical development with anticipated regulatory approval and launch in 2026
- Accretive to adjusted EPS from 2027 with significant sales potential through 2031

GSK plc (LSE/NYSE: GSK) and BELLUS Health Inc. (TSX/NASDAQ: BLU) today announced that they have entered into an agreement under which GSK will acquire BELLUS, a Canada-based, late-stage biopharmaceutical company working to better the lives of patients suffering from refractory chronic cough (RCC) for US\$14.75 per share of common stock in cash representing an approximate total equity value of US\$2.0 billion (£1.6 billion). The acquisition provides GSK access to camlipixant, a potential best-in-class and highly selective P2X3 antagonist currently in phase III development for the first-line treatment of adult patients with RCC.

It is estimated that 28 million patients suffer from chronic cough, with 10 million patients globally and 6 million in the United States (US) and European Union (EU) suffering from RCC for over a year. 1 RCC is defined as a persistent cough for more than eight weeks that does not respond to treatment for an underlying condition or is otherwise unexplained. 2 RCC significantly impacts quality of life, with patients suffering from depression (53%), urinary incontinence (~50%), pain, rib fractures, social withdrawal, and loss of sleep. 3, 4 There are no

approved medicines for RCC in the US and EU.

P2X3 is a validated biological target implicated in cough reflex hypersensitisation, and camlipixant is a highly selective P2X3 antagonist. Current clinical data show that by selectively inhibiting P2X3 receptors, camlipixant may reduce cough frequency for patients suffering from RCC with a relatively low incidence of dysgeusia, the taste disturbance adverse event associated with other medicines that broadly target the P2X2/3 receptor. These taste disturbances frequently lead to patients discontinuing treatment. Notably, low rates of taste-related adverse events were reported at all doses in the phase IIb trial ($\leq 6.5\%$). 5

Luke Miels, Chief Commercial Officer, GSK said:

Patients suffering from severe forms of refractory chronic cough can experience over 900 coughs daily, resulting in quality-of-life issues. Camlipixant, a novel, highly selective P2X3 antagonist, has the potential to be a best-in-class treatment with significant sales potential. This proposed acquisition complements our portfolio of specialty medicines and builds on our expertise in respiratory therapies.

The acquisition of BELLUS is highly synergistic with GSK's expertise in respiratory medicines and is further supported by GSK's leading R&D, manufacturing, and commercialisation capabilities.

Following the anticipated regulatory approval and launch of camlipixant in 2026, the acquisition is expected to be accretive to adjusted EPS from 2027 and has the potential to deliver significant sales through 2031 and beyond.

In December 2021, BELLUS announced positive data from the SOOTHE phase IIb trial, indicating that it met its primary endpoint for the 50 mg and 200 mg twice-daily doses. Based on these data, BELLUS initiated the CALM phase III development programme consisting of the CALM-1 and CALM-2 trials, with data anticipated in H2 2024 and 2025, respectively. BELLUS is also evaluating a QD (once-daily) formulation for camlipixant, which is currently in phase I.

Roberto Bellini, Chief Executive Officer of BELLUS, said:

This acquisition recognises the value of our highly selective

P2X3 antagonist camlipixant and validates the hard work and dedication of all the BELLUS employees in advancing camlipixant to date. As a leader in respiratory research for over five decades, GSK shares our commitment to bettering the lives of individuals suffering from a persistent cough and is the ideal Company to rapidly bring camlipixant to the millions suffering from refractory chronic cough around the world.

The transaction remains subject to regulatory approvals.

Under the terms of the agreement, the acquisition will be effected through a Plan of Arrangement pursuant to the Canada Business Corporations Act in which the shares of BELLUS outstanding will be acquired by the Company in consideration of US\$14.75 per share in cash. Subject to customary conditions, including court approval, the approval of the acquisition by at least 66.67% of the votes cast at a meeting of BELLUS' shareholders and a majority of the votes cast by non-interested shareholders at such meeting, and approval by the appropriate regulatory agencies, the transaction is expected to close in the third quarter of 2023 or earlier.

The per-share price represents a premium of approximately 103% to BELLUS' closing stock price on 17 April 2023 and a premium of approximately 101% to BELLUS' volume-weighted average price (VWAP) over the last 30 trading days. BELLUS' Board of Directors has unanimously recommended that BELLUS' shareholders vote in favour of the approval of the acquisition.

GSK will account for the transaction as a business combination and expects it to be accretive to adjusted EPS in 2027, the expected first full year of camlipixant's sales.

There is no change to GSK's full-year 2023 guidance or the medium-term outlook for 2021-2026 of more than 5% sales and 10% adjusted operating profit CAGR* at CER**.

* CAGR: Compound Annual Growth Rate; **CER: Constant Exchange Rate

PJT Partners is acting as the exclusive financial advisor to GSK. Paul, Weiss, Rifkind, Wharton & Garrison LLP, and Stikeman Elliott LLP serve as legal counsel to GSK in connection with the transaction. Centerview Partners is acting as the exclusive financial advisor, and

Skadden, Arps, Slate, Meagher & Flom LLP, and Davies Ward Phillips & Vineberg LLP serve as legal counsel to BELLUS.

BELLUS is a late-stage biopharmaceutical company working to better the lives of patients suffering from persistent cough.

For over 50 years, GSK has led the way in developing medicines that advance the management of asthma and COPD, from introducing the world's first selective short-acting beta agonist in 1969 to launching six treatments in five years to create today's industry-leading respiratory portfolio.

RCC is a cough that persists for more than eight weeks despite optimal treatment of any underlying conditions or where there is no identifiable underlying cause. 6 Cough hypersensitivity syndrome – excessive coughing, often in response to relatively innocuous stimuli – is now identified as the primary pathology in RCC. RCC is a frequent, yet often under-recognised, medical condition with significant physical, social, and psychological consequences on a patient's quality of life. Two-thirds of patients are women averaging between 50-60 years old. 7 There are currently no approved treatments for this condition in the US or the EU.

Camlipixant is an investigational, twice-daily oral P2X3 receptor antagonist for the treatment of RCC, which is currently being evaluated in the CALM phase III clinical development programme. Given the need for novel and effective medicines for RCC, camlipixant has the potential to be a breakthrough in the treatment landscape.

Camlipixant is not currently approved anywhere in the world.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com/company](https://www.gsk.com/company).

Cautionary statement regarding forward-looking statements relating to BELLUS Health

This press release may include “forward-looking statements” within the meaning of the applicable securities laws, including with respect to the timing and completion of the arrangement, the proposed timing of filings, the impact of the proposed transaction on BELLUS Health, and the operations of BELLUS Health post-transaction. Each forward-

looking statement contained in this press release is based on the current expectations of management and is subject to known and unknown risks and uncertainties and other unknown factors that could cause actual results to differ materially from historical results and those expressed or implied by such statement. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labelled with the terms “believes,” “belief,” “expects,” “intends,” “anticipates,” “will,” or “plans” to be uncertain and forward-looking. Such statements include, but are not limited to, the potential of camlipixant to successfully treat RCC and other hypersensitization-related disorders, the success of BELLUS Health’s preclinical studies and clinical trials, and the timing and outcome of anticipated regulatory approvals. Additional risk factors include, but are not limited to, the impact of general economic conditions, general conditions in the pharmaceutical industry, the impact of the COVID-19 pandemic, including impact to the initiation and completion of clinical trials in a timely manner or at all, changes in the regulatory environment, supply chain impacts, fluctuations in costs, changes to the competitive environment, reliance on third parties to conduct preclinical studies and clinical trials for camlipixant. Furthermore, the risks and uncertainties include, among others, the risk that a condition to closing of the arrangement may not be satisfied, the risk that any required shareholder, court or applicable regulatory approvals for the arrangement may not be obtained or be obtained subject to conditions that are not anticipated, the failure to realize the anticipated benefits of the transaction, the occurrence of any event that could give rise to termination of the transaction, and potential litigation in connection with the transaction or other settlements or investigations that may affect the timing or occurrence of the transaction or result in significant costs of defence, indemnification and liability.

BELLUS Health cautions investors not to rely on the forward-looking statements contained in this press release when making an investment decision in their securities. Investors are encouraged to read BELLUS Health’s filings available on the SEC website at www.sec.gov and on the SEDAR website at www.sedar.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this press release and BELLUS Health undertakes no obligation to update or revise any of these statements, whether as a result of new information, future events or otherwise, except as required by law.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2022, GSK's Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

Song et al. The global epidemiology of chronic cough in adults: a systematic review and meta-analysis. Eur Respir J. 2015; 45: 1479–1481.

Meltzer et al. Prevalence and Burden of Chronic Cough in the United States. J of Allergy Clin Immunol Pract. 2021; 9:4037-44.

Dicpinigaitis et al. Prevalence of Depressive Symptoms Among Patients With Chronic Cough. CHEST. 2006; 130 (6): 1839 – 43.

Chamberlain et al. The impact of chronic cough: a cross-sectional European survey. Lung. 2015 Jun;193(3):401-8.

BELLUS Health Inc. Investor Presentation, Dec 2021.

Meltzer et al. Prevalence and Burden of Chronic Cough in the United States. J of Allergy Clin Immunol Pract. 2021; 9:4037-44.

Morice et al. A worldwide survey of chronic cough: a manifestation of enhanced somatosensory response. Eur Respir J. 2014 Nov;44(5):1149-55.

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