



## Jazz Pharmaceuticals Announces Commercial Availability in Canada of Zepzelca™ (lurbinectedin), the First New Treatment for Stage III or Metastatic Small Cell Lung Cancer in More Than a Decade

November 30, 2021

DUBLIN, Nov. 30, 2021 /CNW/ - Jazz Pharmaceuticals plc (NASDAQ: JAZZ) along with partner PharmaMar (MSE: PHM) have announced the commercial availability of Zepzelca™ (lurbinectedin) after receiving conditional approval by Health Canada in September 2021. Zepzelca is the first new treatment in Canada for adult patients with Stage III or metastatic small cell lung cancer (SCLC) who have progressed on or after platinum-containing therapy in more than a decade.<sup>1</sup>



Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer death in Canada.<sup>2</sup> SCLC is the most aggressive form of lung cancer.<sup>3</sup> It represents a significant health burden, with more than 4,000 cases annually across Canada, and accounts for about 13 per cent of all lung cancers. While patients may initially respond to traditional chemotherapy, they often experience an aggressive recurrence that may not respond to treatment.<sup>4</sup> The general five-year survival rate for people with SCLC is 7 per cent.<sup>5</sup>

"This is a significant milestone for people with relapsed small cell lung cancer and further demonstrates Jazz's commitment to developing life-saving medicines for people with limited options," says Paul Petrelli, general manager, Jazz Pharmaceuticals Canada Inc. "We are proud to introduce this meaningful new treatment to patients in Canada."

The Health Canada conditional approval of Zepzelca was based on overall response rate and duration of response.<sup>1</sup> The planned confirmatory study will be initiated later this year.

"Small cell lung cancer is a disease with a particularly poor prognosis. While chemotherapy is highly effective for most patients initially, the vast majority progress within months of completing treatment. Once the cancer starts to regrow, we are very limited in what we can do to manage their condition," says Dr. Rosalyn Juergens from McMaster University, Juravinski Cancer Centre. "Further research is needed in Canada but the addition of Zepzelca to the second line therapy landscape is welcome news for doctors, patients and their families."

"Patients with small cell lung cancer in the second line and their families have been on the sidelines for far too long. The availability of Zepzelca in Canada is a great new option," says Shem Singh, executive director, Lung Cancer Canada. "It gives patients and their families hope – hope for more time, hope for one more family celebration, hope for one more hug – and that's a very powerful thing. With time being of the essence for small cell lung cancer patients, we call on stakeholders to quickly make this treatment publicly funded for those who can't wait."

The conditional approval of Zepzelca by Health Canada is based on results from a Phase II open-label, multi-centre, multi-cohort, single-arm study (Study B-005) consisting of 105 SCLC patients who were treated with 3.2 mg/m<sup>2</sup> Zepzelca, administered as a 60-minute intravenous infusion repeated every 21 days (one-cycle).<sup>1</sup> The data showed that in patients with relapsed SCLC, Zepzelca demonstrated an overall response rate of 35 per cent and a median duration of response of 5.3 months as measured by investigator assessment.<sup>1</sup>

### About Zepzelca™ (lurbinectedin)

Zepzelca is indicated for the treatment of adult patients with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.<sup>1</sup> Zepzelca works by preventing the cancer cells from growing and spreading to other parts in the body. Zepzelca also reduces the ability of other cells to support the growth of the cancer cells. This helps stop the growth of the cancer cells. The recommended Zepzelca dosing is 3.2 mg/m<sup>2</sup> by intravenous infusion over 60 minutes repeated every 21 days until disease progression or unacceptable toxicity.

The most common (≥20%) reported adverse events (all grades) were fatigue (77%), nausea (37%), neutropenia (33%), decreased appetite (33%), musculoskeletal pain (31%), dyspnea (31%), constipation (31%), respiratory tract infection (26%), vomiting (22%), diarrhea (20%) and cough (20%).<sup>1</sup>

For more information, please refer to the product monograph for Zepzelca in Canada located [here](#).

### About SCLC

Small cell lung cancer is a fast-growing [lung cancer](#) that develops in the tissues of the lungs.<sup>6</sup> By the time a person receives a diagnosis, it has typically spread (metastasized) outside of the lungs. This cancer is also more likely than other types of lung cancer to come back after treatment. Small cell lung cancer is sometimes, but not often, called oat cell cancer because the small, oval-shaped cells look like oat grains under a microscope. People with and without a smoking history are all at risk for lung cancer. However, small cell lung cancer almost always develops in people who have a long history of tobacco use.

### About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases—often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through

innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) and follow @JazzPharma on Twitter.

### About PharmaMar

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation.

PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca™ (lurbinectedin), in the US; and Aplidin® (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and PM14. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar also wholly owns other companies: GENOMICA, a molecular diagnostics company; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

### Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' expectations regarding the timing of confirmatory studies of *Zepzelca* in Canada, its potential to fill an unmet need and have an impact on the SCLC community; and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, including risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients such as those being experienced, and expected to continue to be experienced, by the Company as a result of the effects of the COVID-19 pandemic; and other risks and uncertainties affecting Jazz Pharmaceuticals, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended September 29, 2021, and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

### References

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<sup>1</sup> Jazz Pharmaceuticals Canada Inc. ZEPZELCA™ (lurbinectedin) Product Monograph. September 29, 2021. Available at: <https://pp.jazzpharma.com/pi/zepzelca.ca.PM-en.pdf> Accessed November 30, 2021.

<sup>2</sup> Government of Canada, S. C. (2020, October 1). Canadian cancer Statistics, 2020. The Daily — Canadian cancer statistics, 2020. Retrieved November 30, 2021, from <https://www150.statcan.gc.ca/n1/daily-quotidien/200922/dq200922b-eng.htm>.

<sup>3</sup> Lung Cancer Canada. An Overview of Lung Cancer. Available at: <https://www.lungcancercanada.ca/Lung-Cancer.aspx#Lung%20Cancer> Accessed November 30, 2021.

<sup>4</sup> Ellis, P. M., Anand Swaminath, & Pond, G. R. (2021, July). Patterns of Relapse in Small Cell Lung Cancer: Competing Risks of Thoracic versus CNS Relapse. <https://www.mdpi.com/journal/cancers>. <https://www.mdpi.com/1718-7729/28/4/243>.

<sup>5</sup> The American Cancer Society. Lung Cancer Survival Rates. Available at : <https://www.cancer.org/cancer/lung-cancer/detection-diagnosis-staging/survival-rates.html> Accessed November 30, 2021.

<sup>6</sup> The Cleveland Clinic. Small Cell Lung Cancer. Available at: <https://my.clevelandclinic.org/health/diseases/6202-small-cell-lung-cancer> Accessed November 30, 2021.

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