Bionical Emas and Jazz Pharmaceuticals Enter into an Agreement for Expanded Access to Lurbinectedin in Relapsed Small Cell Lung Cancer in the United States

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WILLINGTON, England and DUBLIN, May 11, 2020 /PRNewswire/ -- Bionical Emas and Jazz Pharmaceuticals (NASDAQ: JAZZ) have entered into an agreement to provide appropriate patients in the United States (U.S.) who have relapsed Small Cell Lung Cancer (SCLC) lurbinectedin via an Expanded Access Program (EAP). Lurbinectedin is an investigational drug under review by the U.S. Food and Drug Administration (FDA).

The EAP is open to patients who are unable to enter clinical trials and for whom there are no appropriate alternative treatments while lurbinectedin is under regulatory review by the FDA. The EAP was originally launched in January 2020 between Bionical Emas and PharmaMar S.A. (PharmaMar), and now has successfully transitioned from PharmaMar to Jazz.

SCLC is an aggressive form of cancer that usually is diagnosed with advanced, often metastatic, disease, and often posing a worse prognosis when compared to other lung cancers.[1] In the United States, approximately 10-15% of lung cancers are small cell.[1] Approximately 30,000 new cases of SCLC are recorded in the U.S. every year.[2]

Lurbinectedin is a selective inhibitor of oncogenic transcription on which many cancers such as SCLC are particularly dependent.

"*We are pleased to be working with Jazz on this important project allowing access to lurbinectedin to appropriate patients via an Expanded Access Program in the U.S.," said* **Tom Watson**, Executive Vice President, Bionical Emas**.**

"*Lurbinectedin provides further hope for patients suffering from relapsed SCLC who currently have limited treatment options. This EAP provides an important opportunity for those patients who are unable to enter clinical trials and for whom there are no appropriate alternative treatments, and we are pleased to support this program," said* **John Efthimiou**, Chief Medical Officer, Bionical Emas.

A new drug application (NDA) for Lurbinectedin is under review by the FDA and has not yet been approved.

Healthcare professionals wishing to request access to lurbinectedin under the EAP or who would like to find out more should do so by emailing Lurbinectedin.EAP@Bionical-emas.com. Further details concerning the EAP can be found on Clinicaltrials.gov.

About Bionical Emas

Bionical Emas is a specialist CRO combining Clinical Development, Early Access Programs and Clinical Trial Supply.

Our Early Access Programs provide access to pre-approved medicines to help patients with unmet medical needs.

Access is provided in response to physician requests, where no alternative treatment options are available, and the patient is not eligible for clinical trials for the condition.

https://bionicalemas.com

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References:

[1]American Cancer Society, https://www.cancer.org/cancer/small-cell-lung-cancer/about/what-is-small-cell-lung-cancer.html (accessed March 31, 2020)

[2]SEER Cancer Stat Facts – Lung and Bronchus Cancer, https://seer.cancer.gov/statfacts/html/lungb.html (accessed March 31, 2020)