Zepzelca® (lurbinectedin) has received the Innovation Passport (Innovative Medicine Designation) by the MHRA (UK Medicines and Healthcare products Regulatory Agency)

Immedica Pharma AB is pleased to announce that Zepzelca® (lurbinectedin) has received the Innovation Passport (Innovative Medicine Designation) by the MHRA (UK Medicines and Healthcare products Regulatory Agency), presented earlier by our valued partner PharmaMar (see full press release below).

Anders Edvell, CEO says: “To be awarded an Innovation Passport under the new Innovative Licensing and Access Pathway means a lot to us. We are excited about engaging with UK healthcare system stakeholders through this new pathway to explore the opportunities for bringing Lurbinectedin to patients as quickly as possible”.

The pressrelease from PharmaMar, follows below.

AUGUST 5, 2022

PharmaMar has announced today that Zepzelca® (lurbinectedin) has received the Innovation Passport (Innovative Medicine Designation) by the MHRA (UK Medicines and Healthcare products Regulatory Agency).

The MHRA’s Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. The ILAP comprises as the first step an “Innovation Passport” designation which supports innovative approaches to the safe, timely and efficient development of medicines to improve patient access. The criteria for the innovation passport include where the condition is life-threatening or seriously debilitating, or where there is a significant patient or public health need and where the medicinal product has the potential to offer benefits to patients (improved efficacy or safety, improved patient care or quality of life as compared to alternative therapeutic options).

Ali Zeaiter, M.D., VP Clinical Development & Regulatory Affairs of PharmaMar, said:

“Lurbinectedin is an innovative medicine that showed clinical benefit for patients with relapsed Small Cell Lung Cancer (SCLC) and obtained provisional approvals in a number of countries (including USA, Canada and Australia) and is being developed in other clinically significant indications. SCLC represents an unmet medical need in the UK and worldwide, and our objectives are aligned with those of the UK public health authorities to facilitate and improve patients access to medicines such as lurbinectedin,” and added: “We believe that the innovation passport designation is an important step towards facilitating SCLC patients’ access to a new treatment option.”

On May 4th 2022, PharmaMar announced it had submitted a conditional marketing authorization application to the UK's MHRA for the treatment with lurbinectedin in adult patients with metastatic Small Cell Lung Cancer who have progressed following prior platinum-based chemotherapy based on data from the Phase II basket trial with lurbinectedin in monotherapy. PharmaMar expects a response to such application by the end of this year or first quarter of 2023. In addition, the LAGOON Phase III trial could be used as a confirmatory trial.

On 2020 PharmaMar and Immedica Pharma AB signed an agreement for the exclusive distribution and marketing of lurbinectedin for the UK and other territories.

Legal warning
This news release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

About Immedica AB
Immedica is a fast-growing private niche pharma group with headquarter in Stockholm, Sweden and commercial coverage across Europe and the Middle East. Immedica has significant know-how and experience in commercialization of niche/specialty care products across Europe and the Middle East, and the company's management team has an outstanding track record of operating niche pharma products internationally. Immedica has capabilities to provide optimal access of specialty care medicines to patients with significant medical needs, including key areas such as regulatory affairs, pharmacovigilance, medical affairs, pricing & reimbursement, quality, and product distribution.More information is available at www.immedica.com

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.

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 www.pharmar.com

About lurbinectedin
Lurbinectedin (PM1183) is a synthetic compound currently under clinical investigation. It is a selective inhibitor of the oncogenic transcription programs on which many tumors are particularly dependent. Together with its effect on cancer cells, lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

For more information please contact

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