



Zepzelca® (lurbinectedin) in combination with atezolizumab receives positive CHMP opinion as first-line maintenance therapy for extensive-stage small cell lung cancer

Stockholm, Sweden, March 27, 2026 – Immedica today announces that Zepzelca® (lurbinectedin), in combination with atezolizumab, has received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) as first-line treatment for adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed following induction therapy with atezolizumab, carboplatin and etoposide.

Extensive-stage small cell lung cancer is an aggressive and fast-growing disease with a poor prognosis and limited treatment options, with the majority of patients diagnosed at an advanced stage.

"Small cell lung cancer remains a highly challenging disease with significant unmet medical need," said Anders Edvell, CEO of Immedica. "The CHMP's positive opinion represents an important step towards bringing this new treatment option to patients in Europe."

The decision is based on results from the Phase 3 IMforte trial, which showed that the lurbinectedin and atezolizumab combination reduced the risk of disease progression or death by 46% and the risk of death by 27%, compared to atezolizumab maintenance therapy alone. Following four cycles of induction therapy, from the point of randomization the median overall survival (OS) for the combination regimen was 13.2 months versus 10.6 months (stratified hazard ratio [HR]=0.73; 95% CI: 0.57–0.95; $p=0.0174$). From the point of randomization, median progression-free survival (PFS) by independent assessment was 5.4 months versus 2.1 months, respectively (stratified HR=0.54, 95% CI: 0.43–0.67; $p<0.0001$). Safety was consistent with the known safety profiles of both treatments. The results were presented at the 2025 American Society of Clinical Oncology (ASCO) annual meeting and simultaneously published in The Lancet.

The CHMP positive opinion will now be reviewed by the European Commission, which is responsible for the final decision on the marketing authorization in the EU.

Immedica has a strategic partnership with PharmaMar, where Immedica holds the distribution rights to Zepzelca in the Nordics, the UK & Ireland, Central Eastern Europe as well as in the Middle East and North Africa.

About small cell lung cancer (SCLC)

SCLC is an aggressive form of lung cancer characterized by rapid growth, early metastasis, and limited therapeutic options. It accounts for about 10–15 % of all lung cancer cases and tends to present at an advanced stage, often requiring systemic therapy. Because of its aggressive nature and propensity for relapse the prognosis remains poor.

About Zepzelca® (lurbinectedin)

Zepzelca® (lurbinectedin), also known as PM1183, is an analog of the marine compound ET-736 isolated from the sea squirt Ecteinascidia turbinata in which a hydrogen atom has been replaced by a methoxy group. 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.

About PharmaMar

PharmaMar is a biopharmaceutical company headquartered in Madrid, Spain, specializing in the discovery, development, and commercialization of anticancer therapies derived from marine biodiversity. The company focuses its R&D efforts on rare and difficult-to-treat cancers, leveraging a proprietary platform of marine-derived compounds and strong collaborations with academic and industry partners.

For more information, visit www.pharmamar.com

About Immedica

Immedica is a pharmaceutical company, headquartered in Stockholm, Sweden, focused on the commercialization of medicines for rare diseases and specialty care products. Immedica's capabilities cover marketing and sales, compliance, pharmacovigilance, quality assurance, regulatory, medical affairs and market access, as well as a global distribution network serving patients in more than 50 countries. Immedica is fully dedicated to helping those living with diseases which have a large unmet medical need. Immedica's therapeutic areas are within RARE metabolic, RARE hematology & oncology, RARE neurology, RARE Endocrinology and specialty care. Immedica was founded in 2018 and employs today around 180 people across Europe, the Middle East and the United States. Immedica is backed by the investment firms KKR and Impilo.

For more information visit www.immedica.com.

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