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Australia approves novel therapy to treat Advanced Small Cell Lung Cancer

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ZEPZELCAÃ?Â® (lurbinectedin) is the first therapy to treat second-line metastatic SCLC in cases of aggressive recurrence of symptoms after initial traditional chemotherapy



Australian patients with an aggressive form of lung cancer (metastatic Small Cell Lung Cancer) can now access a new therapy that may improve outcomes.

The therapy, ZEPZELCA (lurbinectedin) has been approved by the Therapeutic Goods Administration (TGA) "for the treatment of patients with metastatic small cell lung cancer (SCLC) that has progressed on or after prior platinum-containing therapy**".** ZEPZELCA is the first new therapy approved by the TGA to treat second-line SCLC in more than two decades.

The TGA approval of ZEPZELCA has been granted under a provisional regulatory pathway. The US Food and Drug Administration (FDA) and Australia's Therapeutic Goods Administration (TGA) collaborated via 'Project Orbis' to accelerate availability to Australian patients.

The data is published in *The Lancet Oncology* May 2020 issue, demonstrated that in patients with relapsed SCLC, ZEPZELCA provided an Overall Response Rate (ORR) of 35%. The provisional approval is the subject of a further confirmatory study in more than 700 patients with 2nd line SCLC including some Australian sites. This study is expected to be completed in 2025.

Patients may initially respond to traditional chemotherapy, but they often experience an aggressive recurrence that is historically resistant to treatment. ZEPZELCA is an important advance for adult patients whose metastatic SCLC has progressed on or after platinum-based chemotherapy.

ZEPZELCA is being made available in Australia by the independent pharmaceutical Company, Specialised Therapeutics (ST), under exclusive license from an international partner, PharmaMar.

Approval of ZEPZELCA would potentially make a difference for around 400 Australian patients annually who had run out of treatment options. ZEPZELCA is currently available in Australia via a Special Access Program. Commercial supplies of ZEPZELCA will commence in early 2022.