

Intas Pharma and Henlius Biotech strengthen oncology partnership for Europe & India markets

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Intas gains exclusive rights to further develop and commercialise serplulimab in Europe and India



Indian firm Intas Pharmaceuticals has entered into an exclusive license agreement with Shanghai Henlius Biotech, Inc. for the development and commercialisation of serplulimab for Europe and India markets.

Serplulimab, a recombinant humanised anti-PD-1 monoclonal antibody (mAb) injection, is the first innovative monoclonal antibody developed by Henlius. It has been granted orphan drug designation by the US Food and Drug Administration (FDA) and the European Commission (EC) for the treatment of Small Cell Lung Cancer (SCLC). Its marketing application for the first-line treatment for extensive-stage small cell lung cancer (ES-SCLC) is under review by the European Medicines Agency (EMA).

Serplulimab was launched in China under the trade name HANSIZHUANG in March 2022 and has been approved by the National Medical Products Administration (NMPA) for the treatment of microsatellite instability-high (MSI-H) solid tumours, squamous non-small cell lung cancer (sqNSCLC), ES-SCLC, and esophageal squamous cell carcinoma (ESCC).

This collaboration deepens the strategic partnership between the two companies and opens new development opportunities for serplulimab's global layout. Under the terms of the agreement, Henlius will be responsible for clinical development, manufacturing, and supply upon launch.

Henlius will receive: i) a €42 million upfront payment, ii) up to €43 million in regulatory milestones, iii) up to €100 million in commercial sales milestones, and iv) double-digit royalties on net profit from Intas in the licensed territory.

Serplulimab will be commercialised by Intas in India and by its subsidiary, Accord Healthcare in Europe.