Intas Pharmaceuticals Ltd and Henlius Biotech enter into Exclusive License Agreement to commercialise serplulimab - A Novel Anti-PD1 mAb in Europe & India

This collaboration strengthens the Intas novel biologics portfolio and deepens the existing strategic partnership between Henlius & Intas.

Intas gains exclusive rights to further develop and commercialise serplulimab in Europe and India. Henlius will be responsible for clinical development, manufacturing, and supply upon launch.

Serplulimab has been granted orphan drug designations by the European Commission for the treatment of SCLC. The marketing authorisation application for the first-line treatment for ES-SCLC is under review by the EMA.

AHMEDABAD, India, Oct. 27, 2023 /PRNewswire/ -- Intas Pharmaceuticals Limited ("Intas") has entered into an exclusive license agreement with Shanghai Henlius Biotech, Inc. (2696.HK) 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 U.S. 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 EMA. Serplulimab was launched in China under the trade name HANSIZHUANG in March 2022 and has been approved by the NMPA for the treatment of 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 Ltd (Accord), in Europe. As one of the key players in the global oncology

market, Accord has a longstanding commitment to oncology with proven commercial capabilities and currently supplies around one in three injectable oncology medicines in Europe.

In June 2018, Henlius and Accord entered into a license agreement, under which Henlius granted Accord exclusive commercialisation rights of HLX02 (trastuzumab for injection, trade name in China: HANQUYOU; trade name in Europe: Zercepac®; trade names in Australia: Tuzucip®/Trastucip®) in certain countries and regions in Europe, the Middle East, North Africa, and the Commonwealth of Independent States. In 2021, Henlius granted Intas the exclusive rights to develop and commercialize HLX02 in the United States (U.S.) and Canada.

HANSIZHUANG (serplulimab) has become the world's first anti-PD-1 monoclonal antibody approved for the first-line treatment of small cell lung cancer, and has been approved for 4 indications in China, benefiting over 40,000 Chinese patients. Its marketing application has been validated by the European Medicines Agency (EMA) in March 2023," said Jason Zhu, Executive Director, Chief Executive Officer, and Chief Financial Officer of Henlius. "By continuously partnering with Intas, we hope to accelerate serplulimab's wider accessibility globally and contribute to the improvement of patient outcomes."

Ping Cao, Senior Vice President and Chief Business Development Officer of Henlius, said, "Henlius and Intas first entered into a collaboration in 2018. Over the past 5 years, we have worked closely together and expanded the internationalisation of HANQUYOU (Zercepac® in Europe), which has been successfully approved in 40+ of overseas countries, benefiting patients in Europe and MENA. Building on the successful collaboration, we look forward to working with Intas to accelerate the launch of serplulimab in Europe and India, and to continue our mission to offering high-quality and affordable biologics to patients around the world."

Binish Chudgar, Vice-Chairman & Managing Director, Intas Pharmaceuticals Ltd., said, "We are excited to reinforce our long-standing partnership with Henlius. This collaboration will further bolster Intas' global oncology portfolio, underlining our commitment to delivering innovative healthcare solutions worldwide. The forthcoming launch of serplulimab in Europe and India will mark a crucial landmark in our mission to enable access to advanced biologics, ensuring patients across the world receive the high-quality treatments they deserve."

Paul Tredwell, Executive Vice President of EMENA., Accord, said, "I am delighted to strengthen our partnership with Henlius. The launch of serplulimab will further solidify Accord as a leader in providing specialty medicines. This marks our second novel launch in just two years, adding to our existing platform of supplying up to 25% of chemotherapy medicines in our region, exemplifying our commitment to innovation and growth and our mission to improve access to value-based medicines for patients."

About Serplulimab

HANSIZHUANG (recombinant humanized anti-PD-1 monoclonal antibody injection, non-proprietary name: serplulimab injection) is the first anti-PD-1 mAb for the first-line treatment of SCLC. To date, four indications are approved for marketing in China, one marketing application is under review in the EU, and more than 10 clinical trials are ongoing across the world.

HANSIZHUANG was launched in March 2022 and has been approved by the NMPA for the treatment of MSI-H solid tumours, squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), and esophageal squamous cell carcinoma (ESCC). Serplulimab's marketing applications for the first-line treatment for ES-SCLC is under review by the EMA. Focusing on lung and gastrointestinal cancer, the synergy of serplulimab with in-house products of the company and innovative therapies are being actively promoted. It has successively obtained clinical trial approvals in China, the U.S., the EU and other countries and regions to initiate more than 10 clinical trials on immuno-oncology combination therapies in a wide variety of indications. As of now, the company has enrolled more than 3,600 subjects in China, the U.S., Turkey, Poland, Georgia and other countries and regions, and the proportion of Caucasians is over 30% in two MRCTs, making serplulimab an anti-PD-1 mAb with a significant global clinical data pool. The results of three pivotal trials of serplulimab were published in the Journal of the American Medical Association (JAMA), Nature Medicine and the British Journal of Cancer, respectively. Furthermore, serplulimab was recommended by the CSCO Guidelines for Small Cell Lung Cancer, the CSCO Guidelines for Non-Small Cell Lung Cancer, the CSCO Guidelines for Esophageal Cancer, the CSCO Guidelines for Colorectal Cancer, the CSCO Clinical Practice Guidelines on Immune Checkpoint Inhibitor, the China Guidelines for Radiotherapy of Esophageal Cancer, and other definitive guides, providing valuable references for clinical diagnosis and treatment of tumours. In addition, serplulimab was granted orphan drug designations by the U.S. FDA and the EC for the treatment of SCLC, and its bridging head-to-head trial in the United States to compare serplulimab to standard of care atezolizumab (anti-PD-L1 mAb) for the first-line treatment of ES-SCLC is well underway.