

China's CStone inks deal worth \$192.5 M with Istituto Gentili to commercialise cancer drug in Europe

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Gentili will receive exclusive commercialisation rights for sugemalimab in 23 European countries

China-based CStone Pharmaceuticals has announced an exclusive partnership with Istituto Gentili, a leading European biopharmaceutical company with a century-long heritage in oncology, to commercialise sugemalimab across Western Europe and the UK.

Under the terms of the agreement, Gentili will receive exclusive commercialisation rights for sugemalimab in 23 European countries—including 18 EEA countries (Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, and Sweden)—as well as the United Kingdom, Andorra, Monaco, San Marino, and Vatican City.

CStone is eligible to receive up to \$192.5 million in total consideration, comprising an upfront payment and payments tied to regulatory and commercial milestones. Additionally, CStone will supply sugemalimab and recognise close to 50% of net sales from the licensed territories as revenue, while Gentili will lead all local regulatory and commercial operations in the covered regions.

The anti-PD-L1 monoclonal antibody sugemalimab was developed by CStone using OmniRat® transgenic animal platform, which allows creation of fully human antibodies in one step. Sugemalimab is a fully human, full-length anti-PD-L1 immunoglobulin G4 (IgG4) monoclonal antibody, which may reduce the risk of immunogenicity and toxicity for patients.

Dr Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated, "Sugemalimab is the first anti-PD-L1 monoclonal antibody approved in the EU and UK for use in combination with chemotherapy for the first-line treatment of stage IV non-small cell lung cancer (NSCLC), regardless of histology or PD-L1 expression. The European Medicines Agency (EMA) has also accepted a supplemental marketing application for Stage III NSCLC, which, if approved, will make sugemalimab the second PD-(L)1 therapy in Europe for this indication.