Ewopharma AG
Vordergasse 43
8200 Schaffhausen
Switzerland

T +41 52 633 09 99
info@ewopharma.com
www.ewopharma.com

PRESS-RELEASE – FOR IMMEDIATE RELEASE

Sugemalimab Achieves New Regulatory Milestone: European Commission Approves Stage Ⅲ NSCLC Indication

Schaffhausen, Switzerland, 16/12/25 – Ewopharma is pleased to report an important new regulatory milestone for sugemalimab licensed from Chinese partner CStone Pharmaceuticals. In late November 2025, the **European Commission (EC) granted approval for a new indication for sugemalimab as monotherapy for adult patients with unresectable stage III non-small cell lung cancer (NSCLC).** This applies to patients whose tumours express PD-L1 on ≥1% of tumour cells and who do not carry EGFR-sensitising genetic mutations, or ALK, or ROS1 genomic aberrations, and whose disease has not progressed following platinum-based chemoradiotherapy (CRT). The EC had already approved the use of sugemalimab in combination with chemotherapy for the treatment of metastatic (Stage IV) NSCLC in July 2024.

Reto Schaberl, Director Business Development & Specialty Pharma at Ewopharma, comments: "This approval, following a positive opinion from the European Medicines Agency in October, represents an additional authorised indication for patients whose disease has not progressed following platinum-based chemoradiotherapy. It adds a further authorised indication beyond the metastatic setting, as reflected in the approved label." Further information can be found at the European Commission webpage: https://ec.europa.eu/health/documents/community-register/html/h1833.htm.

About Sugemalimab
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.

The EC has approved sugemalimab for two indications:

- In combination with platinum-based chemotherapy for the first-line treatment of patients with metastatic NSCLC with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations (this indication has also been approved by the Medicines and Healthcare products Regulatory Agency [MHRA]);

- Monotherapy for adult patients with unresectable stage III NSCLC with PD-L1 expression on ≥1% of tumour cells and no sensitising EGFR mutations, or ALK, ROS1 genomic aberrations and whose disease has not progressed following platinum-based CRT.

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About Ewopharma AG
Ewopharma AG, headquartered in Schaffhausen (Switzerland), is a pharmaceutical marketing company focused on Central Eastern Europe and Switzerland. With more than 60 years presence in the region, Ewopharma has extensive knowledge of these markets and enjoys a privileged position in the area. The company covers all aspects of market access and commercialisation of ethical pharmaceutical and consumer health products. Further information is available at www.ewopharma.com.

For further information please contact:
Ewopharma AG
Reto Schaberl
Director Business Development & Specialty Pharma
r.schaberl@ewopharma.com