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# **Ligand's Partner CStone Pharmaceuticals Receives Approval in China for Sugemalimab (Cejemly®) for the First-Line Treatment of Advanced Non-Small Cell Lung Cancer in Combination with Chemotherapy**

*Sugemalimab was discovered using the OmniAb platform*

EMERYVILLE, Calif.--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** today announced that its partner CStone Pharmaceuticals (HKEX: 2616) has received approval from China's National Medical Products Administration (NMPA) for sugemalimab (Cejemly®), an OmniAb-derived anti-PD-L1 monoclonal antibody, for the first-line treatment of metastatic (stage IV) non-small cell lung cancer (NSCLC) in combination with chemotherapy.

Sugemalimab is an anti-PD-L1 antibody in development to treat various cancers. Positive results from the planned interim analysis of the Phase 3 study in stage IV NSCLC (GEMSTONE 302) were reported in August 2020 and updated data were presented in a late-breaking oral presentation at the IASLC 2021 World Conference on Lung Cancer, showing that sugemalimab plus chemotherapy continued to demonstrate improvement in progression-free survival (PFS) than seen in the interim analysis. CStone reported in May 2021 that the Phase 3 study evaluating sugemalimab in stage III NSCLC (GEMSTONE-301) met its primary endpoint of prolonged PFS in a planned interim analysis. On September 2, CStone announced that the NMPA accepted the NDA of sugemalimab for consolidation therapy in patients with unresectable stage III NSCLC who have not progressed after concurrent or sequential radiotherapy and chemotherapy.

In addition to NSCLC, sugemalimab is being investigated in a Phase 2 registrational study for relapsed or refractory extranodal natural killer/T-cell lymphoma (R/R ENKTL) and in Phase 3 registrational studies for gastric cancer and esophageal cancer. Sugemalimab has received breakthrough therapy designation from both the U.S. Food and Drug Administration and Center for Drug Evaluation (CDE) of China's NMPA for the treatment of adult patients with R/R ENKTL.

"Today's NMPA approval is an important milestone for CStone and their robust sugemalimab development program," said John Higgins, CEO of Ligand Pharmaceuticals. "This approval comes just months after the first regulatory approval for an OmniAb-derived medicine and further highlights the transformative year for OmniAb as our partners' late-

stage pipelines continue to advance. We believe OmniAb's broad use and differentiated technology will drive continued favorable clinical and regulatory events in the coming years."

### **About sugemalimab**

Sugemalimab (Cejemly) is an investigational anti-PD-L1 monoclonal antibody developed by CStone and discovered using the OmniRat® transgenic animal platform, which can generate fully human antibodies. As a fully human, full-length anti-PD-L1 monoclonal antibody, Cejemly mirrors the natural G-type immunoglobulin 4 (IgG4) human antibody, which may reduce the risk of immunogenicity and potential toxicities in patients.

In the planned interim analysis of the Phase 3 GEMSTONE 302 study for the first-line treatment of patients with stage IV NSCLC, sugemalimab in combination with chemotherapy met the primary endpoint and significantly prolonged progression-free survival (PFS) and reduced the risk of disease progression or death by 50% [95% CI: 0.39, 0.64],  $p < 0.0001$ . Updated data of the GEMSTONE-302 study showed that the risk of disease progression or death was reduced by 52%, and an encouraging trend in overall survival (OS) was observed. The investigator-assessed PFS was 9.0 months vs 4.9 months [HR=0.48 (95% CI: 0.39, 0.60,  $p < 0.0001$ )] and the median OS was 22.8 months vs 17.7 months, HR=0.67, although the OS events had not yet met the pre-defined interim analysis plan. Sugemalimab plus chemotherapy had a well-tolerated safety profile, and no new safety signals were observed.

In the planned interim analysis of the GEMSTONE-301 study in stage III NSCLC, the independent data monitoring committee assessed that it reached the preset primary study endpoint. The results of the trial showed that sugemalimab as a consolidation treatment significantly improved PFS assessed by the blinded independent center review, and the difference was statistically significant and clinically significant. The PFS results assessed by the investigator were consistent with the primary study endpoint. Sugemalimab was well-tolerated with no new safety signals. Subgroup analysis showed that both patients who received concurrent or sequential radiotherapy and chemotherapy before the trial showed clinical benefit. On September 2, 2021, CStone announced that the NMPA accepted the NDA of sugemalimab for stage III NSCLC.

Currently, sugemalimab is being investigated in several ongoing clinical trials, including a Phase 2 registration study for R/R ENKTL and four Phase 3 registrational studies in Stage III NSCLC, Stage IV NSCLC, gastric cancer and esophageal cancer.

### **About OmniAb®**

The OmniAb discovery platform provides Ligand's pharmaceutical industry partners access to the diverse antibody repertoires and high-throughput screening technologies to enable discovery of next-generation therapeutics. At the heart of the OmniAb platform is the Biological Intelligence (BI) of our proprietary transgenic animals, including OmniRat, OmniChicken and OmniMouse that have been genetically modified to generate antibodies with human sequences to facilitate development of human therapeutic candidates. OmniFlic (transgenic rat) and OmniClic (transgenic chicken) address industry needs for bispecific antibody applications through a common light chain approach, and OmniTaur features unique structural attributes of cow antibodies for complex targets. OmniAb animals comprise the most diverse host systems available in the industry and they are optimally leveraged

through computational antigen design and immunization methods, paired with high-throughput microfluidic-based single B cell screening and deep computational analysis of next-generation sequencing datasets to identify fully human antibodies with superior performance and developability characteristics. An established core competency focused on ion channels and transporters further differentiates our technology and creates opportunities to further leverage across modalities, including antibody-drug conjugates and others. The OmniAb suite of technologies and differentiating computational capabilities and BI features are combined to offer a highly efficient and customizable end-to-end solution for the growing discovery needs of the global pharmaceutical industry.

### **About CStone Pharmaceuticals**

CStone Pharmaceuticals is a biopharmaceutical company focused on researching, developing and commercializing innovative immuno-oncology and precision medicines to address the unmet medical needs of cancer patients in China and worldwide. Established in 2015, CStone has assembled a world-class management team with extensive experience in innovative drug development, clinical research and commercialization. The company has built an oncology-focused pipeline of 15 drug candidates with a strategic emphasis on immuno-oncology combination therapies. CStone's vision is to become globally recognized as a world-renowned biopharmaceutical company by bringing innovative oncology therapies to cancer patients worldwide. For more information, please visit [www.cstonepharma.com](http://www.cstonepharma.com).

### **About Ligand**

Ligand is a biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines. Our business model creates value for stockholders by providing a diversified portfolio of biotech and pharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure. Our goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable, diversified and lower-risk business than a typical biotech company. Our business model is based on doing what we do best: drug discovery, early-stage drug development, product reformulation and partnering. We partner with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) ultimately to generate our revenue. Ligand's OmniAb<sup>®</sup> technology platform is a patent-protected transgenic animal platform used in the discovery of fully human monoclonal and bispecific therapeutic antibodies. The Captisol platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand's Pelican Expression Technology is a robust, validated, cost-effective and scalable platform for recombinant protein production that is especially well-suited for complex, large-scale protein production where traditional systems are not. Ligand has established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Amgen, Merck, Pfizer, Sanofi, Janssen, Takeda, Servier, Gilead Sciences and Baxter International. For more information, please visit [www.ligand.com](http://www.ligand.com).

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### **Forward-Looking Statements**

This news release contains forward-looking statements by Ligand that involve risks and

uncertainties and reflect Ligand's judgment as of the date of this release. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding the potential benefits of the OmniAb platform and the potential for further clinical development and commercialization of OmniAb-derived therapeutic candidates. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: Ligand and its partners may not be able to timely or successfully advance any product(s) in its internal or partnered pipeline; development of product candidates by Ligand partners may not be successful; Ligand may not be able to create future revenues and cash flows by developing innovative therapeutics; products under development by Ligand or its partners may not receive regulatory approval; there may not be a market for the product(s) even if successfully developed and approved; Ligand or its partners may not be able to protect their intellectual property and patents covering certain products and technologies may be challenged or invalidated; Ligand's partners may terminate one or more of its agreements or development for commercialization of products; Ligand may not generate expected revenues under its existing license agreements; Ligand and its partners may experience delays in the commencement, enrollment, completion or analysis of clinical testing for its product candidates, or significant issues regarding the adequacy of its clinical trial designs or the execution of its clinical trials, which could result in increased costs and delays, or limit Ligand's ability to obtain regulatory approval; unexpected adverse side effects or inadequate therapeutic efficacy of Ligand's product(s) could delay or prevent regulatory approval or commercialization; Ligand may not be able to successfully implement its strategic growth plan and continue the development of its proprietary programs; and ongoing or future litigation could expose Ligand to significant liabilities and have a material adverse effect on the company. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Additional information concerning these and other risk factors affecting Ligand can be found in prior press releases available at [www.ligand.com](http://www.ligand.com) as well as in Ligand's public periodic filings with the Securities and Exchange Commission available at [www.sec.gov](http://www.sec.gov). Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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