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# Ligand Announces Clinical and Regulatory Progress by Multiple Partners with OmniAb® Antibodies

*Two large pharma partners reach clinical-development milestones with OmniAb-derived antibody programs and Ligand earns $4.5 million in milestone payments*

*CStone Pharmaceuticals announces China NDA submission and data for its OmniAb-derived antibody to treat non-small cell lung cancer in a first-line setting*

SAN DIEGO--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** announces clinical and regulatory progress by multiple partners utilizing antibodies from its OmniAb® discovery platform. Two large multinational pharmaceutical companies with a license to OmniAb have reached clinical-development milestones with their programs. The progress by these companies resulted in a total of $4.5 million in milestone payments being earned by Ligand.

In addition, CStone Pharmaceuticals recently announced that China's National Medical Products Administration has accepted for review CStone's New Drug Application (NDA) for sugemalimab (CS1001), an OmniAb-derived anti-PD-L1 monoclonal antibody used in combination with chemotherapy for the first-line treatment of advanced squamous and non-squamous non-small cell lung cancer (NSCLC). This marks the first regulatory submission by CStone for sugemalimab. Last month, CStone announced a major financial and commercial partnership with Pfizer to commercialize sugemalimab in greater China. Ligand is entitled to a 3% royalty on worldwide commercial sales of sugemalimab.

CStone also announced that positive clinical data based on a pre-planned interim analysis of the GEMSTONE-302 clinical study were disclosed in an oral presentation at European Society for Medical Oncology (ESMO) Asia Virtual Congress 2020 on November 21, 2020 (link to full release here). The GEMSTONE-302 trial is the first randomized, double-blind, Phase 3 study of an anti-PD-L1 monoclonal antibody plus platinum-based chemotherapy as first-line treatment for stage IV squamous or non-squamous NSCLC. The results showed sugemalimab plus chemotherapy as first-line treatment for advanced NSCLC demonstrated statistically significant and clinically meaningful benefit in progression free survival (PFS) compared to chemotherapy across PD-L1 expression levels and histologies. Specifically, sugemalimab in combination with chemotherapy reduced the risk of disease progression or death by 50% and produced an objective response rate (ORR) of 61.4%. The combination therapy was well-tolerated with no new safety signals detected. CStone reported that these Phase 3 data are amongst the best of those reported by other anti-PD-L1 monoclonal antibodies.

"We are very pleased with the progress and impressive data our partners are reporting with

their Ligand OmniAb-derived antibodies," said John Higgins, Chief Executive Officer of Ligand. "There are currently more OmniAb programs than ever under development, and as programs advance Ligand is now collecting more and larger milestone payments that are contributing to our strong financial performance. Next year we anticipate the first two OmniAb-derived antibodies could receive regulatory approvals, and these events could start the first OmniAb royalty revenue to Ligand. With partnership and royalty rights on programs that extend to 2040 and beyond, we believe we are in the early days of a substantial growth trajectory from our OmniAb business."

**About OmniAb®**

OmniAb is a three-species transgenic-animal platform consisting of five different technologies used for producing mono- and bispecific human therapeutic antibodies. OmniRat® animals comprise the industry's first human monoclonal antibody technology based on rats. Because they have a complete immune system with a diverse antibody repertoire, OmniRat animals generate antibodies with human idiotypes as effectively as wild-type animals make rat antibodies. OmniMouse® is a transgenic mouse that complements OmniRat and expands epitope coverage. OmniFlic® is an engineered rat with a fixed light chain for development of bispecific, fully human antibodies. OmniChicken animals comprise the industry's first human monoclonal antibody technology based on chickens. The OmniClic chicken is specifically developed to facilitate the generation of bispecific antibodies and retains the ability to generate diverse, high quality affinity matured antibodies. All five types of OmniAb therapeutic human antibody platform, OmniRat, OmniFlic, OmniMouse, OmniChicken® and OmniClic®, use patented technology, have broad freedom to operate, produce highly diversified, fully human antibody repertoires optimized in vivo for immunogenicity, manufacturability, and therapeutic efficacy, and deliver fully human antibodies with high affinity, specificity, expression, solubility and stability - Naturally Optimized Human Antibodies®.

**About Ligand Pharmaceuticals**

Ligand is a revenue-generating biopharmaceutical company focused on developing or acquiring technologies that help pharmaceutical companies discover and develop medicines. Ligand's 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. Ligand's 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. Ligand's business model is based on doing what Ligand does best: drug discovery, early-stage drug development, product reformulation and partnering. Ligand partners with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) to ultimately generate our revenue. Ligand's OmniAb® technology platform is a patent-protected transgenic animal platform used in the discovery of fully human mono- 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 Protein Expression Technology® is a robust, validated, cost-effective and scalable approach to recombinant protein production, and is especially well-suited for complex, large-scale protein production that cannot be made by more traditional systems. Ab Initio™ technology and

services for the design and preparation of customized antigens enable the successful discovery of therapeutic antibodies against difficult-to-access cellular targets. Ligand has established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Amgen, Merck, Pfizer, Sanofi, Janssen, Takeda, Gilead Sciences and Baxter International. For more information, please visit www.ligand.com.

Follow Ligand on Twitter @Ligand_LGND.

**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. These forward-looking statements include, without limitation, statements regarding: the potential that Ligand will collect more and larger milestone payments from its OmniAb programs; Ligand's expectations regarding its future financial performance including the potential growth from its OmniAb business; the potential that any OmniAb-derived antibodies will receive regulatory approval or whether Ligand will receive any OmniAb royalty revenue thereafter; the amount of time that Ligand will benefit from its partnership and royalty rights; and the potential that CS1001 could be approved to treat lung cancer patients. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: regulatory authorities such as China's National Medical Products Administration or the FDA may not agree with CStone's interpretation of the results from the Phase 3 clinical trial; CS1001 may not be approved for lung cancer or any other indication and Ligand may not receive any additional payments or royalties from the development of CS1001; Ligand may not generate expected revenues under its existing OmniAb license agreements; Ligand's partners may terminate any of its agreements or development or commercialization of any of its products; the OmniAb platform faces specific risks, including the fact that no product using antibodies from the platform has been approved by the FDA or similar regulatory agency; unexpected adverse side effects or inadequate therapeutic efficacy of Ligand's or Ligand's partners' product(s) could delay or prevent regulatory approval or commercialization; and other risks described in Ligand's prior press releases and filings with the SEC. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Ligand disclaims any intent or obligation to update these forward-looking statements after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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