

# Ligand's Partner Gloria Biosciences Receives Approval in China for Zimberelimab for the Treatment of Recurrent or Refractory Classical Hodgkin's Lymphoma

*First regulatory approval of an OmniAb-derived antibody*

EMERYVILLE, Calif.--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** today announced that its partner Gloria Biosciences (GloriaBio) has received approval from China's National Medical Products Administration (NMPA) for zimberelimab (GLS-010), an OmniAb-derived anti-PD-1 monoclonal antibody for the treatment of recurrent or refractory classical Hodgkin's lymphoma (cHL). GloriaBio has development and commercialization rights in China with respect to zimberelimab through a sublicense agreement with Ligand's licensee Wuxi Biologics Ireland Limited.

Zimberelimab is a fully human monoclonal antibody that belongs to a class of immunoncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an important role in the downregulation of the immune system by preventing the activation of T cells. Other anti-PD-1 antibodies have been approved by the U.S. FDA in multiple cancer types. In addition to cHL, GloriaBio is investigating zimberelimab in advanced solid tumors and in March 2021 was granted Breakthrough Therapy Designation for the treatment of patients with recurrent or metastatic cervical cancer in China. Zimberelimab is being developed by Arcus Bioscience in North America, Europe, Japan and certain other territories through a 2017 license agreement.

"We are delighted to see GloriaBio's progress with zimberelimab including receipt of NMPA approval. When we acquired the OmniAb technology in 2016, there were no OmniAb-derived antibodies in the clinic. GloriaBio's approval just five years after our acquisition and just four years after they entered the clinic is truly impressive," said John Higgins, CEO Ligand Pharmaceuticals. "Approval of this OmniAb-derived antibody represents the first of many regulatory events we expect over the coming years from what we believe is the industry's best-in-class antibody discovery engine. Indeed, this is our biggest year ever for regulatory approvals for our partnered products."

## **About Zimberelimab**

Zimberelimab is a fully human monoclonal antibody that binds to PD-1, restoring the antitumor activity of T cells. GloriaBio contracted with Ligand's partner WuXi Biologics to discover and develop GLS-010 using Ligand's transgenic rat platform, OmniRat®. WuXi and GloriaBio subsequently out-licensed zimberelimab rights to Arcus, excluding China and

certain other territories. Arcus, in collaboration with Gilead Sciences, is conducting multiple Phase 1 and Phase 2 trials to evaluate the safety and tolerability of zimberelimab in subjects with prostate, colorectal, non-small cell lung (NSCLC), pancreatic, triple-negative breast and renal cell cancers. A Phase 3 trial was initiated in 2021 to evaluate zimberelimab monotherapy or in combination with Arcus' anti-TIGIT antibody (AB154) in patients with PD-L1-positive locally advanced or metastatic NSCLC.

In a Phase 2 study in Chinese patients with relapsed and refractory cHL zimberelimab showed impressive preliminary efficacy and a manageable safety profile, with an overall response rate of 90.6%, a 6-month progression-free survival rate of 88.2% and treatment-related adverse events (TRAEs) of mostly grade 1-2; most immune-related adverse events were grade 1-2 and did not limit treatment.<sup>1</sup> In a Phase 2 study in Chinese patients with recurrent or metastatic cervical cancer zimberelimab also showed TRAEs of mostly grade 1-2.<sup>2</sup> Zimberelimab also demonstrated encouraging therapeutic activity and manageable safety profile in Chinese patients with relapsed or refractory cHL and recurrent or metastatic cervical cancer, and could be a new safe and effective treatment option. GloriaBio has received approval in China for zimberelimab for the treatment of recurrent or refractory cHL. Under the terms of Ligand's agreement with WuXi, Ligand is entitled to royalties on future product sales.

### **About OmniAb®**

The OmniAb antibody discovery platform provides Ligand's biopharmaceutical partners access to the world's most advanced antibody repertoires and screening technologies to enable unparalleled discovery of next-generation therapeutics. At the heart of the OmniAb platform is the Biological Intelligence™ (BI) of proprietary transgenic animals, including OmniRat, OmniChicken and OmniMouse, each capable of generating high-quality, fully human antibodies that have been naturally optimized through *in vivo* affinity maturation. 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 are optimally leveraged through AI-enhanced 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. The OmniAb suite of technologies and differentiating AI and BI features are combined to offer a highly efficient and customizable end-to-end solution for the growing antibody discovery needs of the global biopharmaceutical industry.

### **About Gloria Biosciences**

GloriaBio is an innovative biopharmaceutical company founded in 2016 that brings together a professional pharmaceutical development and management team with an international perspective. GloriaBio adheres to the core values of transparency and cooperation with a global vision, focusing on the development, production and sales of oncology drugs. After five years of development work, GloriaBio's first commercial drug, zimberelimab injection, was first approved for the treatment of relapsed or refractory cHL with an overall response rate of 91.67%, and will provide long-term survival benefits for patients. Zimberelimab is a

novel fully human anti-PD-1 monoclonal antibody developed based on an international advanced antibody research and development platform. The mission of GloriaBio is to develop cutting-edge biopharmaceutical products, improve the availability of medications and reduce the burden of medications, following ICH and GxP guidelines, integratedly using an extensively certified advanced technology platform and the GMP-compliant biopharmaceutical production lines while cooperating with domestic and foreign partners. GloriaBio is dedicated to the development of science-based and patient-oriented tumor immunotherapy products and to the mission of building a healthy China by providing more innovative, safe and effective solutions. For additional information, please visit [www.gloriabio.com](http://www.gloriabio.com).

## **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 affairs and commercialization) to ultimately generate revenue. Ligand's OmniAb<sup>®</sup> technology platform is a patent-protected technology stack used in the discovery of fully human mono- and bispecific therapeutic antibodies. The Captisol<sup>®</sup> 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<sup>™</sup> 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 traditional systems. Ligand has established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Amgen, Merck, Pfizer, Roche, Jazz Pharmaceuticals, Sanofi, Janssen, Takeda, Gilead Sciences, GSK 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: timing and amount of royalties on future product sales of zimberelimab payable pursuant to Ligand's license agreement with Wuxi; the potential development of zimberelimab by Arcus Biosciences; the potential for additional regulatory approvals we expect from the OmniAb platform; and the intellectual property protections with respect to Ligand's technologies. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: Ligand is dependent on Wuxi to

pay royalties owed on sales in China by GloriaBio; GloriaBio may not generate net sales to generate royalties payable to Wuxi and in turn to Ligand; and other risks described in Ligand's prior press releases and 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.

## References

1. Song Y, Zhu J, Lin N, et al. GLS-010, a novel anti-PD-1 mAb in Chinese patients with relapsed or refractory classical Hodgkin lymphoma: preliminary impressive results of a Phase II clinical trial. Presented at the 62<sup>nd</sup> ASH Annual Meeting & Exposition, December 5, 2020.
2. Wu X, Xia L, Zhou Q, et al. GLS-010 (Zimberelimab), a novel fully human anti-PD-1 mAb in Chinese patients with recurrent/metastatic cervical cancer: results from a multicenter, open-label, single-arm phase II trial. Presented at the 2020 IGCS Annual Global Meeting, September 10, 2020.

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