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# Ligand's Captisol Technology Plays Key Role in the Manufacture of Gilead's Veklury, the First FDA-Approved COVID-19 Treatment

SAN DIEGO--(BUSINESS WIRE)-- **Ligand Pharmaceuticals Incorporated (NASDAQ: LGND)** today highlighted the company's role in the manufacturing of Veklury® (remdesivir), Gilead Sciences' antiviral drug for the treatment of patients with COVID-19 requiring hospitalization. Veklury is formulated with Ligand's Captisol® technology. Approved yesterday by the U.S. Food and Drug Administration, Veklury is the first and only approved COVID-19 treatment in the United States. The drug is now widely available in hospitals across the country, following Gilead's early investments to rapidly expand manufacturing capacity to increase supply.

"We congratulate Gilead on achieving this regulatory milestone," said John Higgins, Chief Executive Officer of Ligand. "Veklury is an important medicine that has already played a vital role in the treatment of many patients with COVID-19 worldwide. In early January Gilead contacted Ligand requesting urgent shipments of Captisol. Over the following weeks and months, the Captisol volume requirements and supply needs expanded significantly, and Ligand has been there to support Gilead in their effort to manufacture millions of treatment courses. While the progression of the pandemic was and still is unknown, Ligand made the strategic and ethical decision to invest significantly in scale-up to ensure we had sufficient capacity to meet the Captisol supply needs for Gilead and members of its international manufacturing consortium. It has been an intense nine months executing on these efforts. We are proud of our contribution to this first and only U.S.-approved treatment for COVID-19, and we are equally proud of our ability to execute so efficiently and smoothly to answer the call."

Higgins continued, "As the number of people with COVID-19 continues to increase in most states and many countries around the world, we believe Ligand is well positioned to meet higher levels of demand for Captisol. Supplying Captisol for remdesivir will continue to be a top priority for the company; however, we remain focused on executing on our strong and highly diversified core business. As described during our recent Analyst & Investor Day, Ligand is positioned for accelerated growth independent of any contribution from remdesivir."

## About Veklury®

Veklury (remdesivir) is a nucleotide analog invented by Gilead, building on more than a decade of the company's antiviral research. Veklury has broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens, including Ebola, SARS, Marburg, MERS and SARS-CoV-2, the virus that causes COVID-19.

Veklury has been approved or authorized for temporary use as a COVID-19 treatment in approximately 50 countries worldwide. In our continuing commitment to develop effective treatments for COVID-19, multiple ongoing international Phase 3 clinical trials are evaluating the safety and efficacy of Veklury for the treatment of COVID-19, in different patient populations, formulations, and in combination with other therapies.

As announced on October 1, 2020, Gilead is now meeting real-time demand for Veklury in the United States and anticipates meeting global demand for Veklury in October, even in the event of potential future surges of COVID-19.

### **About Captisol®**

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella, University Distinguished Professor at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled several FDA-approved products, including Gilead's VEKLURY®, Amgen's KYPROLIS®, Baxter International's NEXTERONE®, Acrotech Biopharma L.L.C.'s and CASI Pharmaceuticals' EVOMELA®, Melinta Therapeutics' BAXDELA™ and Sage Therapeutics' ZULRESSO™. There are many Captisol-enabled products currently in various stages of development. Ligand maintains a broad global patent portfolio for Captisol with more than 400 issued patents worldwide relating to the technology (including 37 in the U.S.) and with the latest expiration date in 2033. Other patent applications covering methods of making Captisol, if issued, extend to 2040.

### **About Ligand**

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. The Pfenex 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. The Vernalis Design Platform (VDP) integrates protein structure determination and engineering, fragment screening and molecular modeling, with medicinal chemistry, to help enable success in novel drug discovery programs against highly challenging targets. 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](http://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. 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: Ligand's ability to supply Captisol to Gilead and other partners, including Ligand's ability to increase supply capacity; and Ligand's belief it is positioned for accelerated growth independent of any contribution from remdesivir. Actual events or results may differ from Ligand's expectations due to risks and uncertainties inherent in Ligand's business, including, without limitation: Ligand may not receive expected revenue from Captisol sales from remdesivir or otherwise; the COVID-19 pandemic has disrupted Ligand's and its partners' business, including delaying manufacturing, preclinical studies and clinical trials and product sales, and impairing global economic activity, all of which could materially and adversely impact Ligand's results of operations and financial condition; remdesivir may be later shown to not be effective or safe for the treatment of COVID-19 and could materially and adversely affect the commercial opportunity for remdesivir; alternative COVID-19 therapies or vaccines may be approved or the risk of coronavirus infection could significantly diminish, any of which could materially and adversely affect the commercial opportunity for remdesivir; Gilead may terminate the supply agreement without cause upon 30 days' prior written notice; Ligand is currently dependent on Hovione as a single source sole supplier for certain Captisol manufacturing functions and failures by such supplier may result in delays or inability to meet the Captisol demands of its partners; Ligand or its Captisol partners may not be able to protect their intellectual property and patents covering certain products and technologies may be challenged or invalidated; Ligand's Captisol partners may terminate agreements or development or commercialization of products and other risk factors described in Ligand's 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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