Ligand CEO Issues Letter to Captisol Customers

SAN DIEGO--(BUSINESS WIRE)-- Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) announces that Chief Executive Officer John Higgins issued a letter to Ligand’s Captisol® customers. The full text of that letter is as follows:

To Our Valued Captisol Customers,

Ligand is in a period of momentous planning and scale-up. As you may know, Captisol is a key ingredient in Gilead Sciences’ antiviral remdesivir, which is being developed as a treatment for COVID-19. This drug has received an unprecedented amount of attention. I want to update you as to where Ligand stands in fulfilling our commitment to all our Captisol customers and discuss our plans to increase manufacturing capacity. On behalf of the entire team at Ligand, I want you to know we are dedicated to fulfilling your Captisol needs with the highest level of service, reliability and quality.

We are proud that our technology helps make important drugs possible. Over the years Ligand has provided Captisol to more than a thousand organizations for an array of medical uses. Captisol is used in the formulation of novel antibiotics and antifungals. It is in drugs to treat a life-threatening cancer, potentially fatal cardiac events and post-partum depression. And now it plays a role in the fight against COVID-19.

Captisol is an engineered mixture of sulfo-butyl-ether cyclodextrins (SBECD) that is complex to manufacture, especially under proprietary and reproducible large-scale GMP processes. We continue investing in technology innovation and in expanding our Captisol Drug Master Files, our safety database and our manufacturing network. We provide the highest-quality pharmaceutical-grade SBECD in the world, at a consistency and quantity that are unmatched.

In January 2020 Gilead informed us they needed Captisol for remdesivir as a potential treatment for COVID-19. That outreach was a natural development as we have had a relationship with Gilead for several years beginning when this drug was being tested for Ebola. We were witnessing the novel coronavirus emerge as a real threat to public health, and as it became clear the virus was not going to be contained and the global health crisis became a pandemic, we anticipated Captisol demand was going to increase substantially. We immediately began coordination on the necessary planning for production needs as initial orders for Captisol were received and steadily grew.

Clinical work with remdesivir in COVID-19 has been promising as studies indicate the drug reduces the length of hospital stay and may lower the mortality rate in patients with severe disease. On May 1 remdesivir received an Emergency Use Authorization from the U.S. Food and Drug Administration and became the first new drug authorized as a treatment for COVID-19. The medical need was obvious, immense and growing. Then on June 1, Gilead
announced additional data in patients with moderate disease showing again that remdesivir has the potential to meaningfully benefit patients.

We are working closely with Gilead to meet the urgent need for supply of this medicine. In light of Gilead’s public statements, we expect their Captisol requirements will increase significantly over the next couple of years, and we expect orders beyond that.

To meet global demand quickly, Gilead is establishing a consortium of generic pharmaceutical companies around the world to manufacture remdesivir. We have established initial agreements with four of those companies and are prepared to fill the full production and supply needs for all companies producing remdesivir.

Over the past five years, on average Ligand has supplied about 20 metric tons (MT) of Captisol per year, and we have reserved manufacturing capacity for at least 60 MT. Given the expected growth in demand, and to ensure our ability to meet all partners’ needs for the full range of products that utilize Captisol, we plan to deploy up to $60 million over the next year to increase our production capacity to as much as 500 MT per year.

Preparing to manufacture and deliver Captisol at this level is a major undertaking. Supporting our plan will require ordering new specialized equipment, securing raw material supplies, increasing our staffing and expanding certain manufacturing steps to additional facilities. While this is a classic scale-up operation, there is also complexity involved in manufacturing Captisol given the ultra-high purity requirements and the significant amounts of purified water and specialized equipment required. We have the experience and financial resources to do it.

We are humbled to play a part in all the critical medicines made possible by Captisol, including remdesivir. And we are proud of our R&D heritage with initial Captisol innovation from internationally recognized pharmaceutical chemists at the University of Kansas, and of our continued investment and innovation in the technology.

This investment in our future is also an investment in your future. Whether a customer measures their Captisol order in grams or in metric tons, we will meet your needs while supporting Gilead. None of this would be possible without our valued network of partners, and I want to acknowledge their outstanding work and also thank you, our customers, for the contributions you are making to global health.

Sincerely,

John Higgins
Chief Executive Officer
Ligand Pharmaceuticals Incorporated

June 1, 2020

About Ligand Pharmaceuticals

Ligand is a revenue-generating 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) 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 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.

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Forward-Looking Statements

This letter contains forward-looking statements that involve risks and uncertainties and reflect Ligand’s judgment as of the date of this release. Words such as “plans,” “believes,” “expects,” and “will” are intended to identify forward-looking statements. These forward-looking statements include statements regarding: Ligand’s ability to supply Captisol and its plans to scale up production of Captisol to meet projected supply requirements of its partners; and the possibility that remdesivir will be further commercialized. Actual events or results may differ from Ligand's expectations due to risks and uncertainties, including: Ligand may be unable to scale-up the supply of Captisol or at acceptable prices; Ligand is currently dependent on a multi-source sole supplier for Captisol and failures by such supplier may result in delays or inability to meet the Captisol demands of its partners; remdesivir may be later shown not to be effective or safe for the treatment of COVID-19 and/or one or more regulatory agencies may revoke its Emergency Use Authorization for remdesivir; and Ligand may not recover its investment if Captisol orders do not meet Ligand's projections. The failure to meet expectations with respect to any of these matters may reduce Ligand's stock price. Additional information concerning these and other risk factors affecting Ligand can be found in prior press releases as well as in Ligand's public periodic filings with the Securities and Exchange Commission. 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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