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Ligand to Advance Clinical Development of Captisol-enabled(R), Propylene Glycol-Free Melphalan for Multiple Myeloma

Product has Potential to Offer Important Advantages Over Current IV Melphalan

SAN DIEGO-- Ligand Pharmaceuticals Incorporated (NASDAQ:LGND) today announced that it has made the strategic decision to internally advance development of its Captisol-enabled melphalan program with the current goal to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by mid-2013 if the development is successful.

Ligand's Captisol-enabled melphalan program, which has been granted Orphan Drug status by the FDA as a conditioning treatment for use in autologous transplant for patients with multiple myeloma, is a new IV formulation of melphalan (currently sold as Alkeran(R) for Injection) that has the potential to offer multiple advantages for clinicians and patients in the multiple myeloma transplant setting. Ligand's formulation completely avoids the use of propylene glycol, which has been used as a co-solvent in other formulations and has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of the Captisol(R) technology to reformulate melphalan is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to safely achieve a higher dose intensity of pre-transplant chemotherapy.

Ligand expects to report the full results of an ongoing Phase II study in the fourth quarter of 2011. A pivotal study is targeted to begin by early 2012 and is currently designed to enroll approximately 60 patients. Ligand currently anticipates the planned timing of study completion to allow for a mid-2013 NDA submission. Ligand plans to pursue a 505(b)(2) NDA application process.

"The decisions to advance development and pursue a regulatory submission path were based on Ligand's analysis of the interim PII data recently presented at the 2011 American Society of Clinical Oncology Annual Meeting, the product profile and market opportunity for this program," said John Higgins, President and Chief Executive Officer of Ligand. "The recent transactions for the Captisol-enabled products Nexterone(R) with Baxter and clopidogrel with The Medicines Company have illuminated the potential for these types of opportunities. The projected return on investment for 505(b)(2) programs make this a great strategic fit with the financial growth story we are building here at Ligand."

Recent ASCO Data Release

Ligand presented interim Phase II data at the 2011 American Society of Clinical Oncology Annual Meeting on June 6, 2011 in a poster presentation. The key findings presented on the

poster included:

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--  All patients achieved myeloablation followed by successful engraftment.
--  Except for expected grade 2-3 toxicities related to high-dose melphalan,
    no additional toxicities were reported.
--  PK analyses revealed that the new propylene glycol-free melphalan met
    the requirements for bioequivalence to Alkeran.
--  Captisol-enabled melphalan demonstrated a marginally greater melphalan
    systemic exposure (~110%) than was realized from Alkeran.
--  Based on these preliminary results from the Phase II trial, the
    follow-on pivotal study will utilize a dosing regimen that appears to be
    comparable to Alkeran. This study will be designed to expose patients
    exclusively to the propylene glycol-free formulation and will further
    establish safety and efficacy measures for the new product.
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About Melphalan

Melphalan HCl for injection (propylene glycol-free), a reformulation of Alkeran for injection, incorporates the Captisol brand of b-cyclodextrin sulfobutyl ethers, sodium salts (also known as [SBE]7m-b-CD) into a freeze-dried product developed by CyDex Pharmaceuticals, Inc. This product is reconstituted and further diluted with normal saline at the time of use. Captisol improves stability, allowing for longer administration durations, slower infusion rates and potentially enabling safe administration of higher doses of melphalan. This may lead to better therapeutic outcomes, which may also permit reaching a wider patient population and use in a number of other lymphoma and leukemia populations that indicate autologous stem cell transplantation as a treatment modality.

About Captisol

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. This unique technology was originally developed by Ligand's subsidiary CyDex Pharmaceuticals and has enabled five FDA-approved products, including Pfizer's VFEND(R) IV and Prism Pharmaceuticals' NEXTERONE(R). There are currently more than 20 Captisol-enabled(R) products in development, including Onyx pharmaceuticals' carfilzomib program.

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company with a business model of developing or acquiring royalty revenue-generating assets and coupling them to a lean corporate cost structure to produce sustained profitability. By diversifying the portfolio of assets across numerous technology types, therapeutic areas, drug targets and industry partners, we offer an opportunity to invest in the increasingly complicated and unpredictable pharmaceutical industry. In comparison to its industry peers, we believe Ligand has assembled one of the largest and most diversified asset portfolios in the industry with significant revenue-generating potential. These therapies address the unmet medical needs of patients for a broad spectrum of diseases including hepatitis C, muscle wasting, Alzheimer's disease, dyslipidemia, diabetes, anemia, COPD, asthma, rheumatoid arthritis and osteoporosis. Ligand has established alliances with several of the world's leading pharmaceutical companies including GlaxoSmithKline, The Medicines Company, Pfizer, Bristol-Myers Squibb and AstraZeneca. For more information, please visit www.ligand.com. Follow Ligand

on Twitter @Ligand_LGND.

Caution Regarding 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 statements include those related to clinical trials of Captisol-enabled Melphalan's profile, market size and possibility of commercial success, efficacy, potency, competitiveness, and the strength of Ligand's product portfolio. Actual events or results may differ from our expectations. For example, there can be no assurance that Captisol-enabled Melphalan or other potential Captisol-enabled drugs will progress through clinical development or receive required regulatory approvals within the expected time lines or at all, that further clinical trials will confirm any safety or other characteristics or profile described in this press release, that there will be a market of any size for Captisol-enabled Melphalan, or that Captisol-enabled Melphalan will be beneficial to patients or successfully marketed. Additional information concerning these and other risk factors affecting Ligand can be found in prior press releases as well as in public periodic filings with the Securities and Exchange Commission, available via www.ligand.com. 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.

Source: Ligand Pharmaceuticals Incorporated