Ligand Receives Orphan Designation for Captisol-Enabled™ Topiramate Injection

SAN DIEGO-- Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) announced that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation for its proprietary Captisol-enabled™ Topiramate Injection for the treatment of partial onset or primary generalized tonic-clonic seizures in hospitalized epilepsy patients who are unable to take oral topiramate.

“The granting of orphan designation for Ligand’s Captisol-enabled Topiramate program is an important step in the future of this potentially life-saving therapeutic, and should provide an additional layer of market exclusivity for the program,” commented Matthew W. Foehr, Executive Vice President and Chief Operating Officer of Ligand. “In Phase 1 trials in healthy volunteers and patients at the University of Minnesota, this product demonstrated a faster onset of action than the orally administered drug. Our goal is to find a committed partner to further progress the clinical development of this asset and add to our portfolio of fully-funded programs.”

“An injectable formulation of Topiramate will provide patients and clinicians with an important new product that ensures continuity of therapy and offers the potential for use in acute management of several neurological disorders,” declared Jim Cloyd, Pharm.D., Lawrence C. Weaver Endowed Chair in Orphan Drug Development, Professor of Experimental and Clinical Pharmacology and Director of the Center for Orphan Drug Research at the University of Minnesota-College of Pharmacy.

Orphan-drug designation is granted to drugs and biologics defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

About Captisol-Enabled™ Topiramate Injection

Ligand is developing a proprietary Captisol-enabled formulation of Topiramate injection for the treatment of partial onset or primary generalized tonic-clonic seizures in hospitalized epilepsy patients who are unable to take oral topiramate. The formulation was initially developed at, and is exclusively licensed from, the University of Minnesota. Topiramate is sold by Janssen Pharmaceuticals, Inc. under the trade name Topamax® and is currently only available as oral formulations. The Captisol-enabled Topiramate Injection formulation is designed to provide an intravenous or intramuscular option for hospitalized epilepsy patients unable to use oral topiramate. Captisol-enabled Topiramate Injection has been studied in Phase 1 clinical trials.
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 at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled six FDA-approved products, including Onyx Pharmaceuticals' Kyprolis®, Baxter International's Nexterone® and Pfizer's Vfend® IV. There are currently more than 30 Captisol-enabled products in development, including Lundbeck’s carbamazepine IV, The Medicines Company's MDCO-157 and Rib-X's delafloxacin IV program.

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company that develops and acquires assets it believes will generate royalty revenues and, under its lean corporate cost structure, produce sustainable profitability. Ligand has a diverse asset portfolio addressing the unmet medical needs of patients for a broad spectrum of diseases including thrombocytopenia, multiple myeloma, diabetes, hepatitis, muscle wasting, dyslipidemia, anemia and osteoporosis. Ligand's Captisol platform technology is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand has established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, Onyx Pharmaceuticals, Merck, Pfizer, Baxter International, Bristol-Myers Squibb, Lundbeck Inc., Eli Lilly & Co., Spectrum Pharmaceuticals and The Medicines Company. Please visit www.captisol.com for more information on Captisol and www.ligand.com for more information on Ligand.

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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. These include statements regarding clinical development of Captisol-enabled Topiramate Injection, 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 Topiramate Injection will progress through clinical development or receive required regulatory approvals within the expected timelines or at all, that further clinical trials will confirm any safety or other characteristics or profile, that there will be a market of any size for Captisol-enabled Topiramate Injection or that Captisol-enabled Topiramate Injection will be beneficial to patients or successfully marketed. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Ligand's stock price. Additional information concerning these and other risk factors affecting Ligand's business can be found in prior press releases available via www.ligand.com as well as in Ligand's public periodic filings with the Securities and Exchange Commission at 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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