

Ligand Partner GlaxoSmithKline Receives FDA Approval for New Indication for PROMACTA® (eltrombopag)

First supportive care treatment approved for patients with thrombocytopenia with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy

SAN DIEGO-- Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) partner GlaxoSmithKline (NYSE: GSK) announced today that the U.S. Food and Drug Administration (FDA) has approved PROMACTA for the treatment of thrombocytopenia (low blood platelet counts) in patients with chronic hepatitis C to allow them to initiate and maintain interferon-based therapy. PROMACTA is the first supportive care treatment available to patients who are ineligible or poor candidates for interferon-based therapy due to their low blood platelet counts. PROMACTA in combination with interferon-based therapy has been shown to improve a patient's chance of achieving a sustained virologic response (SVR) or viral cure.

There are limitations to the use of PROMACTA in patients suffering from chronic hepatitis C-associated thrombocytopenia. These include:

- PROMACTA should not be used in an attempt to normalize platelet counts;
- PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon therapy or limits the ability to maintain optimal interferon-based therapy; and
- Safety and efficacy have not been established in combination with direct-acting antiviral agents approved for treatment of chronic hepatitis C genotype 1 infection.

"This is a tremendous achievement for this field of medicine. Otherwise very sick patients, who had little to no therapeutic options, will now have an opportunity to potentially receive treatment for hepatitis C. We commend GSK's PROMACTA team, and particularly Drs. Arning, Amado and Paoletti, for their leadership and commitment to driving PROMACTA to this regulatory success," commented John Higgins, President and Chief Executive Officer of Ligand Pharmaceuticals. "We are extremely pleased with the decision by the FDA, and look forward to the near-term launch of PROMACTA for this important new indication."

The approval for PROMACTA is based on results from ENABLE 1 and 2 (Eltrombopag to INitiate and Maintain Interferon Antiviral Treatment to Benefit Subjects with Hepatitis C related Liver Disease), two Phase III randomized, double-blind, placebo-controlled, multicenter studies, which collectively enrolled 1,521 patients with platelet counts <75,000/ μ L. ENABLE 1 utilized peginterferon alfa-2a (PEGASYS®) plus ribavirin for antiviral treatment and ENABLE 2 utilized peginterferon alfa-2b (PEGINTRON®) plus ribavirin.

Important Safety Information for PROMACTA

BOXED WARNING

PROMACTA may cause hepatotoxicity. PROMACTA, in combination with interferon and ribavirin in patients with chronic hepatitis C, may increase the risk of hepatic decompensation. Patients receiving therapy with PROMACTA must have regular monitoring of serum liver tests (see Laboratory Monitoring). Discontinue PROMACTA if ALT levels increase to $\geq 3X$ upper limit of normal (ULN) in patients with normal liver function or $\geq 3X$ baseline in patients with pre-treatment elevations in transaminases and are: progressive; or persistent for ≥ 4 weeks; or accompanied by increased direct bilirubin; or accompanied by clinical symptoms of liver injury or evidence of hepatic decompensation. Reinitiating treatment with PROMACTA is not recommended and should be considered only with close medical supervision and under exceptional circumstances where the potential benefit outweighs the risk.

Additional Safety Information Regarding Risk of Hepatotoxicity:

Reinitiating treatment with PROMACTA is not recommended. If the potential benefit for reinitiating treatment with PROMACTA is considered to outweigh the risk for hepatotoxicity, then cautiously reintroduce PROMACTA and measure serum liver tests weekly during the dose adjustment phase. If liver test abnormalities persist, worsen or recur, then permanently discontinue PROMACTA.

Hepatic Decompensation:

Chronic hepatitis C patients with cirrhosis may be at risk of hepatic decompensation and death when treated with alfa interferons. Monitor patients with low albumin levels or with MELD score ≥ 10 at baseline.

Thrombotic/Thromboembolic Complications:

Thrombotic/thromboembolic complications may result from increases in platelet counts with PROMACTA. Reported thrombotic/thromboembolic complications included both venous and arterial events and were observed at low and at normal platelet counts. Consider the potential for an increased risk of thromboembolism when administering PROMACTA to patients with known risk factors for thromboembolism. To minimize the risk for thrombotic/thromboembolic complications, do not use PROMACTA in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain target platelet counts.

In 2 controlled clinical trials in patients with chronic hepatitis C and thrombocytopenia, 3% (31/955) treated with PROMACTA experienced a thrombotic event compared to 1% (5/484) on placebo. The majority of events were of the portal venous system (1% in patients treated with PROMACTA versus $<1\%$ for placebo).

In a controlled trial in non-ITP thrombocytopenic patients with chronic liver disease undergoing elective invasive procedures (N=292), seven thrombotic complications (six patients) were reported within the group that received PROMACTA and three thrombotic complications (two patients) within the placebo group. All of the thrombotic complications reported in the group that received PROMACTA were portal vein thrombosis, with thrombotic

complications occurring in five of the six patients at a platelet count above $200 \times 10^9/L$. PROMACTA is not indicated for the treatment of thrombocytopenia in patients with CLD in preparation for invasive procedures.

Drug Interactions:

PROMACTA must not be taken within 4 hours of any medications or products containing polyvalent cations such as antacids, dairy products, and mineral supplements.

Adverse Reactions:

The most common adverse reactions in 2 randomized placebo-controlled clinical trials in thrombocytopenic patients with chronic hepatitis C ($\geq 10\%$ and greater than placebo) for PROMACTA versus placebo were: anemia (40% vs. 35%), pyrexia (30% vs. 24%), fatigue (28% vs. 23%), headache (21% vs. 20%), nausea (19% vs. 14%), diarrhea (19% vs. 11%), decreased appetite (18% vs. 14%), influenza-like illness (18% vs. 16%), asthenia (16% vs. 13%), insomnia (16% vs. 15%), cough (15% vs. 12%), pruritus (15% vs. 13%), chills (14% vs. 9%), myalgia (12% vs. 10%), alopecia (10% vs. 6%), and peripheral edema (10% vs. 5%).

PROMACTA has both a BOXED WARNING and Medication Guide. Full US Prescribing Information for physicians and Important Safety Information for consumers will be available soon at <http://www.gsk.com/products/index.htm>.

In the meantime, patients and physicians should visit the FDA Web site, www.fda.gov for important safety information.

About Chronic Hepatitis C Patients and Thrombocytopenia

Approximately 4.2 million people in the U.S. have chronic hepatitis C, the most common blood-borne virus. It is estimated that up to 3.5% of these patients have platelet counts $< 75,000/\mu L$, which could make them ineligible to start or maintain their interferon-based therapy.

About PROMACTA[®] (eltrombopag)

Eltrombopag, marketed under the brand names PROMACTA[®] in the U.S. and Revolade[®] in Europe and Rest-of-World, is a thrombopoietin receptor agonist approved in 90 countries around the world as a treatment for thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP).

In the United States, PROMACTA[®] is already indicated for the treatment of thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

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, Merck, Pfizer, Eli Lilly & Company, Baxter International, Bristol-Myers Squibb, Celgene, Onyx Pharmaceuticals, Lundbeck Inc., and The Medicines Company, among others. Please visit www.captisol.com for more information on Captisol. For more information on Ligand, please visit www.ligand.com.

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Forward-Looking Statements

This news release contains certain 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 the potential launch of and commercial sales of PROMACTA (eltrombopag). Actual events or results may differ from Ligand's expectations. There can be no assurance GlaxoSmithKline, or any of our other partners will continue clinical development of any compound(s); that clinical development will be successful; that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack of negative impacts; that drugs will receive required regulatory approvals or that they will be commercially successful therapies, provide new options or be successfully marketed; that our partner portfolio will continue to mature, that our business will continue to grow or that shareholder value will increase, that the FDA will accept any filing, that any future milestone or royalty payments will be received, or that if any future milestones or royalties are received that they will not be subject to sharing obligations with any third party. The failure to meet expectations with respect to any of the foregoing matters may reduce 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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