

LIGAND PHARMACEUTICALS INC
Form 425
December 21, 2009

Filed by: Ligand Pharmaceuticals Incorporated

Pursuant to Rule 425 under the Securities Act of 1933

and deemed filed pursuant to Rule 14a-12 under the

Securities Exchange Act of 1934

Subject Company: Ligand Pharmaceuticals Incorporated

Exchange Act File No. 001-33093

Contacts:

Ligand Pharmaceuticals Incorporated
John L. Higgins, President and CEO or
Erika Luib, Investor Relations
(858) 550-7896

Lippert/Heilshorn & Associates
Don Markley
dmarkley@lhai.com
(310) 691-7100

Ligand Announces Positive Regulatory Opinion in Europe For Revolade

for Chronic Immune Thrombocytopenic Purpura

SAN DIEGO (December 18, 2009) Ligand Pharmaceuticals Incorporated (NASDAQ: LGND) today announced that its partner GlaxoSmithKline (NYSE: GSK) has received a positive opinion for Revolade® (eltrombopag/Promacta)® from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for the oral treatment of thrombocytopenia (reduced platelet count) in adults with the blood disorder chronic immune (idiopathic) thrombocytopenic purpura (ITP).

The CHMP has recommended the marketing authorization of eltrombopag in the European Union for the treatment of ITP in adult patients who have had their spleen removed, and who do not respond to other treatments, such as corticosteroids and immunoglobulins therapies. Eltrombopag may also be considered as a second-line treatment for adult patients where surgery to remove their spleen is contraindicated.

Approval in Europe presents an expanded market opportunity for eltrombopag and is an exciting development for Ligand as it continues to validate Ligand's success in contributing to the discovery of novel and important commercial therapies, said John L. Higgins, President and Chief Executive Officer of Ligand Pharmaceuticals. Eltrombopag enjoys in excess of 10 years remaining patent life in both the U.S. and Europe and the European approval of Revolade expands the commercial potential for the drug. We commend GSK for their clinical and regulatory successes and commitment to developing eltrombopag for other indications.

ITP patients experience bruising and bleeding and, in some cases, serious hemorrhages, which can be fatal. ITP may also affect a patient's quality of life, as it is often associated with fatigue and depression¹ and a fear of bleeding may limit everyday activities.² Traditional treatments with corticosteroids, immunoglobulins or splenectomy (removal of the spleen) all have potential drawbacks for chronic treatment of ITP patients.^{5, 6, 7}

Eltrombopag significantly increases platelet counts

The positive opinion from CHMP is based on two Phase III randomized, double-blind, placebo-controlled clinical trials (TRA100773B⁸ and RAISE TRA102537⁹) and two open-label studies (REPEAT TRA108057¹⁰ and EXTEND TRA105325¹¹) in adults who have previously received treatment for chronic ITP. The studies showed that the patients treated with eltrombopag (plus the standard of care) experienced significant increases in platelet counts, a reduction in the incidence of bleeding and an improvement in quality of life, compared with those receiving placebo (plus the standard of care)^{8,9,11}. Eltrombopag treatment has also allowed patients to reduce the dose of their concomitant medications, such as steroids.⁹

In clinical trials, eltrombopag was well-tolerated.^{8,12} In some cases, nausea and vomiting were recorded in the eltrombopag group and not in the placebo group.⁸ Elevation of liver enzymes was also seen, but these were mostly mild, reversible and not accompanied by any clinically significant symptoms that would indicate impaired liver function.⁸

Eltrombopag is the first oral platelet generator

Eltrombopag is an oral, non-peptide, thrombopoietin receptor agonist. It stimulates the proliferation and differentiation of megakaryocytes, resulting in an increase in platelet counts. Megakaryocytes are the bone marrow cells that give rise to blood platelets.¹³

About eltrombopag

Eltrombopag was given accelerated approval by the U.S. Food and Drug Administration (FDA) under the trade name Promacta[®] in November 2008, for the treatment of chronic ITP in adults who have had an insufficient response to corticosteroids, immunoglobulins or surgical removal of the spleen. Eltrombopag is also approved under the trade name Revolade[®] in Venezuela, Kuwait, Chile and Russia. In addition, orphan designation was granted by the European Commission for eltrombopag for the treatment of ITP on August 3, 2007.¹⁴ Eltrombopag was discovered as a result of a research collaboration between GSK and Ligand Pharmaceuticals (NASDAQ: LGND), and developed by GSK.

About chronic ITP

Chronic ITP is a serious condition, where patients have low platelet levels in the blood. Platelets are essential to normal clotting, so patients with ITP are at increased risk of bleeding, and may develop bruises and experience nose or gum bleeds, have blood in the urine or faeces, abnormally heavy menstrual bleeding, or other types of bleeding that is difficult to stop.¹⁴ Although very rare in occurrence, bleeding in the brain is potentially fatal.¹⁵ Quality of life is adversely affected in patients with chronic ITP, with a fear of bleeding limiting patients' daily activities.² Fatigue and depression are, also, often associated with the disease.¹

Revolade[®] and Promacta[®] are registered trade marks of the GlaxoSmithKline group of companies. Information based on GSK's press release.

About Ligand Pharmaceuticals

Ligand discovers and develops new drugs that address critical unmet medical needs of patients with muscle wasting, frailty, hormone-related diseases, osteoporosis, inflammatory diseases, anemia, asthma, rheumatoid arthritis and psoriasis. Ligand's

proprietary drug discovery and development programs are based on advanced cell-based assays, gene-expression tools, ultra-high throughput screening and one of the world's largest combinatorial chemical libraries. Ligand has strategic alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, Celgene, Cephalon, GlaxoSmithKline, Merck and Pfizer. With more than 20 molecules in various stages of development, Ligand utilizes proprietary technologies for identifying drugs with novel receptor and enzyme drug targets.

References

1. Platelet Disorder Support Association (PDSA): About ITP. <http://www.pdsa.org/itp-information/index.html> Accessed November 2009.
2. Mathias SD, Gao SK, Miller KL, et al. Impact of chronic immune thrombocytopenic purpura (ITP) on health-related quality of life: a conceptual model starting with the patient perspective. *Health Qual Life Outcomes* 2008; 6:13.
3. National Heart, Lung, and Blood Institute: Diseases and Conditions Index. http://www.nhlbi.nih.gov/health/dci/Diseases/Itp/ITP_WhatIs.html. Accessed May 2009.
4. Cines DB, McMillan R. Management of Adult Idiopathic Thrombocytopenic Purpura. *Annu Rev Med*, 2004;56:425-52
5. Stasi R, Provan D. Management of Immune Thrombocytopenic Purpura in Adults. *Mayo Clin Proc*. 2004;79:504-522
6. McMillan R, Durette C. Long-term outcomes in adults with chronic ITP after splenectomy failure. *Blood*. 2004;104: 956-960
7. Bussel JB, Eldor A, Kelton JG, et al. IGIV-C, a novel intravenous immunoglobulin: evaluation of safety, efficacy, mechanisms of action, and impact on quality of life. *Thromb Haemost*. 2004; 91:771-8
8. Bussel JB, Provan D, Shamsi T, et al. Effect of eltrombopag on platelet counts and bleeding during treatment of chronic idiopathic thrombocytopenic purpura: a randomised, double-blind, placebo-controlled trial. *Lancet* 2009;373:641-8.
9. Cheng G, Saleh M, Bussel J, et al. Oral eltrombopag for the long-term treatment of patients with chronic idiopathic thrombocytopenic purpura: results of a Phase III, double-blind, placebo-controlled study (RAISE). *Blood* 2008;112:400. [ASH Annual Meeting Abstracts].
10. Psaila B, Bussel J, Vasey S, et al. Efficacy and safety of repeated intermittent treatment with eltrombopag in patients with chronic ITP. Abstract 0294 presented at the 13th congress of the European Haematology Association, June 2008.
11. Saleh M, Bussel JB, Cheng G, et al. Eltrombopag is efficacious in patients with refractory chronic idiopathic thrombocytopenic purpura (ITP) - data from the EXTEND Study. *Blood* 2008; 112:401 [ASH Annual Meeting Abstracts].
12. Bussel JB, Cheng G, Saleh MN, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. *N Engl J Med* 2007;357:2237-47.

13. Erickson-Miller CL, Delorme E, Tian SS, et al. Preclinical activity of eltrombopag (SB-497115), an oral, nonpeptide thrombopoietin receptor agonist. *Stem Cells* 2009; 27:424-30.
14. EMEA. Committee for Orphan Medicinal Products. Public summary of positive opinion for orphan designation of eltrombopag olamine for the treatment of idiopathic thrombocytopenic purpura, 2009:1-4.
15. National Heart, Lung, and Blood Institute: Diseases and Conditions Index.
http://www.nhlbi.nih.gov/health/dci/Diseases/Itp/ITP_WhatIs.html. Accessed November 2009.

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 forward-looking statements include comments regarding eltrombopag and other drug candidates, data analysis and evaluation of eltrombopag, utility or potential benefits to patients, the potential commercial market for eltrombopag and plans for continued development and further studies of eltrombopag. Actual events or results may differ from Ligand's expectations. For example, there can be no assurance that other trials or evaluations of eltrombopag or other product candidates will be favorable or that they will confirm results of previous studies, that data evaluation will be completed or demonstrate any hypothesis or endpoint, that eltrombopag or other product candidates will provide utility or benefits to certain patients, that any presentations will be favorably received, that eltrombopag or other product candidates will be useful, that marketing applications will be filed or, if filed, approved, or that clinical or commercial development of these product candidates will be initiated, completed or successful or that our rights to eltrombopag and other related product candidates will not be successfully challenged. 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 can be found in prior press releases available at www.ligand.com as well as in public periodic filings with the Securities and Exchange Commission, available at www.sec.gov. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this press release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

###