November 1, 2018

Rigel to Present Data on Fostamatinib in Three Presentations at the 60th American Society of Hematology Annual Meeting & Exposition

Data related to fostamatinib accepted for oral presentation and two poster presentations

SOUTH SAN FRANCISCO, Calif., Nov. 1, 2018 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), today announced that two-year safety and efficacy data from its FIT Phase 3 extension study (FIT3) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment has been accepted for an oral presentation at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition to be held December 1-4, 2018, in San Diego, CA. Additionally, data from the open-label extension period of the SOAR Phase 2 clinical study in patients with warm antibody autoimmune hemolytic anemia (AIHA) and data from the exploratory analyses of the relationship between anti-platelet antibodies in adult patients with ITP and their response to fostamatinib[1] have been accepted for two separate poster presentations.

Fostamatinib disodium hexahydrate is an oral drug designed to inhibit spleen tyrosine kinase (SYK), a key signaling component of the body's immune process that is believed to lead to platelet destruction in ITP and red blood cell destruction in AIHA. Fostamatinib is commercially available in the U.S. under the brand name TAVALISSE™ (fostamatinib disodium hexahydrate) tablets, which is the first and only SYK inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic ITP who have had an insufficient response to a previous treatment. Fostamatinib[1] is currently being investigated in AIHA, a rare, serious blood disorder in which the immune system produces antibodies that result in the destruction of the body's own red blood cells, and for which there are no approved therapies.

Oral Presentation
Abstract #736
Two-Year Safety and Efficacy Outcomes with Fostamatinib in Adult Patients with Immune Thrombocytopenia (ITP): Open-Label Extension to Phase 3 Trial Program

Session Name: 311. Disorders of Platelet Number or Function: Advances in the Treatment of ITP
Presenter: Anne-Marie Duliege, MD, Executive Vice President and Chief Medical Officer
Date: Monday, December 3, 2018
Presentation Time: 3:30 PM PST
Location: San Diego Convention Center, Room 31B

Poster Presentations

Abstract #3612

Fostamatinib[1], a Spleen Tyrosine Kinase Inhibitor, for the Treatment of Warm Antibody Autoimmune Hemolytic Anemia: Initial Results of the Multicenter, Open-Label Extension Period of the SOAR Phase 2 Study

Session Name: 101. Red Cells and Erythropoiesis, Structure and Function, Metabolism, and Survival, Excluding Iron: Poster III
Date: Monday, December 3, 2018
Presentation Time: 6:00 PM - 8:00 PM PST
Location: San Diego Convention Center, Hall GH

Abstract #3766

Prediction of Response to Fostamatinib based on the Presence of Plasma Platelet Autoantibodies in Adult Patients with Immune Thrombocytopenia (ITP) – Exploratory Analyses from Phase 3 Studies

Session Name: 311. Disorders of Platelet Number or Function: Poster III
Date: Monday, December 3, 2018
Presentation Time: 6:00 PM - 8:00 PM PST
Location: San Diego Convention Center, Hall GH

The conference abstracts can be accessed here.

To learn more about Rigel Pharmaceuticals and TAVALISSE™ visit booth #1449 during ASH 2018.

About ITP

In patients with ITP, the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. Common symptoms of ITP are excessive bruising and bleeding. People suffering with chronic ITP may live with an increased risk of severe bleeding events that can result in serious medical complications or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPOs) and splenectomy. However, not all patients respond to existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About AIHA

Autoimmune hemolytic anemia (AIHA) is a rare, serious blood disorder in which the immune system produces antibodies that result in the destruction of the body's own red blood cells. AIHA affects approximately 40,000 adult patients in the US and can be a severe, debilitating disease. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients.

About TAVALISSE

Indication
TAVALISSE™ (fostamatinib disodium hexahydrate) tablets is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Important Safety Information
Warnings and Precautions

- Hypertension can occur with TAVALISSE treatment. Patients with pre-existing hypertension may be more susceptible to the hypertensive effects. Monitor blood pressure every 2 weeks until stable, then monthly, and adjust or initiate antihypertensive therapy for blood pressure control maintenance during therapy. If increased blood pressure persists, TAVALISSE interruption, reduction, or discontinuation may be required.
- Elevated liver function tests (LFTs), mainly ALT and AST, can occur with TAVALISSE. Monitor LFTs monthly during treatment. If ALT or AST increase to >3 x upper limit of normal, manage hepatotoxicity using TAVALISSE interruption, reduction, or discontinuation.
- Diarrhea occurred in 31% of patients and severe diarrhea occurred in 1% of patients treated with TAVALISSE. Monitor patients for the development of diarrhea and manage using supportive care measures early after the onset of symptoms. If diarrhea becomes severe (≥Grade 3), interrupt, reduce dose or discontinue TAVALISSE.
- Neutropenia occurred in 6% of patients treated with TAVALISSE; febrile neutropenia occurred in 1% of patients. Monitor the ANC monthly and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction, or discontinuation.
- TAVALISSE can cause fetal harm when administered to pregnant women. Advise pregnant women the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Verify pregnancy status prior to initiating TAVALISSE. It is unknown if TAVALISSE or its metabolite is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during TAVALISSE treatment and for at least 1 month after the last dose.

Drug Interactions

- Concomitant use of TAVALISSE with strong CYP3A4 inhibitors increases exposure to the major active metabolite of TAVALISSE (R406), which may increase the risk of adverse reactions. Monitor for toxicities that may require a reduction in TAVALISSE dose.
- It is not recommended to use TAVALISSE with strong CYP3A4 inducers, as concomitant use reduces exposure to R406.
- Concomitant use of TAVALISSE may increase concentrations of some CYP3A4 substrate drugs and may require a dose reduction of the CYP3A4 substrate drug.
- Concomitant use of TAVALISSE may increase concentrations of BCRP substrate drugs (eg, rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (eg, digoxin), which may require a dose reduction of the BCRP and P-gp substrate drug.

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile

neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).
- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Please see www.TAVALISSE.com for full Prescribing Information.

To report side effects of prescription drugs to the FDA, visit www.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

TAVALISSE is a trademark of Rigel Pharmaceuticals, Inc.

About Rigel (www.rigel.com)

Rigel Pharmaceuticals, Inc., is a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with immune and hematologic disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's first FDA approved product is TAVALISSE™ (fostamatinib disodium hexahydrate), an oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Rigel's clinical programs include an upcoming Phase 3 study of fostamatinib[1] in autoimmune hemolytic anemia and an ongoing Phase 1 study of R835[1], a proprietary molecule from its interleukin receptor associated kinase (IRAK) program. In addition, Rigel has product candidates in development with partners BerGenBio AS, Daiichi Sankyo, and Aclaris Therapeutics.

[1] The product for this use or indication is investigational and has not been proven safe or effective by any regulatory authority.

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