June 13, 2019

# Rigel to Present Two Posters Highlighting Fostamatinib at the 24th Congress of the European Hematology Association (EHA)

SOUTH SAN FRANCISCO, June 13, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today announced that it will present data on fostamatinib disodium hexahydrate (fostamatinib) in two posters at the 24th Congress of the European Hematology Association (EHA) in Amsterdam, The Netherlands, on June 13-16, 2019. Data presented will overview long-term safety and efficacy of fostamatinib from the 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. Additionally, Rigel will highlight data from its open-label extension period of the SOAR Phase 2 clinical study in patients with warm antibody autoimmune hemolytic anemia (AIHA). The abstracts are available on the EHA website at www.ehaweb.org/congress.

Fostamatinib 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), 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 a Phase 3 registrational trial in AIHA, a rare, serious blood disorder in which the immune system produces antibodies that result in the destruction of the body's own healthy red blood cells and for which there are currently no approved therapies.

**Poster Presentations**
**Abstract #PF703**
**Title: Long-term Fostamatinib Treatment of Adults with Immune Thrombocytopenia (ITP) During the Phase 3 Clinical Trial Program**
Session Title: Platelets disorders
Date: Friday, June 14
Presentation Time: 5:30 - 7:00 PM CEST
Location: RAI Amsterdam – Amsterdam, Netherlands

**Abstract # PF427**
**Title: Fostamatinib, a Spleen Tyrosine Kinase Inhibitor, for the Treatment of Warm**

**Antibody Autoimmune Hemolytic Anemia: Initial Results of the Open-Label Extension Period of the SOAR Phase 2 Study**
Session Title: Enzymopathies, membranopathies and other anemias
Date: Friday, June 14
Presentation Time: 5:30 - 7:00 PM CEST
Location: RAI Amsterdam – Amsterdam, Netherlands

## 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 are adequately treated with existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

## About AIHA

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 U.S. 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 (e.g., rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (e.g., 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 registered 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), the only 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 a Phase 3 study of TAVALISSE in warm autoimmune hemolytic anemia (AIHA) and a Phase 1 study of R835, a proprietary

molecule from its interleukin receptor associated kinase (IRAK) program. In addition, Rigel has product candidates in clinical development with partners BerGenBio ASA, Daiichi Sankyo, Aclaris Therapeutics, and AstraZeneca.

[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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View original content to download multimedia: http://www.prnewswire.com/news-releases/rigel-to-present-two-posters-highlighting-fostamatinib-at-the-24th-congress-of-the-european-hematology-association-eha-300866982.html

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