

May 29, 2018



## **Rigel Announces Availability of TAVALISSE™ (fostamatinib disodium hexahydrate) in the U.S.**

### **Launches RIGEL ONECARE™ to Support Patients and Providers**

SOUTH SAN FRANCISCO, Calif., May 29, 2018 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), today announced that TAVALISSE™ (fostamatinib disodium hexahydrate) is available by prescription for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. TAVALISSE, an oral spleen tyrosine kinase (SYK) inhibitor that targets the underlying autoimmune cause of the disease by impeding platelet destruction, was approved by the U.S. Food and Drug Administration in April 2018.



"Healthcare providers and adults living with chronic ITP have been in need of a new and different treatment option," said Raul Rodriguez, president and CEO of Rigel Pharmaceuticals. "We're excited to bring TAVALISSE to this patient population, and to have an experienced team in place to answer questions and help patients and providers to start accessing TAVALISSE."

To assist with access to TAVALISSE, Rigel is also introducing RIGEL ONECARE™. This is a comprehensive support center to help patients and physicians navigate through insurance coverage requirements and provide financial assistance when needed, along with other support programs. Every patient will have a personalized Nurse Navigator to assess a patient's individual case.

For more information, visit [www.TAVALISSE.com](http://www.TAVALISSE.com) or contact Rigel ONECARE at 833-RIGELOC (833-744-3562).

Rigel will be at the ASCO Annual Meeting being held June 1-5, 2018 in Chicago, Booth #24160.

To view the TAVALISSE™ approval press release and multimedia assets, please visit: <https://www.multivu.com/players/English/8297951-rigel-pharmaceuticals-ity-tavalisse-fda-approval/>

### **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 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](http://www.TAVALISSE.com) for full Prescribing Information.

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

TAVALISSE and RIGEL ONECARE are trademarks of Rigel Pharmaceuticals, Inc. RIGEL ONECARE is a patient support center sponsored by Rigel Pharmaceuticals, Inc.

## **About Rigel ([www.rigel.com](http://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 current clinical programs include Phase 2 studies of fostamatinib in autoimmune hemolytic anemia and IgA nephropathy. In addition, Rigel has product candidates in development with partners BerGenBio AS, Daiichi Sankyo, and Aclaris Therapeutics.

### **Forward Looking Statements**

*This release contains forward-looking statements relating to, among other things, the availability of TAVALISSE to patients and Rigel's ability to help patients navigate through issues relating to access to TAVALISSE. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "planned," "will," "may," "should," "expect," and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Rigel's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the commercialization of TAVALISSE; risks that the FDA or other regulatory authorities may make adverse decisions regarding TAVALISSE; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the period ended March 31, 2018. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.*

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