April 17, 2018

Rigel Announces FDA Approval of TAVALISSE™ (fostamatinib disodium hexahydrate) for Chronic Immune Thrombocytopenia (ITP) in Adult Patients

TAVALISSE Offers First-in-Class Treatment with Unique Mechanism of Action

U.S. Commercial Launch Expected in Late May 2018

Conference Call and Webcast to be Held Today at 5:00 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., April 17, 2018 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that the U.S. Food and Drug Administration (FDA) approved TAVALISSE™ (fostamatinib disodium hexahydrate) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. TAVALISSE is an oral spleen tyrosine kinase (SYK) inhibitor that targets the underlying autoimmune cause of the disease by impeding platelet destruction, providing an important new treatment option for adult patients with chronic ITP. Rigel plans to launch TAVALISSE in the United States in late May 2018.

To view the multimedia assets associated with this release, please click: https://www.multivu.com/players/English/8297951-rigel-pharmaceuticals-itp-tavalisse-fda-approval/

"Chronic ITP is challenging to treat because the heterogeneity of the disease makes it difficult to predict how an individual patient will respond to available treatments and not all patients can find a treatment that works well for them," said James Bussel, M.D., professor emeritus of pediatrics at Weill Cornell Medicine and the principal study investigator on the FIT Phase 3 program. Dr. Bussel has served as a consultant and paid member of the advisory board for Rigel Pharmaceuticals, Inc. "The FDA approval of fostamatinib arms physicians with a new treatment option, which works via a novel mechanism."

The FDA approval of TAVALISSE was supported by data from the FIT clinical program, which included two randomized placebo-controlled Phase 3 trials (Studies 047 and 048) and

an open-label extension (Study 049), as well as an initial proof of concept study. The New Drug Application (NDA) included data from 163 ITP patients and was supported by a safety database of more than 4,600 subjects across other indications in which fostamatinib has been evaluated.

"People living with chronic ITP often feel they have an invisible disease -- one that can not only impact quality of life, but also be life threatening," said Caroline Kruse, executive director of the Platelet Disorder Support Association, a patient advocacy organization dedicated to ITP patients. "That's why we encourage members of our community to learn about their disease, understand treatment strategies, and seek support so that they can advocate for their best care. The availability of a new treatment option provides the ITP community with more choices."

Different Treatment Approach
TAVALISSE is designed to inhibit SYK, a key signaling component in the body's immune process that can lead to platelet destruction in ITP patients. TAVALISSE may address an underlying autoimmune cause of ITP by impeding platelet destruction.

"We are excited to bring this new medicine to the population of adult patients with chronic ITP in need of additional therapies. I want to thank the patients, caregivers and physicians who contributed to our fostamatinib clinical program, and also the Rigel team for all of their dedication and hard work to bring the company to this historic day," said Raul Rodriguez, president and CEO of Rigel Pharmaceuticals. "This regulatory milestone, our first product approval, validates the therapeutic effect of SYK inhibition in an autoimmune disease."

Rigel will be providing product information at the ASCO Annual Meeting being held June 1-5, 2018 in Chicago, Booth #24160, or you can visit www.TAVALISSE.com.

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 include excessive bruising, bleeding and fatigue. 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 have an adequate treatment response 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 for full Prescribing Information.

To report side effects of prescription drugs to the FDA, visitwww.fda.gov/medwatch

or call 1-800-FDA-1088 (800-332-1088).

Trademarks for TAVALISSE are owned by or licensed by Rigel.

Conference Call and Webcast Today at 5:00PM Eastern Time

Rigel will hold a live conference call and webcast today at 5:00pm Eastern Time (2:00pm Pacific Time).

Participants can access the live conference call by dialing (855) 892-1489 (domestic) or (720) 634-2939 (international) and using the Conference ID number 5189918. The slide presentation accompanying the conference call can be accessed from Rigel's website at www.rigel.com/webcasts. The webcast will be archived and available for replay after the call via the Rigel website.

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 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 U.S. commercial launch of TAVALISSE; the benefits and value to patients of TAVALISSE; Rigel's ability to transition to an organization prepared to launch its first commercial product; Rigel's belief that fostamatinib may be an important alternative for patients with ITP; and the timing and results of Rigel's clinical trials. 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 Annual Report on Form 10-K for the period ended December 31, 2017. 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.

Contact: Raul Rodriguez
Phone: 650.624.1302
Email: ir@rigel.com

Media Contact: Jessica Daitch
Phone: 917.816.6712
Email: jessica.daitch@syneoshealth.com

View original content:http://www.prnewswire.com/news-releases/rigel-announces-fda-approval-of-tavalisse-fostamatinib-disodium-hexahydrate-for-chronic-immune-thrombocytopenia-itp-in-adult-patients-300631702.html

SOURCE Rigel Pharmaceuticals, Inc.