October 29, 2018

Rigel Pharmaceuticals Enters Collaboration and License Agreement with Kissei Pharmaceutical Co., Ltd. to Develop and Commercialize TAVALISSE™ (fostamatinib disodium hexahydrate) in Japan and other Asian Countries

- Kissei gains exclusive rights to fostamatinib in all current and potential indications in Japan and other Asian countries

- Rigel receives an upfront cash payment of $33 million with the potential for up to $147 million in development and commercial milestone payments

- Rigel to receive product transfer price payments in the mid to upper twenty percent range based on tiered net sales for exclusive supply of TAVALISSE

SOUTH SAN FRANCISCO, Calif., Oct. 29, 2018 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today announced that it had entered into an exclusive license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to develop and commercialize TAVALISSE™ in all current and potential indications in Japan, China, Taiwan and the Republic of Korea. Kissei is a Japan-based pharmaceutical company addressing patients' unmet medical needs through its research, development and commercialization efforts, as well as through collaborations with partners. TAVALISSE is commercially available in the U.S. for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

"Kissei is a leading Japanese pharmaceutical company with significant development experience and a track record of commercial success in Asian markets. Their commitment to develop TAVALISSE in ITP, and potential future indications in these territories, makes Kissei

an optimal partner as we seek to expand the global market opportunity for this important new therapeutic," said Raul Rodriguez, president and CEO of Rigel. "This agreement demonstrates our approach to entering strategic markets outside of the U.S. and emphasizes the unmet need that exists for chronic ITP, among other rare blood disorders."

Under the terms of the agreement, Rigel will receive an upfront cash payment of $33 million, with the potential for an additional $147 million in development and commercial milestone payments, and will receive product transfer price payments in the mid to upper twenty percent range based on tiered net sales for the exclusive supply of TAVALISSE. Kissei receives exclusive rights to TAVALISSE in ITP and all future indications in Japan, China, Taiwan, and the Republic of Korea. Rigel retains the global rights, excluding these Asian countries, to develop and commercialize TAVALISSE in ITP and any additional indications.

On May 29, 2018, TAVALISSE was launched for commercial use in the U.S. Kissei will initially seek local country approval for TAVALISSE in ITP and conduct clinical studies as required by the country's Pharmaceuticals and Medical Devices Agency. Japan has the third highest prevalence of chronic ITP in the world behind the U.S. and EU. The EU is another significant market in which Rigel is exploring partnership opportunities.

"Our extensive experience with in-licensed and proprietary therapies provides the infrastructure and expertise needed to successfully commercialize fostamatinib in Japan, and other markets," said Mutsuo Kanzawa, Chairman and CEO of Kissei. "We look forward to working closely with Rigel to demonstrate the value of this medication in addressing the significant unmet medical needs of patients with chronic ITP and other rare blood disorders."

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 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).**

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 in autoimmune hemolytic anemia and an ongoing Phase 1 study of R835, 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.

About Kissei (https://www.kissei.co.jp)

Kissei is a Japanese pharmaceutical company with approximately 70 years of history, specialized in the field of urology, kidney-dialysis and unmet medical needs. Silodosin is a Kissei product for the treatment of the signs and symptoms of benign prostatic hyperplasia which is sold worldwide through its licensees. Kissei aims to develop innovative pharmaceutical products that contribute to the improvement of medicine and the health of people around the world by aggressive incorporation of leading-edge technology and joint research and collaborations with our foreign and domestic partners.

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, the payments that will be received by Rigel under the Collaboration and License Agreement and that ITP will be the first indication pursued under such agreement in Japan. 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," 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; Rigel's partners' ability to obtain marketing approval for fostamatinib; and whether and when any of the milestone payments or product transfer price payments will ever be paid under Rigel's collaboration agreements, 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 June 30, 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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