October 18, 2019

Rigel Receives Positive Trend Vote from CHMP for Fostamatinib Disodium Hexahydrate for Adult Patients with Chronic Immune Thrombocytopenia (ITP) in Europe

SOUTH SAN FRANCISCO, Calif., Oct. 18, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), has adopted a positive trend vote on the Marketing Authorization Application (MAA) for fostamatinib disodium hexahydrate (fostamatinib). The indication for the positive trend vote is for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments.

"During the EMA review process for fostamatinib in adult chronic ITP, we have had very constructive interactions with the committee," said Raul Rodriguez, president and CEO of Rigel. "We are pleased with this positive trend vote from the CHMP this week, which brings us one step closer to potentially providing a new therapeutic option for a patient population that has a clear unmet clinical need."

The CHMP intends to hold a final vote on their recommendation at their November meeting. Pending a formal positive CHMP opinion, the European Commission, which has the authority to approve medicines for use in Europe, would be expected to render their decision approximately 60 days after the opinion is received.

Fostamatinib is commercially available in the U.S. and is the first and only spleen tyrosine kinase (SYK) inhibitor indicated for the treatment of thrombocytopenia in U.S. adult patients with chronic ITP who have had an insufficient response to a previous treatment. Europe is the second largest market for adult chronic ITP treatments after the United States.

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 (Thrombopoietin Receptor Agonists) 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 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 current clinical programs include a Phase 3 study of fostamatinib in autoimmune hemolytic anemia (AIHA) 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 clinical development with partners BerGenBio ASA, Daiichi Sankyo, Aclaris Therapeutics, and AstraZeneca.

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

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, the CHMP opinion and the potential approval and subsequent launch in Europe of fostamatinib for the treatment of chronic ITP, and the timing thereof. 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 "potential," "will," "may," "expect," "intention," 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 and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; 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 quarter ended June 30, 2019. 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: David Burke
Phone: 650.624.1232
Email: dburke@rigel.com

View original content to download multimedia:http://www.prnewswire.com/news-releases/rigel-receives-positive-trend-vote-from-chmp-for-fostamatinib-disodium-hexahydrate-for-adult-patients-with-chronic-immune-thrombocytopenia-itp-in-europe-300941069.html

SOURCE Rigel Pharmaceuticals, Inc.