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Rigel Provides Update on FDA Review of Fostamatinib for ITP

SOUTH SAN FRANCISCO, Calif., Oct. 2, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that during the company's mid-cycle meeting with the U.S. Food and Drug Administration (FDA) the FDA indicated that, at this point, it is not planning to hold an Oncology Drugs Advisory Committee (ODAC) meeting to discuss the New Drug Application (NDA) for fostamatinib in patients with chronic or persistent immune thrombocytopenia (ITP). Additionally, the FDA indicated that it anticipates meeting the Prescription Drug User Fee Act (PDUFA) action date for the application review, which is April 17, 2018. In an earlier communication, the FDA had conditionally approved the proprietary name TavalisseTM.

"Since we submitted our NDA this spring, we have worked collaboratively with the FDA to answer routine questions as they arise," said Anne-Marie Duliege, MD, executive vice president and chief medical officer of Rigel. "Our positive interactions with the FDA, including their customary biomedical monitoring (BIMO) inspections at our facilities and clinical sites, are in-line with our expectations and have progressed well. We will continue to work closely with the agency and remain committed to bringing fostamatinib to patients with ITP who are in need of new treatment options."

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 increased risk of severe bleeding events that can result in serious medical complication, or even death. Currently approved therapies for ITP include steroids, blood platelet production boosters (TPO-RAs) and splenectomy. However, not all patients derive a benefit from 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 hematological disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's current clinical programs include clinical trials of fostamatinib, an oral spleen

tyrosine kinase (SYK) inhibitor, in a number of indications. Rigel has submitted and the FDA has accepted for review, an NDA for fostamatinib in patients with chronic or persistent immune thrombocytopenia (ITP). 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 FDA's indication that it is not planning to hold an ODAC meeting to discuss the NDA for fostamatinib in patients with chronic or persistent ITP, the timing of the FDA's application review of our NDA submission and Rigel's belief that fostamatinib may be an attractive alternative for patients with ITP. 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," "expect," "hope" 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, the FDA may later decide to hold an ODAC meeting; delays in the FDA's review of the submitted NDA by the PDUFA action date; the FDA may interpret Rigel's findings differently, which could result in the FDA not approving any submitted NDA; the availability of resources to develop Rigel's product candidates; Rigel's need for additional capital in the future to sufficiently fund Rigel's operations and research; the uncertain timing of completion of and the success of clinical studies; market competition, risks associated with and Rigel's dependence on Rigel's corporate partnerships; 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, 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: invrel@rigel.com

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



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