

# Rigel to Present One-Year Efficacy and Safety Results for Fostamatinib in ITP at the 2017 American Society of Hematology Annual Meeting

SOUTH SAN FRANCISCO, Calif., Dec. 8, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that the one-year efficacy and safety results from its FIT Phase 3 clinical program of fostamatinib for chronic or persistent immune thrombocytopenia (ITP) will be featured in an oral presentation at the 2017 American Society of Hematology Annual Meeting being held in Atlanta, GA from December 9 to December 12, 2017.

During the presentation, James B. Bussel, M.D., professor emeritus of pediatrics at Weill Cornell Medicine and the principal study investigator on the FIT Phase 3 program who has served as a member of an advisory/scientific board for Rigel Pharmaceuticals, will share an overview of the FIT clinical program.

## **Oral Presentation Details:**

<u>TITLE</u>: Long-Term Maintenance of Platelet Responses in Adult Patients with Persistent/Chronic Immune Thrombocytopenia Treated with Fostamatinib: 1-Year Efficacy and Safety Results

Session Name: 311. Disorders of Platelet Number or Function: ITP: clinical aspects

Session Date: Saturday, December 9, 2017 Session Time: 7:30 AM - 9:00 AM EST Presentation Time: 8:15 AM EST

Location: Georgia World Congress Center, Bldg B, Lvl 3, B304-B305 (Atlanta, GA)

### **About Fostamatinib in ITP**

Fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor, is an investigational drug for adult patients with chronic or persistent immune thrombocytopenia (ITP). The New Drug Application (NDA) for fostamatinib for adult patients with chronic or persistent ITP, which was previously granted Orphan Drug designation, is currently under review by the U.S. Food and Drug Administration with a Prescription Drug User Fee Act (PDUFA) goal date of April 17, 2018. The conditionally approved proprietary name for fostamatinib (as confirmed by the FDA) is TAVALISSE<sup>TM</sup>.

The NDA is supported by data from the FIT Phase 3 clinical program, which was comprised

of three studies, two randomized placebo-controlled studies (Studies 047 and 048) and an open-label extension study (Study 049). Together with an initial proof of concept study, the NDA included 163 ITP patients. Across all indications, fostamatinib has been evaluated in over 4,600 subjects. Data from all studies, including preclinical evaluation and drug manufacturing data, were included in the NDA submission.

## 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. 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 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 timing of enrollment and results of on-going clinical trials and the results of the FDA's review of Rigel's NDA for fostamatinib in patients with chronic or persistent 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," and similar expressions are intended to identify these forward-looking statements. These forwardlooking 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 interpret Rigel's findings differently, which could result in the FDA not approving the 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; 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 September 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.

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