

June 22, 2017



## **Rigel Announces Oral Presentation of TAVALISSE™ (fostamatinib disodium) Phase 3 Clinical Data at the European Hematology Association 22nd Annual Congress**

SOUTH SAN FRANCISCO, Calif., June 22, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that data from its FIT Phase 3 clinical program evaluating the safety and efficacy of TAVALISSE™ (fostamatinib disodium) in patients with chronic or persistent immune thrombocytopenia (ITP) will be presented on Saturday, June 24, 2017, from 12:30 - 12:45pm (CEST) at the European Hematology Association 22<sup>nd</sup> Annual Congress (EHA) in Madrid, Spain. Earlier this week, Rigel announced the FDA has set an expected action date of April 17, 2018, to complete its review of fostamatinib under the Prescription Drug User Fee Act (PDUFA). The FDA previously granted Orphan Drug designation to fostamatinib for the treatment of patients with ITP.

The oral presentation, entitled "Treatment of Primary Adult Chronic Immune Thrombocytopenia (CITP) with Fostamatinib, an Oral SYK Inhibitor: Results of Two Randomized, Placebo-Controlled Phase 3 Studies," is authored by James B. Bussel, M.D., professor of Pediatrics, Pediatrics in Obstetrics and Gynecology, and Pediatrics in Medicine at Weill Cornell Medical College and the principal study investigator on the FIT Phase 3 program, and colleagues.

The details are as follows:

Session Title: Acquired and inherited platelet disorders

Oral Presentation: "Treatment of Primary Adult Chronic Immune Thrombocytopenia (CITP) with Fostamatinib, an Oral SYK Inhibitor: Results of Two Randomized, Placebo-Controlled Phase 3 Studies"

Date: Saturday, June 24, 2017

Time: 12:30 - 12:45pm CEST

Location: IFEMA - Feria de Madrid: Avda. del Partenón, 5, 28042 Madrid, Spain, Room N101

Final Abstract Code: S435

**[About the FIT Phase 3 Clinical Program](#)**

The recently accepted NDA is supported by data from the Phase 3 clinical program for fostamatinib in ITP, 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 (TPO-RAs) 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 TAVALISSE™ (fostamatinib disodium)**

TAVALISSE™ is an oral investigational drug candidate designed to inhibit SYK kinase, a key signaling member in the immune process that leads to platelet destruction in ITP. Unlike other therapies that modulate the immune system in different ways or stimulate platelet production, fostamatinib may address an underlying autoimmune cause of ITP by impeding platelet destruction.

### **About Rigel ([www.rigel.com](http://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 an NDA to the FDA 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 a response from the FDA to our NDA submission. 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 "will," "may," "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, 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; 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 March 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.*

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