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Rigel Announces Tavalisse™ as Proprietary Name for Fostamatinib in the United States

SOUTH SAN FRANCISCO, Calif., April 27, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proprietary name Tavalisse™ for the company's investigational product candidate, fostamatinib disodium, an oral spleen tyrosine kinase (SYK) inhibitor. In addition, Rigel has applied to the U.S. Patent and Trademark Office to obtain federal registration of the Tavalisse mark.

The name Tavalisse (pronounced - ta vah lees') was developed based on the FDA's Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names. Created with the help of experts in this field, the proprietary name development included input from prescribers, pharmacists, linguists and employees to create a unique and approachable name.

Earlier this month, the company announced that it submitted a New Drug Application (NDA) to the FDA for Tavalisse in patients with chronic and persistent immune thrombocytopenia (ITP). The FDA previously granted Orphan Drug designation to Tavalisse for the treatment of patients with ITP.

The NDA is supported by data from the Phase 3 clinical program for Tavalisse 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). In total, 163 ITP patients have been treated with Tavalisse and included in the NDA submission. Across all indications, Tavalisse has been evaluated in over 4,600 subjects.

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, a portion of patients do not derive a benefit from existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About Tavalisse

Tavalisse is an oral investigational drug candidate with a unique mechanism of action designed to inhibit SYK kinase, a key player 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, Tavalisse may address the underlying autoimmune cause of ITP by impeding platelet destruction.

About Rigel (www.rigel.com)

Rigel Pharmaceuticals, Inc. is a clinical-stage biotechnology company dedicated to the discovery and development of novel, targeted drugs in the therapeutic areas of immunology, oncology and immuno-oncology. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's current clinical programs include clinical studies of Tavalisse, an oral spleen tyrosine kinase (SYK) inhibitor, in a number of indications. The company submitted a NDA to the FDA for Tavalisse in patients with chronic and persistent immune thrombocytopenia (ITP) in April 2017. Rigel is also conducting Phase 2 clinical studies with Tavalisse in autoimmune hemolytic anemia (AIHA) and IgA nephropathy (IgAN). In addition, Rigel has two oncology product candidates in development with partners BerGenBio AS and Daiichi Sankyo.

Forward Looking Statements

This release contains forward-looking statements. 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," "potential," 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 not accept the NDA; the FDA may interpret Rigel's findings differently, which could result in the FDA not approving any submitted NDA; risks related to changes in estimated cash position based on the completion of financial closing procedures and the audit of Rigel's financial statements; as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2016. 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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