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Rigel Submits New Drug Application to FDA for Fostamatinib in Chronic ITP

SOUTH SAN FRANCISCO, Calif., April 17, 2017 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for fostamatinib in patients with chronic and persistent immune thrombocytopenia (ITP).

"This NDA submission in support of fostamatinib in ITP is a major milestone in bringing new treatment options to patients suffering from this disease," said Raul Rodriguez, Rigel's president and chief executive officer. "We look forward to working closely with the FDA as they review the submission over the coming months."

The 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). In total, 163 ITP patients have been evaluated and included in the NDA submission. 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. The Company expects to receive notification regarding the acceptance of the NDA by the FDA in June 2017.

The FDA previously granted Orphan Drug designation to fostamatinib for the treatment of patients with ITP.

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 Fostamatinib

Fostamatinib 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, fostamatinib 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 fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor in a number of indications. The company completed and reported results from the Phase 3 clinical program for fostamatinib in chronic immune thrombocytopenia (ITP) in 2016. Rigel is also conducting a Phase 2 clinical study with fostamatinib in autoimmune hemolytic anemia (AIHA) and a Phase 2 clinical study for 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 relating to, among other things, the timing of a response from the FDA to 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," 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; 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; 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/rigel-submits-new-drug-application-to-fda-for-fostamatinib-in-chronic-itp-300440366.html

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