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Rigel Completes Enrollment of First Phase 3 Study of Fostamatinib in ITP (FIT)

SOUTH SAN FRANCISCO, Calif., Jan. 28, 2016 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (NASDAQ: RIGL) today announced that the first of two Phase 3 clinical studies of fostamatinib in immune thrombocytopenic purpura (ITP) completed patient enrollment this month. The results from this first study are expected in the middle of 2016, with the results from the second study expected shortly thereafter.

The FIT program consists of two identical studies of 75 patients each. The patients will have been diagnosed with persistent or chronic ITP, and have blood platelet counts consistently below 30,000 per microliter of blood. Study subjects remain on treatment for 24 weeks. The primary efficacy endpoint of this program is a stable platelet response by week 24 with platelet counts at or above 50,000 per microliter of blood for at least four of the final six qualifying blood draws. For additional information about the FIT studies, visit http://tinyurl.com/RigelPhase3ITP.

Fostamatinib and 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. ITP patients can suffer extraordinary bruising, bleeding and fatigue as a result of low platelet counts. Current therapies for ITP include steroids, blood platelet production boosters (TPOs) and splenectomy. Rigel believes that fostamatinib may address the autoimmune basis of the disease.

The U.S. Food and Drug Administration has granted Orphan Drug designation to fostamatinib for the treatment of patients with ITP. For additional information about ITP, visit http://www.rigel.com/index.php/pipeline/fostamatinib-itp/.

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 fostamatinib, an oral spleen tyrosine kinase (SYK) inhibitor, which is in Phase 3 clinical trials for ITP; a Phase 2 clinical trial for IgA nephropathy (IgAN); and a planned Phase 2 clinical trial for autoimmune hemolytic anemia (AIHA) in 2016. In addition, Rigel has two oncology

product candidates in Phase 1 development with partners BerGenBio AS and Daiichi Sankyo.

This press release contains "forward-looking" statements, including, without limitation, statements related to Rigel's clinical development plans, including the timing, design and nature of planned clinical trials and the timing and nature of results of those trials, as well as the potential activity of fostamatinib with respect to 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 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 trials, 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 September 30, 2015. 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-completes-enrollment-of-first-phase-3-study-of-fostamatinib-in-itp-fit-300211230.html

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