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Rigel Completes Enrollment of FIT Phase 3 Program for Fostamatinib in ITP

SOUTH SAN FRANCISCO, Calif., April 1, 2016 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL) today announced it has completed enrollment for both studies in the FIT Phase 3 clinical program of fostamatinib, its oral spleen tyrosine kinase (SYK) inhibitor, in immune thromboycytopenic purpura (ITP). The first study in this program completed enrollment at the end of January and the second study has now completed enrollment. The results from the first study are expected in the middle of 2016, with the results for the second study expected shortly thereafter.

Earlier this year Rigel initiated a Phase 2 clinical trial in a second autoimmune disorder of the blood, autoimmune hemolytic anemia (AIHA). The purpose of this clinical trial is to evaluate the safety and efficacy of fostamatinib in patients with chronic AIHA. This disorder affects an estimated 40,000 Americans, for whom no approved treatment options currently exist.

FIT Phase 3 Program of Fostamatinib in ITP

The FIT program consists of two identical studies of approximately 75 patients each. The patients 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 up to 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.

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.

Fostamatinib and AIHA

AIHA is a rare, serious blood disorder where the immune system produces antibodies that result in the destruction of the body's own red blood cells. Symptoms can include fatigue, shortness of breath, rapid heartbeat, jaundice or enlarged spleen. While no medical treatments are currently approved for AIHA, physicians generally treat acute and chronic cases of the disorder with corticosteroids, other immuno-suppressants, or splenectomy.

Research has shown that inhibiting SYK with fostamatinib may reduce the destruction of red blood cells.

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 autoimmune hemolytic anemia (AIHA); and a Phase 2 clinical trial for IgA nephropathy (IgAN). 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, 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 Annual Report on Form 10-K for the year ended December 31, 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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