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Rigel Initiates Phase 2 Clinical Trial Of Fostamatinib In Autoimmune Hemolytic Anemia

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2016 /PRNewswire/ -- Rigel Pharmaceuticals Inc. (Nasdaq: RIGL) today announced that it has initiated a Phase 2 clinical trial to evaluate fostamatinib, its oral SYK inhibitor, as a potential treatment for 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.

"This autoimmune hemolytic anemia program represents an exciting opportunity to evaluate fostamatinib in an underserved patient group and build upon the synergies that exist between AIHA and our Phase 3 ITP program," said Raul Rodriguez, president and chief executive officer of Rigel. "We believe fostamatinib, if approved by the FDA for the treatment of AIHA, will be the first marketed treatment for patients with this rare hematological disorder," he added.

Fostamatinib in AIHA Study Design

The trial is a Phase 2 open-label, multi-center, two-stage study that will evaluate the efficacy and safety of fostamatinib in patients with warm antibody AIHA who have previously received treatment for the disorder, but have relapsed.

Stage 1 will enroll 17 patients who will receive 150 mg of fostamatinib orally twice a day for a period of 12 weeks. The patients will return to the clinic every two weeks for blood draws and medical assessment.

The primary efficacy endpoint of this study is to achieve increased hemoglobin levels by week 12 of greater than 10 g/dL, and greater than or equal to 2 g/dL higher than baseline. Rigel expects to have results of the Stage 1 segment of the trial by year-end 2016.

Stage 2 will begin after enrollment in Stage 1 has been completed and will include an additional 20 patients who will receive the same treatment protocol as Stage 1.

Autoimmune Hemolytic Anemia
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 spleen tyrosine kinase (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 Rigel's Phase 2 clinical trial of fostamatinib for AIHA, and the timing and nature of results of its trials. 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 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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