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Rigel Granted Orphan Drug Designation for Fostamatinib in ITP

SOUTH SAN FRANCISCO, Calif., Sept. 8, 2015 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation to Fostamatinib, Rigel's oral spleen tyrosine kinase (SYK) inhibitor which is currently in Phase 3 clinical studies in patients with chronic immune thrombocytopenic purpura (ITP). Rigel's Phase 3 program for Fostamatinib in ITP, called FIT, has surpassed the half-way point in enrollment and Rigel expects the program to read out results in mid-2016.

"Receiving this Orphan Drug designation from the FDA is a positive step forward in the development of Fostamatinib," said Raul Rodriguez, president and chief executive officer of Rigel. "We look forward to completing our Phase 3 program and intend to file a New Drug Application for Fostamatinib in ITP in the U.S.," he added.

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.

Orphan Drug Designation

Orphan Drug designation is granted to compounds that are in development for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. This designation can provide numerous benefits to the companies developing these drugs for these indications, including possibly a market exclusivity period, tax credits, waived FDA fees and research and development grants and others.

About Rigel (www.rigel.com)

Rigel Pharmaceuticals, Inc. is a clinical-stage biotechnology company focused on the discovery and development of novel, small-molecule drugs for the treatment of immune diseases and cancers. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. Rigel currently has the following product candidates in development: Fostamatinib, an oral SYK inhibitor, which is in Phase 3 clinical trials for ITP

and a Phase 2 clinical trial for IgA nephropathy (IgAN); R348, a topical ophthalmic JAK/SYK inhibitor, in a Phase 2 clinical trial for dry eye in ocular graft-versus-host disease (GvHD); two oncology product candidates in Phase 1 development with partners BerGenBio AG and Daiichi Sankyo; and two preclinical programs with partners AstraZeneca, for R256 in asthma, and Bristol-Myers Squibb, for TGF beta inhibitors in immuno-oncology.

This release contains forward-looking statements relating to, among other things, the results of Rigel's Phase 3 clinical studies with Fostamatinib in ITP, the potential filing and timing of filing of a New Drug Application for Fostamatinib and Rigel's product pipeline and development programs. 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 three months ended June 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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