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Rigel Receives Positive CHMP Opinion for Fostamatinib Disodium Hexahydrate for Adult Patients with Chronic Immune Thrombocytopenia (ITP) in Europe

SOUTH SAN FRANCISCO, Calif., Nov. 15, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency, has adopted a positive opinion for Rigel's Marketing Authorization Application (MAA) for fostamatinib disodium hexahydrate (fostamatinib) for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments.

The CHMP reviews medical product applications and provides their opinion to the European Commission (EC), which has the authority to approve medicines for use in Europe. The positive opinion will now be reviewed by the EC, which will issue a decision on the approval of fostamatinib in Europe within approximately 70 days.

"We are extremely encouraged by the CHMP's positive opinion and look forward to the final decision on our MAA from the European Commission," said Raul Rodriguez, Rigel's president and CEO. "We are excited by the potential to provide adult chronic ITP patients in Europe with a new treatment option that addresses the primary cause of their disease. Our European partner, Grifols, is preparing diligently for a prospective commercial launch in 2020."

The CHMP based its opinion on data provided from the FIT Phase 3 clinical program, which included two randomized placebo-controlled trials (FIT1 and FIT2) and an open-label extension trial (FIT3). The MAA included data from 163 ITP patients and was supported by a safety database of more than 4,600 subjects across all other indications in which fostamatinib has been evaluated.

Fostamatinib is commercially available in the U.S. and is the first and only spleen tyrosine kinase (SYK) inhibitor indicated for the treatment of thrombocytopenia in U.S. adult patients with chronic ITP who have had an insufficient response to a previous treatment. Europe is the second largest market for adult chronic ITP treatments after the United States.

About ITP

In patients with ITP (immune thrombocytopenia), 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 an increased risk of severe bleeding events that can result in serious medical complications or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPO-RAs) and splenectomy. However, not all patients are adequately treated with existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About Rigel (www.rigel.com)

Rigel Pharmaceuticals, Inc., is a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with immune and hematologic disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's first FDA approved product is TAVALISSE® (fostamatinib disodium hexahydrate) tablets, the only oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Rigel's current clinical programs include a Phase 3 study of fostamatinib in autoimmune hemolytic anemia (AIHA); a recently completed Phase 1 study of R835, a proprietary molecule from its interleukin receptor associated kinase (IRAK) program; and an ongoing Phase 1 study of R552, a proprietary molecule from its receptor-interacting protein kinase (RIP1) inhibitor program. In addition, Rigel has product candidates in clinical development with partners Aclaris Therapeutics, AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, the CHMP opinion and the potential approval and subsequent 2020 commercial launch in Europe of fostamatinib for the treatment of chronic ITP, and the timing thereof. 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 "potential," "will," "may," "expect," "prospective," 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, risks and uncertainties associated with the commercialization and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; 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, 2019. 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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