March 27, 2025

Rigel Announces Settlement Agreement Resolving TAVALISSE® (fostamatinib disodium hexahydrate) Patent Litigation

SOUTH SAN FRANCISCO, Calif., March 27, 2025 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today announced that it has entered into a settlement agreement with Annora Pharma Private Ltd., Hetero Labs Ltd., and Hetero USA, Inc. (collectively "Annora") resolving patent litigation related to Rigel's product TAVALISSE® (fostamatinib disodium hexahydrate). The litigation resulted from submission by Annora of an Abbreviated New Drug Application to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of TAVALISSE in the United States. Under the terms of the settlement agreement, Annora will have a license to sell its generic product in Q2 2032 or earlier under certain circumstances. In accordance with the agreement, the parties terminated all ongoing litigation between Rigel and Annora regarding TAVALISSE patents pending in New Jersey.

"The resolution of this patent litigation underscores the strength of Rigel's intellectual property protecting TAVALISSE, an innovative treatment for people with immune thrombocytopenia," said Raul Rodriguez, Rigel's president and CEO. "We remain committed to advancing our portfolio of novel therapies with the potential to improve the lives of patients with hematological disorders and cancer, and to continue to develop and enhance our intellectual property portfolio."

About ITP

In patients with immune thrombocytopenia (ITP), 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. Patients 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 respond to existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About TAVALISSE®

TAVALISSE (fostamatinib disodium hexahydrate) tablets is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Please click here for Important Safety Information and Full Prescribing Information for TAVALISSE.

To report side effects of prescription drugs to the FDA,www.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

TAVALISSE is a registered trademark of Rigel Pharmaceuticals, Inc.

About Rigel

Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) is a biotechnology company dedicated to discovering, developing and providing novel therapies that significantly improve the lives of patients with hematologic disorders and cancer. Founded in 1996, Rigel is based in South San Francisco, California. For more information on Rigel, the Company's marketed products and pipeline of potential products, visit www.rigel.com.

Forward Looking Statements

This press release contains forward-looking statements relating to, among other things, expected generic product market entry, the strength of our intellectual property portfolio and our ability to develop and enhance it, TAVALISSE as a treatment for immune thrombocytopenia, and expectations to grow and advance ourcommercial portfolio. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements can be identified by words such as "anticipates", "plan", "potential", "may", "look to", "expects", "will", "initial", "promising", and similar expressions in reference to future periods. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Rigel's current beliefs, expectations, and assumptions and hence they inherently involve significant risks, uncertainties and changes in circumstances that are difficult to predict and many of which are outside of our control. Therefore, you should not rely on any of these forward-looking statements. 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 fostamatinib, olutasidenib and pralsetinib; risks that the FDA, European Medicines Agency, PMDA or other regulatory authorities may make adverse decisions regarding fostamatinib, pralsetinib or olutasidenib; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that fostamatinib, pralsetinib or olutasidenib 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 Annual Report on Form 10-K for the year ended December 31, 2024 and subsequent filings. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. Rigel does not undertake any obligation to update forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise, and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

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