September 3, 2024

Rigel Expands Relationship with Kissei to include REZLIDHIA® (olutasidenib) in Japan, the Republic of Korea and Taiwan

- *Kissei gains exclusive rights to develop and commercialize olutasidenib in all current and potential indications in Japan, the Republic of Korea and Taiwan*
- *Rigel will receive an upfront cash payment of $10.0 million with the potential for up to $152.5 million in future development, regulatory, and commercial milestone payments*
- *Rigel to receive product transfer price payments in the mid-twenty to lower-thirty percent range based on tiered net sales for exclusive supply of REZLIDHIA*

SOUTH SAN FRANCISCO, Calif., Sept. 3, 2024 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today announced it has entered into an exclusive license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to develop and commercialize REZLIDHIA® (olutasidenib) in all current and potential indications in Japan, the Republic of Korea (Korea) and Taiwan. REZLIDHIA is commercially available to patients in the U.S. for the treatment of relapsed or refractory (R/R) mutated isocitrate dehydrogenase-1 (mIDH1) acute myeloid leukemia (AML). Rigel has an existing agreement with Kissei to develop and commercialize TAVALISSE® (fostamatinib disodium hexahydrate) for the treatment of chronic immune thrombocytopenia (ITP) and in all other potential indications in Japan, China, Taiwan and the Republic of Korea.

"Kissei has an excellent track record of development and commercial success with in-licensed products for the Asian market, including with Rigel's TAVALISSE. The approval and launch of TAVALISSE in Japan, combined with the strong relationship we have built with Kissei, made expanding our partnership to include REZLIDHIA a natural next step," said Raul Rodriguez, Rigel's president and CEO. "From our experience, we are confident in Kissei's ability and commitment to bring REZLIDHIA to patients in their territories."

Under the terms of the agreement, Rigel will receive an upfront cash payment of $10.0 million from Kissei, with the potential for up to an additional $152.5 million in development, regulatory and commercial milestone payments. Rigel will receive product transfer price payments in the mid-twenty to lower-thirty percent range based on tiered net sales for the exclusive supply of REZLIDHIA. Kissei receives exclusive rights to REZLIDHIA in AML and all future indications in Japan, Korea and Taiwan. Kissei will initially seek approval for

REZLIDHIA in Japan for R/R mIDH1 AML and will be responsible for conducting clinical studies as required by the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA).

"We are pleased to expand our relationship with Rigel to develop and commercialize olutasidenib in Japan, Korea and Taiwan, leveraging our extensive infrastructure and our expertise in the hematology-oncology space," said Mutsuo Kanzawa, Chairman and CEO of Kissei. "In Japan, there are estimated to be 11,000 AML patients, with a higher incidence than any other subtypes of leukemia. Despite the current treatment options available, there are still clear unmet medical needs in the AML treatment landscape."

Kissei is a Japanese pharmaceutical company with approximately 80 years of history, specialized in the field of urology, kidney-dialysis and unmet medical needs. Kissei aims to develop innovative pharmaceutical products that contribute to the improvement of medicine and the health of people around the world by aggressive incorporation of leading-edge technology and joint research and collaborations with its foreign and domestic partners.

Rigel retains the global rights, excluding these Asian countries, to develop and commercialize REZLIDHIA for all indications, and is currently exploring other ex-US partnership opportunities.

In August 2022, Rigel and Forma Therapeutics, Inc., now Novo Nordisk (Forma), announced an exclusive, worldwide license agreement to develop, manufacture and commercialize REZLIDHIA. Pursuant to the agreement, Forma is entitled to a certain portion of Rigel's sublicensing revenue from olutasidenib.

About AML

Acute myeloid leukemia (AML) is a rapidly progressing cancer of the blood and bone marrow that affects myeloid cells, which normally develop into various types of mature blood cells. AML occurs primarily in adults and accounts for about 1 percent of all adult cancers. The American Cancer Society estimates that there will be about 20,800 new cases in the United States, most in adults, in 2024.[1]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[2] Refractory AML, which affects between 10 and 40 percent of newly diagnosed patients, occurs when a patient fails to achieve remission even after intensive treatment.[3] Quality of life declines for patients with each successive line of treatment for AML, and well-tolerated treatments in relapsed or refractory disease remain an unmet need.

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 respond to existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About REZLIDHIA®
REZLIDHIA is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Please click here for Important Safety Information and Full Prescribing Information, including Boxed WARNING, for REZLIDHIA.

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, visitwww.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

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.

1. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised June 5, 2024. Accessed June 30, 2024: https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html
2. Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3. Reviewed October 2021. Accessed June 30, 2024: https://media.leukaemiacare.org.uk/wp-content/uploads/Relapse-in-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf
3. Thol F, Schlenk RF, Heuser M, Ganser A. *How I treat refractory and early relapsed acute myeloid leukemia*. Blood (2015) 126 (3): 319-27. Accessed June 30, 2024. doi: https://doi.org/10.1182/blood-2014-10-551911

Forward-Looking Statements
This press release contains forward-looking statements relating to, among other things, Rigel's receipt of payments from Kissei under the License Agreement and the Supply Agreement, and the success of Rigel's collaboration with Kissei. 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 "plan", "potential", "may", "look to", "expects", "will", "intends" 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 olutasidenib; risks that the FDA, European Medicines Agency, PMDA or other regulatory authorities may make adverse decisions regarding olutasidenib; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that olutasidenib may have unintended side effects, adverse reactions or incidents of misuses; 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, 2023 and Quarterly Report on Form 10-Q for the quarter ended June 30, 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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