January 13, 2025

Rigel Provides Business Update and 2025 Outlook

- *Preliminary fourth quarter 2024 total revenue of approximately $57.6 million which includes TAVALISSE® net product sales of $31.0 million, REZLIDHIA® net product sales of $7.4 million and GAVRETO® net product sales of $8.1 million*
- *R289 granted Orphan Drug designation by the FDA for the treatment of MDS*
- *Rigel anticipates 2025 total revenue of approximately $200 to $210 million*

SOUTH SAN FRANCISCO, Calif., Jan. 13, 2025 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today provided a business update including preliminary total revenue and net product sales for the fourth quarter of 2024, ongoing activity from the commercial business and development pipeline, and its financial outlook for 2025.

"2024 was a transformational year for Rigel as we successfully executed on our corporate strategy to grow our hematology and oncology focused organization. We generated record sales of both TAVALISSE and REZLIDHIA and welcomed a third product to our commercial portfolio, GAVRETO, which made a substantial contribution to our sales in the latter half of the year. This commercial success, combined with our commitment to financial discipline, enabled Rigel to reach financial breakeven, a key milestone for the company," said Raul Rodriguez, Rigel's president and CEO. "In addition, we advanced our development pipeline, with the Phase 1b study of R289 in lower-risk MDS continuing to enroll patients and publishing promising initial safety and efficacy data. Building on this progress, we will continue to implement effective strategies that further grow and advance our portfolio in 2025, thereby generating significant value for Rigel and our shareholders."

Preliminary 2024 Financial Results and Business Update

Preliminary Financial Results

- While Rigel is still determining final results for the fourth quarter of 2024, the company expects to report fourth quarter total revenue of $57.6 million, compared to $35.8 million for the same period of 2023.
- Rigel expects to report fourth quarter net product sales of $46.5 million, compared to $29.5 million for the same period of 2023, including:
    - TAVALISSE® (fostamatinib disodium hexahydrate) net product sales of $31.0

million compared to $25.7 million for the same period of 2023.

- REZLIDHIA® (olutasidenib) net product sales of $7.4 million compared to $3.9 million for the same period of 2023.
- GAVRETO® (pralsetinib) net product sales of $8.1 million. GAVRETO became commercially available from Rigel in June 2024.
- The following table summarizes total bottles shipped for the fourth quarter:

	TAVALISSE	REZLIDHIA	GAVRETO*
Bottles shipped to patients and clinics	2,855	503	874
Change in bottles remaining in distribution channel	317	62	64
Total bottles shipped	3,172	565	938

*GAVRETO bottle count represents 60-count bottle equivalent

- Contract revenues from collaborations for the fourth quarter of 2024 is expected to be approximately $11.1 million, including a $4.0 million upfront cash payment from Dr. Reddy's Laboratories Ltd. (Dr. Reddy's); $3.6 million of revenue from Grifols S.A. related to delivery of drug supplies and earned royalties; $2.9 million of revenue from Kissei Pharmaceutical Co., Ltd. (Kissei) related to delivery of drug supplies; and $0.3 million of revenue from Medison Pharma Trading AG related to delivery of drug supplies and earned royalties.
- For the full year, Rigel expects to report total revenue of $179.3 million, including net product sales of $144.9 million and contract revenues from collaborations of $34.4 million, compared to total revenue of $116.9 million in 2023, which included net product sales of $104.3 million, contract revenues from collaborations of $11.5 million and government contract revenue of $1.1 million.
- Rigel expects to report cash, cash equivalents, and short-term investments of approximately $77.3 million as of December 31, 2024, compared to $56.9 million as of December 31, 2023.

The above information is preliminary, has not been audited, and is subject to change upon the audit of Rigel's financial statements for the year ended December 31, 2024. Rigel expects to provide complete fourth quarter and full year 2024 financial results in March 2025.

Commercial Update

- TAVALISSE surpassed $100 million in net product sales in 2024, reporting $104.8 million in net product sales.
- Rigel entered into an exclusive license agreement with Dr. Reddy's in November to develop and commercialize REZLIDHIA in all potential indications throughout Dr. Reddy's territory, which includes Latin America, South Africa, certain countries in the Commonwealth of Independent States (CIS), India, certain countries in Southeast Asia and North Africa, Australia and New Zealand. Rigel is entitled to receive an upfront cash payment of $4.0 million with the potential for up to $36.0 million in future regulatory and commercial milestone payments.
- In December, Rigel's partner Knight Therapeutics announced Mexico's Comisión Federal para la Protección contra Riesgos Sanitarios approved TAVALISSE for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Clinical and Development Update

- R289[1], a novel and selective dual IRAK1/4 inhibitor, has been granted Fast Track designation for the treatment of previously-treated transfusion dependent lower-risk MDS and Orphan Drug designation for the treatment of MDS by the U.S. Food and Drug Administration (FDA).
- Rigel continues to advance its Phase 1b clinical study evaluating the safety, tolerability, pharmacokinetics, and preliminary efficacy of R289 in patients with relapsed or refractory (R/R) lower-risk myelodysplastic syndrome (MDS). Enrollment in the fifth dose level (500mg / 250mg split dose) is ongoing.
- Rigel presented initial data from the ongoing Phase 1b clinical study of R289 at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition in December, demonstrating that R289 was generally well tolerated in this heavily pretreated R/R lower-risk MDS patient population, the majority of whom were high transfusion burden (HTB) at baseline.
- In an ad-hoc analysis of the R289 Phase 1b initial data, responding patients (those achieving transfusion independence) appeared to have a greater increase in hemoglobin level over time compared to non-responding patients.
- Also at the ASH Annual Meeting, four posters were presented on olutasidenib, which included data that adds to the growing body of evidence supporting the benefits of its use in patients with m*IDH1* AML.
- As part of a multi-year strategic development alliance, Rigel and The University of Texas MD Anderson Cancer Center (MD Anderson), opened enrollment for two trials in December. The trials are a Phase 2 study in patients with *IDH1*-mutated clonal cytopenia of undetermined significance (CCUS), lower-risk MDS and chronic myelomonocytic leukemia (CMML), and a Phase 1/2 study of olutasidenib maintenance therapy following an allogeneic stem cell transplant for patients with *IDH1*-mutated myeloid malignancies. The Phase 1b/2 triplet therapy trial of decitabine and venetoclax in combination with olutasidenib in patients with m*IDH1* AML is ongoing.
- In December, in a paper titled "Olutasidenib demonstrates significant clinical activity in mutated *IDH1* acute myeloid leukaemia arising from a prior myeloproliferative neoplasm", was published by Stéphane de Botton, M.D., Ph.D., head of translational research in hematology, Institut Gustave Roussy, France, in the *British Journal of Haematology*.
- In November, the National Comprehensive Cancer Network® (NCCN®) added olutasidenib to the latest NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes. Olutasidenib was added as a recommended option to the following treatment algorithms: Management of Lower-Risk Disease, Management of Lower-Risk Disease - Evaluation of Related Anemia and Management of Higher-Risk Disease, and was recommended as NCCN Category 2B in all circumstances. If m*IDH1* positive, olutasidenib was either recommended as a single agent, in combination with azacitidine, or both.*

*NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

2025 Outlook

Rigel anticipates 2025 total revenue of approximately $200 to $210 million, including:

- Net product sales of approximately $185 to $192 million
- Contract revenues from collaborations of approximately $15 to $18 million.

The company anticipates it will report positive net income for the full year 2025, while funding existing and new clinical development programs.

In addition, Rigel plans to initiate a Phase 2 clinical study in recurrent glioma in 2025.

Additional information is included in Rigel's corporate presentation, which can be found in the Investor Relations section of the company's website at www.rigel.com.

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 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.[2]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[3] 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.[4] 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 NSCLC

It is estimated that over 230,000 adults in the U.S. will be diagnosed with lung cancer in 2024. Lung cancer is the leading cause of cancer death in the U.S, with NSCLC being the most common type accounting for 80-85% of all lung cancer diagnoses.[5] RET fusions are implicated in approximately 1-2% of patients with NSCLC.[6]

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.

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 GAVRETO®
GAVRETO is indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).*

*Thyroid indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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

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

TAVALISSE, REZLIDHIA and GAVRETO are registered trademarks 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.

1. R289 is an investigational compound not approved by the FDA.
2. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised June 5, 2024. Accessed January 3, 2025: https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html
3. Leukaemia Care. Relapse in Acute Myeloid Leukaemia (AML). Version 3. Reviewed October 2021. Accessed January 3, 2025: https://media.leukaemiacare.org.uk/wp-content/uploads/Relapse-in-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf
4. 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 January 3, 2025. doi: https://doi.org/10.1182/blood-2014-10-551911
5. The American Cancer Society. Key Statistics for Lung Cancer. Revised January 29, 2024. Accessed January 3, 2025: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html
6. Kato, S. et al. RET Aberrations in Diverse Cancers: Next-Generation Sequencing of 4,871 Patients. Clin Cancer Res. 2017;23(8):1988-1997 doi: 10.1158/1078-0432.CCR-

16-1679

Forward Looking Statements

This press release contains forward-looking statements relating to, among other things, expected commercial and financial results for the fourth quarter and year ended December 31, 2024, projected financial performance and outlook for 2025, expectations to grow and advance our commercial portfolio and hematology and oncology pipeline, results of our study of R289 in lower-risk MDS including safety and efficacy data, continued ability for developing and commercializing TAVALISSE, REZLIDHIA, and GAVRETO domestically and in certain international markets, and expectations for Rigel's partnering and collaboration efforts. 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", "outlook", "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 Quarterly Report on Form 10-Q for the quarter ended September 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.

Contact for Investors & Media:

Investors:
Rigel Pharmaceuticals, Inc.
650.624.1232
ir@rigel.com

Media:
David Rosen
Argot Partners
646.461.6387
david.rosen@argotpartners.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/rigel-provides-business-update-and-2025-outlook-302348874.html

SOURCE Rigel Pharmaceuticals, Inc.