

May 22, 2025



## Rigel Announces Poster Presentations at the 2025 ASCO Annual Meeting and EHA2025 Congress

- *Final data from the GAVRETO<sup>®</sup> (pralsetinib) Phase 1/2 ARROW study in RET fusion-positive NSCLC and other solid tumors*
- *Supportive data for REZLIDHIA<sup>®</sup> (olutasidenib) utilization in patients with mIDH1 R/R AML*

SOUTH SAN FRANCISCO, Calif., May 22, 2025 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today announced seven upcoming poster presentations at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) 2025 Congress. The ASCO Annual Meeting is being held in Chicago, Illinois and virtually from May 30 to June 3, 2025. The EHA2025 Congress is being held in Milan, Italy and virtually from June 12 to June 15, 2025.

Rigel's poster presentations will include data for GAVRETO<sup>®</sup> (pralsetinib) for the treatment of metastatic rearranged during transfection (*RET*) fusion-positive non-small cell lung cancer (NSCLC), including final data from the Phase 1/2 ARROW study, and REZLIDHIA<sup>®</sup> (olutasidenib) for the treatment of relapsed or refractory (R/R) mutated isocitrate dehydrogenase-1 (*mIDH1*) acute myeloid leukemia (AML).

"We look forward to several posters highlighting the strength of our hematology and oncology product portfolio at ASCO and EHA, including the final efficacy and safety data from the Phase 1/2 ARROW study of GAVRETO. The study data continue to demonstrate GAVRETO's clinically meaningful and durable responses in patients with *RET* fusion-positive NSCLC, regardless of prior therapies, with a manageable safety profile. The study also showed promising anti-tumor activity in patients with various *RET* fusion-positive solid tumors, suggesting the potential for GAVRETO to address these unmet needs," said Raul Rodriguez, Rigel's president and CEO. "In addition, the collective data being presented on REZLIDHIA support its duration of response and potential clinical benefit when used in earlier lines of treatment for R/R AML patients and in primary refractory patients who are traditionally difficult to treat."

ASCO Annual Meeting abstracts may be accessed online via <https://www.asco.org/abstracts>.

Details of the poster presentations are as follows:

### **ASCO Poster Presentations**

**Saturday, May 31, 2025, 1:30pm to 4:30pm CT**

**Abstract #:** 8644

**Title:** Efficacy and Safety of Pralsetinib in Patients with Advanced *RET*-fusion-positive NSCLC: Final Data from the Phase 1/2 ARROW Study

**Presenter:** Gilberto de Lima Lopes, M.D., MBA

- Final top-line efficacy and safety in *RET* fusion-positive NSCLC patients produced clinically meaningful and durable responses regardless of prior therapies, with a manageable safety profile. These results support the findings in previously published results, with a longer follow up period.
- Overall response rate (ORR) was 70.3% and median duration of response (DOR) was 19.1 months in the measurable disease population (n=259). In the efficacy population (n=281), median overall survival (OS) was 44.3 months with median follow up of 47.6 months. Median progression-free survival (PFS) was 13.1 months overall but was longer in the United States (25.9 months) vs. Asia (12.6 months) or Europe (12.9 months).

**Sunday, June 1, 2025, 9:00am to 12:00pm CT**

**Abstract #:** 6545

**Title:** A Phase 2 Study of Olutasidenib in Relapsed/Refractory AML: Outcomes by Number of Prior Treatment Regimens

**Presenter:** Eunice S. Wang, M.D.

- A post-hoc analysis of the pivotal cohort from the Phase 1/2 study evaluated outcomes in patients with R/R *m/DH1* AML who received olutasidenib after either 1-2 or  $\geq 3$  prior lines of therapy.
- Patients in the 1-2 prior regimens group showed higher ORR and complete response (CR) / complete response with hematologic improvement (CRh) rates and longer median OS than those with  $\geq 3$  prior lines of therapy, providing a rationale for initiating olutasidenib earlier in the R/R treatment paradigm.

**Abstract #:** 6546

**Title:** Matching-adjusted Indirect Comparison (MAIC) of Olutasidenib and Ivosidenib in *IDH1*-mutated Relapsed/Refractory AML

**Presenter:** Justin M. Watts, M.D.

- In the absence of a head-to-head trial, a matching-adjusted indirect comparison (MAIC) analysis compared relative treatment effects of olutasidenib vs. ivosidenib in *m/DH1* R/R AML, leveraging registrational data for olutasidenib and ivosidenib to match patients using key baseline clinical variables.
- Naïve and adjusted rates of response for olutasidenib vs. ivosidenib were comparable (adjusted point estimate favored olutasidenib for CR and ivosidenib for CR+CRh), while a longer duration of CR+CRh was observed with olutasidenib. Adjusted OS was similar between the two groups, although the hazard ratio (HR) favored olutasidenib.
- Results rely on the assumption of no unmeasured confounders, which reflects a limitation of the methodology.

**Monday, June 2, 2025, 1:30pm to 4:30pm CT**

**Abstract #:** 3116

**Title:** Efficacy and Safety of Pralsetinib in *RET* Fusion-positive Solid Tumors: Final Data from the ARROW Trial

**Presenter:** Vivek Subbiah, M.D.

- Final results from the Phase 2 portion of ARROW in patients with *RET* fusion-positive solid tumors other than NSCLC and thyroid cancer showed an ORR of 46.4% (13/28), including an ORR for pancreatic cancer of 100% (5/5).
- Overall, 10.7% (3/28) achieved complete response (pancreatic cancer, n=2; cancer of unknown primary, n=1) and 35.7% (10/28) achieved partial response. Median PFS was 7 months and median DOR was 11.1 months. Median OS was 10.3 months.
- Pralsetinib demonstrated robust and durable anti-tumor activity, with responses observed in many tumor types. These data validate *RET* fusions as a tissue-agnostic target with sensitivity to RET inhibition and activity beyond NSCLC and thyroid cancer, further supporting the promising potential of pralsetinib to address the unmet medical need in these patients.

EHA2025 Congress abstracts may be accessed online via the [EHA Library](#). Details of the poster presentations and publications are as follows:

### **EHA Poster Presentations**

**Friday, June 13, 2025, Time 18:30 to 19:30 CEST**

**Abstract #:** PF511

**Title:** Efficacy and Safety of Olutasidenib Monotherapy in Primary Refractory AML: A Post Hoc Analysis of a Phase 2 Study

**Presenter:** Antonio Curti, M.D., Ph.D.

- In the pivotal cohort of R/R AML patients, 46 were primary refractory to first line treatment or subsequent induction therapy. With olutasidenib therapy, the ORR was 50% (23/46) and 30% (14/46) achieved a CR/CRh, with a median duration of CR/CRh of 17.6 months.
- The most commonly occurring treatment-emergent adverse events (AEs) were nausea (41%), vomiting (30%), and an increase in white blood cells (30%), with no new safety signals observed.
- Olutasidenib as a single agent demonstrated clinically meaningful activity and a durable response in patients with primary refractory AML, with an acceptable tolerability profile, suggesting it may be an effective therapeutic option for this patient population with a traditionally poor prognosis.

**Abstract #:** PF516

**Title:** Effect of Mutation Type and Co-mutations on Response to Olutasidenib in Patients With R/R Mutated *IDH1* AML

**Presenter:** Stéphane de Botton, M.D., Ph.D.

- In the final five-year analysis of the registrational trial, mutational analysis showed durable responses across *IDH1*-R132 mutation types, particularly in the absence of RTK pathway co-mutations.
- Response rates were lower in patients with  $\geq 4$  co-mutations.

- Results show that it is possible for patients with deleterious co-mutations (i.e., FLT3, TP53, etc.) to respond favorably to olutasidenib, although the sample sizes are small for some co-mutations.

**Abstract #:** PF530

**Title:** Olutasidenib as Maintenance Therapy after Treatment Response in Mutated *IDH1* Acute Myeloid Leukemia

**Presenter:** Andrew H. Wei, MBBS, Ph.D.

- In a separate cohort (n=18) of the Phase 2 trial, olutasidenib was evaluated as maintenance therapy in patients who achieved minimal residual disease (MRD)-positive CR or CR with incomplete blood count recovery (CRi) with prior treatment. The 4-month relapse-free survival (RFS) was 83% with a median RFS of 18.4 months. At 12 months, RFS was 71% and OS was 89%. RFS at 2 years was 48%.
- Two patients who had received prior venetoclax therapy entered with a CRi, improved to a CRh and ultimately a CR during the study.
- Most common treatment-emergent AEs were fatigue (33%), headache (33%) and nausea (28%), with no new safety signals.
- Olutasidenib as a single agent demonstrated clinically meaningful activity as a maintenance strategy in a subset of AML patients with CR/CRi and persistent MRD  $\geq 0.01\%$  after prior therapy. The analysis supports the potential benefit of switching to olutasidenib upon response to therapy.

**EHA Publications**

**Abstract #:** PB2499

**Title:** Comparative Effectiveness of Olutasidenib and Ivosidenib in *IDH1* Relapsed or Refractory Acute Myeloid Leukemia Patients Post-Venetoclax: Insights From 2102-HEM-101 and a Real-World External Control

**Authors:** Catherine Lai, M.D., MPH, Thomas Leahy, Ph.D., CStat, Alex Turner, Ph.D., Amber Thomassen, AGNP-BC, AOCNP, Lixia Wang, Ph.D., Aaron D. Sheppard, Ph.D., Jorge E. Cortes, M.D.

**Abstract #:** PB2492

**Title:** A Phase 2 Study of Olutasidenib in Relapsed/Refractory AML: Outcomes by Number of Prior Treatment Regimens

**Authors:** Eunice S. Wang, M.D., Jorge E. Cortes, M.D., Andrew H. Wei, M.D., Stéphane de Botton, M.D., Ph.D., Antonio Curti, M.D., Ph.D., Pau Montesinos, M.D., Ph.D., Karen W.L. Yee, M.D., Joseph G. Jurcic, M.D., William B. Donnellan, M.D., Jay Yang, M.D., Brian A. Jonas, M.D., Ph.D., Aaron D. Sheppard, Ph.D., Hua Tian, M.D., Justin M. Watts, M.D.

**Abstract #:** PB2528

**Title:** Matching-adjusted Indirect Comparison (MAIC) of Olutasidenib (OLU) and Ivosidenib (IVO) in isocitrate dehydrogenase-1 (*IDH1*)-mutated Relapsed/Refractory (R/R) AML

**Authors:** Brian A. Jonas, M.D., Ph.D., Justin M. Watts, M.D., Eunice S. Wang, M.D., Florence R. Wilson, MSc, Julie Park, MMath, Shannon Cope, MSc, Aaron D. Sheppard, Ph.D., Jorge E. Cortes, M.D., Stéphane de Botton, M.D., Ph.D.

**About NSCLC**

It is estimated that over 226,000 adults in the U.S. will be diagnosed with lung cancer in

2025. Lung cancer is the leading cause of cancer death in the U.S, with non-small cell lung cancer (NSCLC) being the most common type accounting for 85-90% of all lung cancer diagnoses.<sup>1</sup> *RET* fusions are implicated in approximately 1-2% of patients with NSCLC.<sup>2</sup>

### **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 22,010 new cases in the United States, most in adults, in 2025.<sup>3</sup>

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.<sup>4,5</sup> 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.<sup>6</sup> 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 GAVRETO® (pralsetinib)**

#### **INDICATIONS**

GAVRETO (pralsetinib) 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
- 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)\*

\*This 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).

#### **IMPORTANT SAFETY INFORMATION**

- **Interstitial Lung Disease (ILD)/Pneumonitis:** Severe, life-threatening, and fatal ILD/pneumonitis can occur in patients treated with GAVRETO. Pneumonitis occurred in 12% of patients who received GAVRETO, including 3.3% with Grade 3-4, and 0.2% with fatal reactions. Monitor for pulmonary symptoms indicative of ILD/pneumonitis. Withhold GAVRETO and promptly investigate for ILD in any patient who presents with acute or worsening of respiratory symptoms (e.g., dyspnea, cough, and fever). Withhold, reduce dose or permanently discontinue GAVRETO based on severity of confirmed ILD.
- **Hypertension:** Occurred in 35% of patients, including Grade 3 hypertension in 18% of patients. Overall, 8% had their dose interrupted and 4.8% had their dose reduced for hypertension. Treatment-emergent hypertension was most commonly managed with anti-hypertension medications. Do not initiate GAVRETO in patients with uncontrolled hypertension. Optimize blood pressure prior to initiating GAVRETO. Monitor blood

pressure after 1 week, at least monthly thereafter and as clinically indicated. Initiate or adjust anti-hypertensive therapy as appropriate. Withhold, reduce dose, or permanently discontinue GAVRETO based on the severity.

- **Hepatotoxicity:** Serious hepatic adverse reactions occurred in 1.5% of patients treated with GAVRETO. Increased aspartate aminotransferase (AST) occurred in 49% of patients, including Grade 3 or 4 in 7% and increased alanine aminotransferase (ALT) occurred in 37% of patients, including Grade 3 or 4 in 4.8%. The median time to first onset for increased AST was 15 days (range: 5 days to 2.5 years) and increased ALT was 24 days (range: 7 days to 3.7 years). Monitor AST and ALT prior to initiating GAVRETO, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose or permanently discontinue GAVRETO based on severity.
- **Hemorrhagic Events:** Serious, including fatal, hemorrhagic events can occur with GAVRETO. Grade  $\geq 3$  events occurred in 4.1% of patients treated with GAVRETO including one patient with a fatal hemorrhagic event. Permanently discontinue GAVRETO in patients with severe or life-threatening hemorrhage.
- **Tumor Lysis Syndrome (TLS):** Cases of TLS have been reported in patients with medullary thyroid carcinoma receiving GAVRETO. Patients may be at risk of TLS if they have rapidly growing tumors, a high tumor burden, renal dysfunction, or dehydration. Closely monitor patients at risk, consider appropriate prophylaxis including hydration, and treat as clinically indicated.
- **Risk of Impaired Wound Healing:** Impaired wound healing can occur in patients who receive drugs that inhibit the vascular endothelial growth factor (VEGF) signaling pathway. Therefore, GAVRETO has the potential to adversely affect wound healing. Withhold GAVRETO for at least 5 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of GAVRETO after resolution of wound healing complications has not been established.
- **Embryo-Fetal Toxicity:** Based on findings from animal studies and its mechanism of action, GAVRETO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with GAVRETO and for 2 weeks after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with GAVRETO and for 1 week after the last dose.
- **Common adverse reactions ( $\geq 25\%$ )** were musculoskeletal pain, constipation, hypertension, diarrhea, fatigue, edema, pyrexia, and cough. **Common Grade 3/4 laboratory abnormalities ( $\geq 2\%$ )** were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased phosphate, decreased leukocytes, decreased sodium, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), decreased calcium (corrected), decreased platelets, increased alkaline phosphatase, increased potassium, decreased potassium, and increased bilirubin.
- Avoid coadministration of GAVRETO with **strong or moderate CYP3A inhibitors, P-gp inhibitors, or combined P-gp and strong or moderate CYP3A inhibitors**. If coadministration cannot be avoided, reduce the GAVRETO dose. Avoid coadministration of GAVRETO with **strong or moderate CYP3A inducers**. If coadministration cannot be avoided, increase the GAVRETO dose.
- **Lactation:** Advise women not to breastfeed during treatment with GAVRETO and for 1

week after the last dose.

- **Pediatric Use:** Monitor open growth plates in adolescent patients. Consider interrupting or discontinuing GAVRETO if abnormalities occur.

[Click here](#) for Important Safety Information and Full Prescribing Information.

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

## **About REZLIDHIA®**

### **INDICATION**

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.

### **IMPORTANT SAFETY INFORMATION**

#### **WARNING: DIFFERENTIATION SYNDROME**

Differentiation syndrome, which can be fatal, can occur with REZLIDHIA treatment. Symptoms may include dyspnea, pulmonary infiltrates/pleuropericardial effusion, kidney injury, hypotension, fever, and weight gain. If differentiation syndrome is suspected, withhold REZLIDHIA and initiate treatment with corticosteroids and hemodynamic monitoring until symptom resolution.

### **WARNINGS AND PRECAUTIONS**

#### **Differentiation Syndrome**

REZLIDHIA can cause differentiation syndrome. In the clinical trial of REZLIDHIA in patients with relapsed or refractory AML, differentiation syndrome occurred in 16% of patients, with grade 3 or 4 differentiation syndrome occurring in 8% of patients treated, and fatalities in 1% of patients. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells and may be life-threatening or fatal. Symptoms of differentiation syndrome in patients treated with REZLIDHIA included leukocytosis, dyspnea, pulmonary infiltrates/pleuropericardial effusion, kidney injury, fever, edema, pyrexia, and weight gain. Of the 25 patients who experienced differentiation syndrome, 19 (76%) recovered after treatment or after dose interruption of REZLIDHIA. Differentiation syndrome occurred as early as 1 day and up to 18 months after REZLIDHIA initiation and has been observed with or without concomitant leukocytosis.

If differentiation syndrome is suspected, temporarily withhold REZLIDHIA and initiate systemic corticosteroids (e.g., dexamethasone 10 mg IV every 12 hours) for a minimum of 3 days and until resolution of signs and symptoms. If concomitant leukocytosis is observed, initiate treatment with hydroxyurea, as clinically indicated. Taper corticosteroids and hydroxyurea after resolution of symptoms. Differentiation syndrome may recur with premature discontinuation of corticosteroids and/or hydroxyurea treatment. Institute supportive measures and hemodynamic monitoring until improvement; withhold dose of REZLIDHIA and consider dose reduction based on recurrence.

#### **Hepatotoxicity**

REZLIDHIA can cause hepatotoxicity, presenting as increased alanine aminotransferase (ALT), increased aspartate aminotransferase (AST), increased blood alkaline phosphatase, and/or elevated bilirubin. Of 153 patients with relapsed or refractory AML who received

REZLIDHIA, hepatotoxicity occurred in 23% of patients; 13% experienced grade 3 or 4 hepatotoxicity. One patient treated with REZLIDHIA in combination with azacitidine in the clinical trial, a combination for which REZLIDHIA is not indicated, died from complications of drug-induced liver injury. The median time to onset of hepatotoxicity in patients with relapsed or refractory AML treated with REZLIDHIA was 1.2 months (range: 1 day to 17.5 months) after REZLIDHIA initiation, and the median time to resolution was 12 days (range: 1 day to 17 months). The most common hepatotoxicities were elevations of ALT, AST, blood alkaline phosphatase, and blood bilirubin.

Monitor patients frequently for clinical symptoms of hepatic dysfunction such as fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. Obtain baseline liver function tests prior to initiation of REZLIDHIA, at least once weekly for the first two months, once every other week for the third month, once in the fourth month, and once every other month for the duration of therapy. If hepatic dysfunction occurs, withhold, reduce, or permanently discontinue REZLIDHIA based on recurrence/severity.

### **ADVERSE REACTIONS**

The most common ( $\geq 20\%$ ) adverse reactions, including laboratory abnormalities, were aspartate aminotransferase increased, alanine aminotransferase increased, potassium decreased, sodium decreased, alkaline phosphatase increased, nausea, creatinine increased, fatigue/malaise, arthralgia, constipation, lymphocytes increased, bilirubin increased, leukocytosis, uric acid increased, dyspnea, pyrexia, rash, lipase increased, mucositis, diarrhea and transaminitis.

### **DRUG INTERACTIONS**

- Avoid concomitant use of REZLIDHIA with strong or moderate CYP3A inducers.
- Avoid concomitant use of REZLIDHIA with sensitive CYP3A substrates unless otherwise instructed in the substrates prescribing information. If concomitant use is unavoidable, monitor patients for loss of therapeutic effect of these drugs.

### **LACTATION**

Advise women not to breastfeed during treatment with REZLIDHIA and for 2 weeks after the last dose.

### **GERIATRIC USE**

No overall differences in effectiveness were observed between patients 65 years and older and younger patients. Compared to patients younger than 65 years of age, an increase in incidence of hepatotoxicity and hypertension was observed in patients  $\geq 65$  years of age.

### **HEPATIC IMPAIRMENT**

In patients with mild or moderate hepatic impairment, closely monitor for increased probability of differentiation syndrome.

[Click here](#) for Important Safety Information and Full Prescribing Information, including **Boxed WARNING**.

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



GAVRETO and REZLIDHIA 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](http://www.rigel.com).

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3. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised March 4, 2025. Accessed March 31, 2025: <https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html>
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6. Thol F, Schlenk RF, Heuser M, Ganser A. How I treat refractory and early relapsed acute myeloid leukemia. Blood (2015) 126 (3): 319-27. 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, the potential for the referenced clinical trials or trial results to strengthen our commercial portfolio, GAVRETO's success in treating both RET fusion-positive NSCLC and RET fusion-positive solid tumors, and the benefit of REZLIDHIA as an earlier line treatment for R/R AML. 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 most recent Annual Report on Form 10-K, and subsequent filings, including Quarterly Reports on Form 10-Q. 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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