October 19, 2026

Rigel Highlights New GAVRETO® (pralsetinib) Data Across RET Fusion-Positive Cancers in Oral and Poster Presentations at ESMO Congress 2026

- *Pooled ARROW and TAPISTRY analysis demonstrated a 53% overall response rate in patients with RET fusion-positive solid tumors*
- *Additional analyses highlight first-line clinical outcomes and patient-reported quality of life in RET fusion-positive NSCLC and efficacy and safety in RET fusion-positive thyroid cancer*

SOUTH SAN FRANCISCO, Calif., Oct. 19, 2026 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today announced analysis of the pooled efficacy and safety data from two clinical trials of GAVRETO® (pralsetinib), ARROW (NCT03037385) and TAPISTRY (NCT04589845), in patients with rearranged during transfection (*RET*) fusion-positive solid tumors will be presented in a rapid oral session at the European Society For Medical Oncology (ESMO) Congress 2026 on Sunday, October 25, 2026.

In addition, the ESMO Congress will feature two poster presentations and an ePoster with additional clinical and health-related quality of life data from the TAPISTRY clinical trial in patients with *RET* fusion-positive thyroid cancer and ARROW trial in patients with *RET* fusion-positive non-small cell lung cancer (NSCLC). The ESMO Congress is being held in Madrid, Spain and virtually from October 23 to October 27, 2026.

"These analyses reinforce the breadth of evidence supporting pralsetinib across*RET* fusion-positive cancers and provide important new insights into its clinical activity, durability and impact on patients," said Alison L. Hannah, M.D., Rigel's chief medical officer. "We are particularly encouraged by the findings across multiple solid tumor types, as well as the first-line clinical outcomes and quality-of-life data in *RET* fusion-positive NSCLC, which further our understanding of the potential role of pralsetinib for patients whose tumors are driven by *RET* fusions."

Key highlights from the presentations at ESMO include:

- In a pooled analysis of 49 patients with*RET* fusion-positive solid tumors from the

ARROW and TAPISTRY studies excluding NSCLC and thyroid tumors, pralsetinib demonstrated robust and durable activity across a range of tumor types, including pancreatic and colorectal, with an overall response rate (ORR) of 53% and median duration of response of 12.2 months. Notably, patients with previously-treated pancreatic tumors had an ORR of 88% (7/8). These data support the potential use of pralsetinib in a tumor-agnostic approach for *RET* fusion-positive solid tumors.

- In the TAPISTRY clinical trial cohort that evaluated pralsetinib in 16 response-evaluable thyroid cancer patients with *RET* fusion-positive tumors, pralsetinib demonstrated robust and durable activity against *RET* fusion-positive thyroid cancer with an ORR of 81.3% and manageable safety, results that are consistent with the ARROW study and further highlight its utility in this population.
- In patients with *RET* fusion–positive NSCLC enrolled in ARROW, patients treated with pralsetinib in the first-line setting had a higher investigator-assessed ORR than patients who had received standard of care first-line therapies before ARROW enrollment (75% vs. 26%). Median times to progression, treatment discontinuation, and next treatment or death were also longer with first-line pralsetinib. These findings support pralsetinib as an effective first-line therapy and are consistent with treatment guidelines recommending selective *RET* inhibition for patients with *RET* fusion-positive advanced NSCLC.
- In the ARROW clinical trial, pralsetinib therapy was associated with clinically meaningful improvements in Health-Related Quality of Life (HRQoL) among patients with advanced or metastatic *RET* fusion-positive NSCLC, with at least 75% of evaluable patients experiencing improved or stable scores across all assessed domains at Cycle 12 Day 1.

ESMO Congress 2026 abstracts may be accessed online via theESMO 2026 – Conference Calendar.

Abstract Title	Lead Author / Presenter	Presentation Type / Abstract #	Session Title	Session Date / Time
Efficacy and Safety of Pralsetinib in *RET* Fusion-Positive Solid Tumors: Pooled Analysis of the ARROW and TAPISTRY Trials	Jacqueline Vuky, MD	Rapid Oral #1005RO	Rapid Oral: Developmental therapeutic	October 25, 8:30 – 10:00 am CET
Pralsetinib for Advanced *RET* Fusion-Positive Thyroid Cancer: Results from the TAPISTRY Clinical Trial	Do-Youn Oh, MD, PhD	Poster Presentation #4215P	Poster Display Session: Thyroid Cancer	October 26, 12:00 – 12:45 pm CET
Clinical Outcomes With First-Line Pralsetinib vs Other Accepted Therapies in ARROW Patients with *RET* Fusion-Positive NSCLC	Vivek Subbiah, MD	Poster Presentation #2718P	Poster Display Session: NSCLC, metastatic	October 26, 12:00 – 12:45 pm CET
Health-Related Quality of Life (HRQoL) Among Patients With Advanced or Metastatic *RET*-Fusion-Positive NSCLC Treated With Pralsetinib in ARROW	Giuseppe Curigliano, MD, PhD	ePoster Presentation #2808eP	N/A	N/A

About NSCLC

It is estimated that over 229,000 adults in the U.S. will be diagnosed with lung cancer in 2026. 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 77% of all lung cancer diagnoses.[1] *RET* fusions are implicated in approximately 1-2% of patients with NSCLC.[2]

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

WARNING: SERIOUS INFECTIONS, INCLUDING OPPORTUNISTIC INFECTIONS
GAVRETO may increase the risk for serious infections, including bacterial, fungal, viral and opportunistic infections, which can lead to hospitalization or death. Withhold, reduce the dose or permanently discontinue GAVRETO based on severity.

WARNINGS AND PRECAUTIONS

- **Serious Infections, Including Opportunistic Infections:** GAVRETO may increase the risk for serious infections, including fatal and opportunistic infections. In the AcceleRET-Lung trial, infections occurred in 72% of patients who received GAVRETO, including 18% with Grade 3 and 3.7% with Grade 4 and 7% with fatal outcomes. Among the patients who received chemotherapy/immunotherapy, infections occurred in 52%, including 10% with Grade 3. Infections in the GAVRETO arm included pneumonia, urinary tract infection, opportunistic infections (such as pneumocystis jirovecii pneumonia and fungal infections) and others. Monitor patients for signs and symptoms of infection and treat appropriately. Withhold, reduce the dose, or permanently discontinue GAVRETO based on severity.
- **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 ≥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.

ADVERSE REACTIONS

- Common adverse reactions (≥25%) were musculoskeletal pain, constipation, hypertension, diarrhea, fatigue, edema, pyrexia, and cough. Common Grade 3/4 laboratory abnormalities (≥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.

DRUG INTERACTIONS

- **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, including Boxed WARNING.**

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

GAVRETO 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.

1. The American Cancer Society. Key Statistics for Lung Cancer. Revised January 13, 2026. Accessed October 1, 2026: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html
2. 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, the presentation and availability of data at ESMO Congress 2026 and the potential therapeutic benefits and clinical utility of pralsetinib across RET fusion-positive cancers, including its clinical activity, durability and impact on patients and its potential role for patients with RET fusion-positive tumors. 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 "reinforce," "support," "encouraged," "potential," "will" and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are based on Rigel's current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, risks that results from pooled or subgroup analyses, analyses involving small or selected patient populations, cross-treatment comparisons or patient-reported outcomes may be affected by limitations in the underlying data and may not be predictive of future clinical outcomes or results in broader patient populations; risks that further data, analyses or experience may alter Rigel's current understanding of the safety, efficacy, durability, patient-reported outcomes or therapeutic utility of pralsetinib; risks that the data may not support conclusions regarding the potential role of pralsetinib across tumor types or in the first-line setting; risks associated with the timing and availability of data analyses and scientific presentations; and other risks described from time to time in Rigel's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 and subsequent filings. Any forward-looking statement contained in this press release speaks only as of the date on which it was made. Rigel undertakes no obligation to update any forward-looking statements contained herein, except as required by law.

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