November 4, 2026

Rigel Announces Oral Presentation of Phase 1b Data for R289 in Patients with Lower-Risk MDS at the 68th American Society of Hematology Annual Meeting and Exposition

- *Oral presentation to feature updated data from the dose escalation and dose expansion phases of the ongoing Phase 1b study evaluating R289, Rigel's dual IRAK1/4 inhibitor, in patients with relapsed or refractory lower-risk MDS*
- *Three poster presentations will highlight data for TAVALISSE® (fostamatinib disodium hexahydrate) in patients with chronic ITP and wAIHA*

SOUTH SAN FRANCISCO, Calif., Nov. 4, 2026 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL), a commercial stage biotechnology company focused on hematologic disorders and cancer, today announced that data from the ongoing Phase 1b clinical study of R289[1], a potent and selective inhibitor of interleukin receptor-associated kinases 1 and 4 (IRAK1/4), in patients with lower-risk myelodysplastic syndrome (MDS) who are relapsed or refractory (R/R) to prior therapies will be presented in an oral session at the 68th American Society of Hematology (ASH) Annual Meeting and Exposition on Saturday, December 12, 2026. In addition, the ASH Annual Meeting will feature three poster presentations for TAVALISSE® (fostamatinib disodium hexahydrate) in patients with immune thrombocytopenia (ITP) and warm autoimmune hemolytic anemia (wAIHA). The ASH Annual Meeting is taking place from December 12-15, 2026, in New Orleans, Louisiana and virtually.

"Data from the dose escalation phase of the ongoing Phase 1b study of R289 in patients with relapsed or refractory lower-risk MDS was presented at an oral session at last year's ASH," said Alison L. Hannah, M.D., Rigel's chief medical officer. "This year the data from our randomized dose expansion phase will also be presented at an oral session, providing an update on both efficacy, including the reduction of transfusion dependence, and safety. We continue to be encouraged by our evolving data in this heavily pretreated patient population."

Key highlights from the ASH abstracts include:

- In the ongoing Phase 1b study of R289 in patients with R/R lower-risk MDS, there were 64 patients enrolled as of July 16, 2026, including 33 patients in the dose escalation phase and 31 patients in the dose expansion phase. At the data cut off, R289 continues to be generally well tolerated in this elderly, heavily pretreated lower-risk MDS patient population, the majority of whom were considered to have high transfusion burden (HTB) disease at baseline. Updated study data as of a planned mid-November data cut will be presented in the oral session, including preliminary efficacy data from the dose expansion phase of the study.
- In a retrospective real-world analysis of 90 patients with ITP receiving fostamatinib plus a thrombopoietin receptor agonist (TPO-RA), combination treatment was associated with increased platelet counts. Among 38 patients with available measurements during months 7-12, 81.6% had platelet counts ≥50 × 10^3/μL, an increase from 33.3% of 90 patients at baseline. These findings support a treatment approach targeting multiple mechanisms of disease through the combination of fostamatinib and TPO-RAs.
- Data from an interim analysis investigating fostamatinib in 799 patients enrolled in the ongoing post-marketing surveillance in Japan will be presented. No new safety signals were detected. Platelet counts increased within two weeks of fostamatinib initiation, with responses maintained at 12 months in a subset of patients who continued treatment and had available follow-up data.
- In an open-label long-term extension study enrolling 71 patients with wAIHA that were treated with fostamatinib, durable hemoglobin responses were observed in >50% of patients during follow-up through Week 104. The long-term safety profile was consistent with the established safety profile of fostamatinib, with no new safety signals identified. Fostamatinib remains investigational in this setting.

ASH Annual Meeting abstracts may be accessed online at www.hematology.org.

Abstract Title	Lead Author / Presenter	Presentation Type / Publication #	Session Title	Session Date / Time (CT)
R289				
Dose Escalating / Dose Expansion Study of R289, a Dual IRAK 1/4 Inhibitor, in Patients with Relapsed/Refractory (R/R) Lower Risk Myelodysplastic Syndrome (LR-MDS)	Guillermo Garcia-Manero, MD	Oral presentation Publication #251	637. Myelodysplastic Syndromes: Clinical and Epidemiological: Novel Therapeutic Strategies and Prognostic Stratification in MDS and MDS/MPN	Saturday, December 12, 2026 3:00pm – 3:15pm
TAVALISSE (fostamatinib disodium hexahydrate)				
Platelet Responses with Combination Therapy of Fostamatinib and Thrombopoietin Receptor Agonists in Immune Thrombocytopenia: An Updated Real-World Analysis	David J. Kuter, MD, DPhil	Poster presentation Publication #1250	311. Disorders of Platelet Number or Function: Clinical and Epidemiological: Poster I	Saturday, December 12, 2026 5:30pm – 7:30pm
Real-world safety, effectiveness, and predictors of responses to fostamatinib in patients with ITP: interim analysis of a nationwide post-marketing surveillance in Japan	Masataka Kuwana, MD	Poster presentation Publication #1252	311. Disorders of Platelet Number or Function: Clinical and Epidemiological: Poster I	Saturday, December 12, 2026 5:30pm – 7:30pm
Hemoglobin Responses With Fostamatinib in a Long-Term Extension Trial in Warm Autoimmune Hemolytic Anemia	David J. Kuter, MD, DPhil	Poster presentation Publication #4619	101. Red Cells and Erythropoiesis, Excluding Iron: Poster III	Monday, December 14, 2026 6:00pm – 8:00pm
REZLIDHIA (olutasidenib)				
Efficacy of Olutasidenib After Venetoclax in IDH1-Mutated Relapsed/Refractory Acute Myeloid Leukemia: A Systematic Literature Review and Meta-Analysis	Jorge E. Cortes, MD	Publication only #7191	N/A	N/A

About R289

R289 is a prodrug of R835, an IRAK1/4 dual inhibitor, which has been shown in preclinical studies to block inflammatory cytokine production in response to toll-like receptor (TLR) and interleukin-1 receptor (IL-1R) family signaling. TLRs and IL-1Rs play a critical role in the innate immune response and dysregulation of these pathways can lead to various inflammatory conditions. Chronic stimulation of both these receptor systems is thought to cause the pro-inflammatory environment in the bone marrow responsible for persistent cytopenias in lower-risk MDS patients.[2]

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 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 22,720 new cases in the United States, most in adults, in 2026.[3]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[4,5] 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.[6] 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 TAVALISSE®

Indication

TAVALISSE (fostamatinib disodium hexahydrate) 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.

Important Safety Information

Warnings and Precautions

- Hypertension can occur with TAVALISSE treatment. Patients with pre-existing hypertension may be more susceptible to the hypertensive effects. Monitor blood pressure every 2 weeks until stable, then monthly, and adjust or initiate antihypertensive therapy for blood pressure control maintenance during therapy. If increased blood pressure persists, TAVALISSE interruption, reduction, or discontinuation may be required.
- Elevated liver function tests (LFTs), mainly ALT and AST, can occur with TAVALISSE. Monitor LFTs monthly during treatment. If ALT or AST increase to ≥3 x upper limit of normal, manage hepatotoxicity using TAVALISSE interruption, reduction, or discontinuation.
- Diarrhea occurred in 31% of patients and severe diarrhea occurred in 1% of patients treated with TAVALISSE. Monitor patients for the development of diarrhea and manage using supportive care measures early after the onset of symptoms. If diarrhea becomes severe (≥Grade 3), interrupt, reduce dose or discontinue TAVALISSE.
- Neutropenia occurred in 6% of patients treated with TAVALISSE; febrile neutropenia occurred in 1% of patients. Monitor the ANC monthly and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction, or discontinuation.
- TAVALISSE can cause fetal harm when administered to pregnant women. Advise pregnant women the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Verify pregnancy status prior to initiating TAVALISSE. It is unknown if TAVALISSE or its metabolite is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during TAVALISSE treatment and for at least 1 month after the last dose.

Drug Interactions

- Concomitant use of TAVALISSE with strong CYP3A4 inhibitors increases exposure to the major active metabolite of TAVALISSE (R406), which may increase the risk of adverse reactions. Monitor for toxicities that may require a reduction in TAVALISSE dose.
- It is not recommended to use TAVALISSE with strong CYP3A4 inducers, as concomitant use reduces exposure to R406.
- Concomitant use of TAVALISSE may increase concentrations of some CYP3A4 substrate drugs and may require a dose reduction of the CYP3A4 substrate drug.
- Concomitant use of TAVALISSE may increase concentrations of BCRP substrate drugs (eg, rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (eg, digoxin), which may require a dose reduction of the BCRP and P-gp substrate drug.

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).
- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Click here **for Important Safety Information and Full Prescribing Information.**

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

TAVALISSE 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.

1. R289 is an investigational compound not approved by the FDA.
2. Sallman DA et al. *Unraveling the Pathogenesis of MDS: The NLRP3 Inflammasome and Pyroptosis Drive the MDS Phenotype*. Front Oncol. June 16, 2016. doi: https://doi.org/10.3389/fonc.2016.00151
3. The American Cancer Society. Key Statistics for Acute Myeloid Leukemia (AML). Revised January 13, 2026. Accessed October 30, 2026: https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html
4. Patel, A, et al. *Outcomes of Patients With Acute Myeloid Leukemia Who Relapse After 5 Years of Complete Remission*. 2021 Sep 7;28(7):811-814. doi: https://doi.org/10.3727/096504020X15965357399750
5. Thol F, Ganser, A. *Treatment of Relapsed Acute Myeloid Leukemia*. Curr. Treat. Options on Oncol. (2020) 21: 66. doi: https://doi.org/10.1007/s11864-020-00765-5
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 within the meaning of the Private Securities Litigation Reform Act of 1995 relating to, among other things, the anticipated timing and content of presentations at the 2026 American Society of Hematology Annual Meeting and Exposition; the planned data cutoff and availability of updated data from the ongoing Phase 1b study of R289; the progress and potential outcomes of the dose escalation and dose expansion phases of that study; the potential safety, tolerability and efficacy of R289, including its potential to reduce transfusion dependence in patients with lower-risk myelodysplastic syndrome; and the potential therapeutic benefits and clinical utility of fostamatinib in the patient populations and treatment settings described in this release.

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 "anticipates," "believes," "expects," "intends," "may," "plans," "potential," "will" and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. They are based on Rigel's current beliefs, expectations and assumptions and involve significant risks and uncertainties that are difficult to predict and, in many cases, are beyond Rigel's control. Actual results and the timing of events could differ materially from those expressed or implied by these forward-looking statements as a result of various risks and uncertainties, including, without limitation, risks that clinical studies, data collection, analyses or presentations may be delayed or may not proceed as anticipated; risks that preliminary, interim or limited clinical data may not be predictive of final results, results in larger patient populations or results in subsequent clinical trials; limitations of retrospective, observational, uncontrolled and subgroup analyses, including potential selection bias, confounding factors and incomplete follow-up; risks that clinical trial results may not be predictive of real-world outcomes; risks that additional data, analyses or experience may alter assessments of the safety, tolerability, efficacy or therapeutic potential of R289 or fostamatinib; risks that R289 or fostamatinib may have unintended side effects or adverse reactions; risks that clinical results or decisions by regulatory authorities may not support further development or approval for investigational uses; risks associated with reliance on third parties for clinical development, manufacturing, supply and other services; the availability and allocation of financial, personnel and other resources to fund Rigel's development programs; competition from other therapies; and other risks described in the "Risk Factors" section of Rigel's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 and subsequent filings with the Securities and Exchange Commission. Any forward-looking statement in this press release speaks only as of the date on which it is made. Rigel undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise, except as required by law.

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