August 8, 2018

# Rigel Announces Second Quarter 2018 Financial Results and Provides Company Update

## $1.8 Million in Net Product Sales for TAVALISSE™ (fostamatinib disodium hexahydrate)

## Conference Call and Webcast Today at 5:00PM Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 8, 2018 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL), today reported financial results for the second quarter of 2018 and provided an update on the commercial launch of TAVALISSE™ and the clinical development pipeline.

**Recent Highlights:**

- On May 29, Rigel launched TAVALISSE™ (fostamatinib disodium hexahydrate) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
- The TAVALISSE commercial team, at over 50 employees strong, is fully deployed and supporting ITP-prescribing physicians across the United States.
- RIGEL ONECARE™, Rigel's comprehensive physician and patient support center, is assisting patients with access to TAVALISSE through insurance coverage and other patient support programs.

"The second quarter of 2018 marked Rigel's pivotal transition to a commercial stage company with the successful launch of TAVALISSE. We are truly excited to be communicating TAVALISSE's attractive value proposition to patients, physicians and payers: namely, its unique mechanism of action that targets an underlying cause of the disease, efficacy, oral dosing, safety profile, and comprehensive patient support and access programs", stated Raul Rodriguez, president and CEO of Rigel. "Beyond executing on our goal of making TAVALISSE a commercial success in chronic ITP following steroid treatment, the company continues to make exciting pipeline progress that we expect will fully leverage the commercial capabilities we now have in place. We look forward to providing a comprehensive corporate and pipeline update at our upcoming Investor and Analyst Day, which will be held in New York City this fall."

**Financial Update**
For the second quarter of 2018, Rigel reported a net loss of $25.6 million, or $0.16 per share, compared to a net loss of $19.1 million, or $0.16 per share, in the same period of 2017.

For the second quarter of 2018, Rigel reported net product sales from TAVALISSE of $1.8 million. The Company recognizes revenue using the sell-in methodology when products are delivered to its distributors. TAVALISSE was made available by prescription for the treatment of chronic ITP on May 29, 2018. There were no product sales or contract revenues from collaborations in the second quarter of 2017.

Rigel reported total costs and expenses of $27.9 million in the second quarter of 2018, compared to $19.3 million for the same period in 2017. The increase in costs and expenses was primarily due to the increases in personnel costs for Rigel's customer-facing team, as well as third party costs related to Rigel's commercial launch of TAVALISSE in chronic ITP.

For the six months ended June 30, 2018, Rigel reported a net loss of $49.9 million, or $0.32 per share, compared to a net loss of $34.5 million, or $0.29 per share, for the same period of 2017.

As of June 30, 2018, Rigel had cash, cash equivalents and short-term investments of $135.0 million, compared to $115.8 million as of December 31, 2017. Rigel expects that its cash, cash equivalents and short-term investments will be sufficient to support its current and projected funding requirements, including the on-going commercial launch of TAVALISSE for chronic ITP in the U.S., into the fourth quarter of 2019.

**Development Pipeline Update**
In the second quarter, Rigel continued to support the investigation of fostamatinib for other serious, autoimmune conditions including autoimmune hemolytic anemia (AIHA) and IgA nephropathy (IgAN). Updates regarding pivotal programs in both indications are expected by the fall of 2018.

In June, Rigel announced the initiation of a Phase 1 study in healthy subjects to assess safety, tolerability, pharmacokinetics and pharmacodynamics of R835, a proprietary molecule from its interleukin receptor associated kinase (IRAK) program. Preclinical studies show that R835 inhibits both the IRAK1 and IRAK4 signaling pathways, which play a key role in inflammation and immune responses to tissue damage. Dual inhibition of IRAK1 and IRAK4 allows for more complete suppression of pro-inflammatory cytokine release. The Phase 1 study is a randomized, placebo-controlled, double-blind trial in up to 91 healthy subjects, ages 18 to 55. The study design will assess the tolerability and safety of R835 in both single ascending and multiple ascending doses.

Rigel reported that its clinical stage partnerships continue to make progress. BerGenBio (with bemcentinib) and Daiichi-Sankyo (with DS-30232) continue to enroll patients in numerous clinical trials in various solid tumors and AML. In June, Aclaris Therapeutics announced positive interim data from their Phase 2 study of the licensed topical JAK inhibitor, ATI-502, in patients with alopecia areata. Bristol Myers Squibb has informed Rigel that they will be terminating their preclinical collaboration.

**About ITP**

In patients with 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. 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 (TPOs) and splenectomy. However, not all patients are adequately treated with existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

**About R835**

The investigational candidate, R835, is an orally available, potent and selective inhibitor of IRAK1 and IRAK4 that blocks inflammatory cytokine production in response to toll-like receptor (TLR) and the interleukin-1 family receptor (IL-1R) signaling. TLRs and IL-1Rs play a critical role in the innate immune response and dysregulation of these pathways can lead to a variety of inflammatory conditions. R835 is active in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout.

**Conference Call and Webcast With Slides Today at 5:00PM Eastern Time**

Rigel will hold a live conference call and webcast today at 5:00pm Eastern Time (2:00pm Pacific Time).

Participants can access the live conference call by dialing 855-892-1489 (domestic) or 720-634-2939 (international) and using the Conference ID number 8192317. The webcast, with slide presentation, can be accessed from Rigel's website at www.rigel.com. The webcast will be archived and available for replay after the call via the Rigel website.

**About TAVALISSE**

**Indication**

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.

**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.

**Please see www.TAVALISSE.com for full Prescribing Information.**

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

TAVALISSE and RIGEL ONECARE are trademarks of Rigel Pharmaceuticals, Inc.
RIGEL ONECARE is a patient support center sponsored by Rigel Pharmaceuticals, Inc.

**About Rigel (www.rigel.com)**
Rigel Pharmaceuticals, Inc., is a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with immune and hematologic disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's first FDA approved product is TAVALISSE™ (fostamatinib disodium hexahydrate), an oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult

patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. Rigel's current clinical programs include Phase 2 studies of fostamatinib in autoimmune hemolytic anemia and IgA nephropathy. In addition, Rigel has product candidates in development with partners BerGenBio AS, Daiichi Sankyo, and Aclaris Therapeutics.

**Forward Looking Statements**

*This release contains forward-looking statements relating to, among other things, the potential success of the U.S. commercial launch of TAVALISSE; the availability of TAVALISSE to patients; the benefits and value to patients of TAVALISSE; Rigel's ability to identify partners for commercialization of fostamatinib in ex-U.S. territories; the sufficiency of Rigel's cash, cash equivalents and short-term investments and the timing of its current cash runway; Rigel's interactions with the FDA; and the timing and results of Rigel's clinical trials. 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 "planned," "will," "may," "should," "expect," "goal," and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Rigel's current expectations and inherently involve significant risks and uncertainties. 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 of TAVALISSE; risks that the FDA or other regulatory authorities may make adverse decisions regarding TAVALISSE; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE 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 period ended March 31, 2018. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.*

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**RIGEL PHARMACEUTICALS, INC.**
**STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (unaudited) | | | |
| Revenues: | | | | |
| Product sales, net | $ 1,787 | $ - | $ 1,787 | $ - |
| Contract revenues from collaborations | — | — | — | 3,584 |
| Total revenues | 1,787 | — | 1,787 | 3,584 |
| Costs and expenses: | | | | |
| Cost of product sales | 30 | — | 30 | — |
| Research and development (see Note A) | 10,797 | 11,524 | 22,039 | 23,900 |
| Selling, general and administrative (see Note A) | 17,071 | 7,820 | 30,563 | 15,230 |
| Total costs and expenses | 27,898 | 19,344 | 52,632 | 39,130 |
| Loss from operations | (26,111) | (19,344) | (50,845) | (35,546) |
| Interest income | 554 | 197 | 903 | 353 |
| Gain on disposal of assets | — | — | — | 732 |
| Net loss | $ (25,557) | $ (19,147) | $ (49,942) | $ (34,461) |
| Net loss per share, basic and diluted | $ (0.16) | $ (0.16) | $ (0.32) | $ (0.29) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 161,577 | 122,500 | 154,385 | 118,074 |

**Note A**

| | | | | |
|---|---|---|---|---|
| Stock-based compensation expense included in: | | | | |
| Selling, general and administrative | $ 779 | $ 764 | $ 1,719 | $ 1,359 |
| Research and development | 333 | 336 | 933 | 696 |
| | $ 1,112 | $ 1,100 | $ 2,652 | $ 2,055 |

**SUMMARY BALANCE SHEET DATA**
**(in thousands)**

| | June 30, 2018 | December 31, 2017 (1) |
|---|---|---|
| | (unaudited) | |
| Cash, cash equivalents and short-term investments | $ 134,992 | $ 115,751 |
| Total assets | 141,219 | 119,111 |
| Stockholders' equity | 123,567 | 100,646 |

(1) Derived from audited financial statements

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