August 6, 2019

Rigel Announces Second Quarter 2019 Financial Results and Provides Business Update

TAVALISSE® net product sales increased 26% quarter over quarter to $10.2 million

First patients enrolled in Phase 3 pivotal trial of TAVALISSE in warm autoimmune hemolytic anemia (AIHA)

Conference call and webcast today at 4:30PM Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 6, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL), today reported financial results for the second quarter ended June 30, 2019, including sales of TAVALISSE® (fostamatinib disodium hexahydrate) tablets, for the treatment of adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

"Execution is the key to Rigel's success, and has enabled us to increase awareness of the benefits of TAVALISSE for chronic ITP as seen by the 26% growth in net product sales quarter over quarter," stated Raul Rodriguez, president and CEO. "Our commercial team continues to drive uptake of our product and the interest level among the patient and physician communities is very encouraging. In parallel, our pivotal trial of TAVALISSE in warm autoimmune hemolytic anemia is underway and enrolling patients. With the only warm AIHA treatment in a Phase 3 trial and no FDA-approved therapy for the indication, this is a substantial opportunity for Rigel."

Financial Update

For the second quarter of 2019, Rigel reported a net loss of $20.6 million, or $0.12 per share, compared to a net loss of $25.6 million, or $0.16 per share, in the same period of 2018.

For the second quarter of 2019, Rigel reported net product sales from TAVALISSE of $10.2 million, compared to $1.8 million in the same period of 2018. The increase in net product sales reflects the expansion of TAVALISSE use since its commercial launch in May 2018.

Contract revenues from collaborations were $234,000 for the three months ended June 30, 2019, which were related to Rigel's collaboration agreements with Kissei Pharmaceutical Co., Ltd. and Grifols, S.A. There were no contract revenues from collaborations during the three months ended June 30, 2018.

Rigel reported total costs and expenses of $31.7 million in the second quarter of 2019, compared to $27.9 million for the same period in 2018. The increase in costs and expenses was primarily due to increased personnel costs for Rigel's customer-facing team and third-party costs related to Rigel's commercial launch of TAVALISSE in chronic ITP, as well as research and development costs related to its Phase 3 pivotal trial of TAVALISSE in patients with warm AIHA.

For the six months ended June 30, 2019, Rigel reported a net loss of $38.2 million, or $0.23 per share, compared to a net loss of $49.9 million, or $0.32 per share, for the same period of 2018.

Rigel reported total revenues of $23.0 million for the six months ended June 30, 2019, compared to $1.8 million for the same period in 2018. Total revenues for the six months ended June 30, 2019 consisted of $18.2 million in net product sales and $4.8 million in revenue related to Rigel's collaboration agreements with Grifols and Kissei. Total revenues for the six months ended June 30, 2018 consisted of $1.8 million in net product sales. There were no contract revenues from collaborations for the six months ended June 30, 2018.

Total costs and expenses for the six months ended June 30, 2019 were $62.7 million, compared to $52.6 million, for the same period of 2018. The increase in total costs and expenses was primarily related to the increase in personnel costs for Rigel's customer-facing team, as well as third party costs related to Rigel's ongoing commercialization of TAVALISSE in chronic ITP.

As of June 30, 2019, Rigel had cash, cash equivalents and short-term investments of $112.4 million, compared to $128.5 million as of December 31, 2018.

Business Update

- Sales of TAVALISSE have achieved consecutive double-digit quarterly growth since product launch in May of 2018. This reflects an increase in prescribers, a broadening awareness among patients and physicians, growing early line use, and continued strong refill rates.
- Rigel has received the EMA's 180-day questions related to the European marketing authorization application (MAA) for fostamatinib in chronic ITP. The approval process remains on track for a potential EMA decision by the end of this year.
- The first patients have been enrolled in FORWARD (Fostamatinib Research in Warm Antibody AIHA Disease), Rigel's pivotal Phase 3 clinical trial in warm AIHA. The addition of clinical trial sites is ramping. Topline results are expected in mid 2021, positioning TAVALISSE to potentially become the first FDA-approved treatment for warm AIHA.
- At the 2019 Congress of the European Hematology Association (EHA), Rigel presented TAVALISSE data supporting its ability to improve the lives of patients with chronic ITP and highlighting its clinical trial progress in warm AIHA. These data were presented in two posters which highlighted long-term safety and efficacy results of

TAVALISSE in a Phase 3 extension study for the treatment of chronic ITP, as well as a Phase 2 open-label extension study in patients with warm AIHA.

- Rigel plans to provide data from its Phase 1 trial of R835[1], an IRAK 1/4 inhibitor, in the second half of 2019.
- The company continues to explore additional opportunities to expand its pipeline, which includes pursuing other indications for TAVALISSE to take advantage of the anticipated product exclusivity until 2031.

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, platelet production amplifiers (TPO-RAs - thrombopoietin receptor agonists), 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 AIHA

AIHA is a rare, serious blood disorder in which the immune system produces antibodies that result in the destruction of the body's own red blood cells. AIHA affects approximately 40,000 adult patients in the U.S. and can be a severe, debilitating disease. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients.

About R835[1]

The investigational candidate, R835, is an orally available, potent and selective inhibitor of IRAK1 and IRAK4 that has been shown preclinically to block inflammatory cytokine production in response to toll-like receptor (TLR) and the 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 a variety of inflammatory conditions. R835 is active in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout. The safety and efficacy of R835 has not been established by the FDA or any healthcare authority.

Conference Call and Webcast with Slides Today at 4:30PM Eastern Time

Rigel will hold a live conference call and webcast today at 4:30pm Eastern Time (1:30pm Pacific Time).

Participants can access the live conference call by dialing (877) 407-8309 (domestic) or (201) 689-8057 (international). The conference call and accompanying slides will also be webcast live and 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 (e.g., rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (e.g., 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 is a registered trademark of 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), the only 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 a Phase 3 study of fostamatinib in autoimmune hemolytic anemia (AIHA) and an ongoing Phase 1 study of R835, a proprietary molecule from its interleukin receptor associated kinase (IRAK) program. In addition, Rigel has product candidates in clinical development with partners BerGenBio ASA, Daiichi Sankyo, Aclaris Therapeutics, and AstraZeneca.

[1] The product for this use or indication is investigational and has not been proven safe or effective by any regulatory authority.

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, Rigel's ability to drive interest in and sales of TAVALISSE; the potential for fostamatinib in ITP to obtain approval in the EU by the end of 2019; expectations related to the market opportunity for ITP; Rigel's ability to broaden its pipeline; and the design, 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," "expect," "anticipate," 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 and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; 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, 2019. 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,	
	2019	2018	2019	2018
	(unaudited)			
Revenues:				
Product sales, net	$ 10,173	$ 1,787	$ 18,227	$ 1,787
Contract revenues from collaborations	234	—	4,804	—
Total revenues	10,407	1,787	23,031	1,787
Costs and expenses:				
Cost of product sales	311	30	418	30
Research and development (see Note A)	13,226	10,797	24,175	22,039
Selling, general and administrative (see Note A)	18,209	17,071	38,155	30,563
Total costs and expenses	31,746	27,898	62,748	52,632
Loss from operations	(21,339)	(26,111)	(39,717)	(50,845)
Interest income	733	554	1,513	903
Net loss	$ (20,606)	$ (25,557)	$ (38,204)	$ (49,942)
Net loss per share, basic and diluted	$ (0.12)	$ (0.16)	$ (0.23)	$ (0.32)
Weighted-average shares used in computing net loss per share, basic and diluted	167,191	161,577	167,182	154,385

Note A

Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,742	$ 779	$ 3,908	$ 1,719
Research and development	911	333	1,698	933
	$ 2,653	$ 1,112	$ 5,606	$ 2,652

SUMMARY BALANCE SHEET DATA
(in thousands)

	June 30, 2019	December 31, 2018 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 112,377	$ 128,537
Total assets	156,158	139,109
Stockholders' equity	78,291	109,877

(1) Derived from audited financial statements

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