May 7, 2019

Rigel Announces First Quarter 2019 Financial Results and Provides Company Update

TAVALISSE® net product sales of $8.1 million on 1,019 bottles, a 10% increase quarter-over-quarter

Total revenues of $12.6 million, including $4.6 million from collaborations

Opened clinical trial sites for Phase 3 study of fostamatinib in warm autoimmune hemolytic anemia (AIHA); expect to enroll first patient this month

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

SOUTH SAN FRANCISCO, Calif., May 7, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq:RIGL), today reported financial results for the first quarter ended March 31, 2019, including sales of TAVALISSE® (fostamatinib disodium hexahydrate), for the treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

"Since the U.S. launch of TAVALISSE one year ago, a growing number of physicians are utilizing our product in earlier lines of therapy and with an increasing number of their chronic ITP patients," stated Raul Rodriguez, president and CEO. "Internationally, the recent collaboration with Grifols in Europe enhances our potential access to a majority of the ex-U.S. ITP market. Meanwhile, our pipeline is expanding with the initiation of our Phase 3 trial in warm autoimmune hemolytic anemia and additional ongoing clinical and research projects."

Financial Update

For the first quarter of 2019, Rigel reported a net loss of $17.6 million, or $0.11 per share, compared to a net loss of $24.4 million, or $0.17 per share, in the same period of 2018.

For the first quarter of 2019, Rigel reported total revenues of $12.6 million, consisting of $8.1 million in net product sales of TAVALISSE and $4.6 million in contract revenues from collaborations. The increase in net product sales of TAVALISSE reflects the continuing growth of its business since commercial launch in May 2018. There were no net product sales nor contract revenues from collaborations in the first quarter of 2018.

Contract revenues from collaborations of $4.6 million during the three months ended March 31, 2019 primarily related to a portion of the $30.0 million upfront fee recognized as revenue upon delivery of license rights to Grifols, S.A. and Rigel's performance of certain research and development services. There were no contract revenues from collaborations during the three months ended March 31, 2018.

Rigel reported total costs and expenses of $31.0 million in the first quarter of 2019, compared to $24.7 million for the same period in 2018. The increase in costs and expense was primarily due to the increases in personnel costs, including its customer-facing and medical affairs teams, and third-party costs to support Rigel's commercialization of TAVALISSE.

As of March 31, 2019, Rigel had cash, cash equivalents and short-term investments of $127.9 million, compared to $128.5 million as of December 31, 2018.

Business Update

- Rigel's launch of TAVALISSE in the U.S. continued to build upon its early success with growth driven by expansion of the prescriber base, steady use of the product as an early treatment option in steroid refractory patients, physicians prescribing to an increased number of patients, and strong reimbursement from the payer community.
- Rigel advanced the regulatory review of fostamatinib in chronic ITP by responding to day-120 questions from the European Medicines Agency (EMA) and remains on track for potential approval in the EU by the end of 2019.
- In January, Rigel entered into a collaboration with Grifols, S.A. for the rights to fostamatinib in all indications in Europe and Turkey enabling a commercial launch preparation well ahead of the anticipated approval date.
- Kissei Pharmaceuticals, Rigel's collaborator in Japan, has initiated discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) to define a path towards fostamatinib approval in Japan.
- In warm AIHA, Rigel opened clinical trial sites for its pivotal Phase 3 clinical study of fostamatinib. The clinical trial protocol calls for approximately 80 patients in a 24-week study with enrollment of the first patient expected this month. Topline trial results are projected in early 2021, positioning fostamatinib to potentially be the first FDA-approved treatment for this indication.
- The company's research and development team continues to investigate potential molecules that modulate the immune system, including R835, Rigel's IRAK 1/4 inhibitor currently in Phase 1 development. In addition, Rigel has four partnered programs that are in Phase 1 and 2 of their clinical development and continue to advance.

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 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 (IL-1R) family receptor 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 855-892-1489 (domestic) or 720-634-2939 (international) and using the Conference ID number 3999559. 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 (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 partnership with Grifols, Kissei and other partnering opportunities across its pipeline; the utility of fostamatinib in other indications, including warm autoimmune hemolytic anemia and other indications; expectations related to the market opportunity for ITP; Rigel's ability to broaden its pipeline; the potential opportunity for fostamatinib to obtain approval in the EU by the end of 2019; 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 Annual Report on Form 10-K for the year ended December 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 March 31,	
	2019	2018
	(unaudited)	
Revenues:		
Product sales, net	$ 8,054	—
Contract revenues from collaborations	4,570	—
Total revenues	12,624	—
Costs and expenses:		
Cost of product sales	107	—
Research and development (see Note A)	10,949	11,242
Selling, general and administrative (see Note A)	19,946	13,492
Total costs and expenses	31,002	24,734
Loss from operations	(18,378)	(24,734)
Interest income	780	349
Net loss	$ (17,598)	$ (24,385)
Net loss per share, basic and diluted	$ (0.11)	$ (0.17)
Weighted-average shares used in computing net loss per share, basic and diluted	167,173	147,114

Note A

Stock-based compensation expense included in:		
Selling, general and administrative	$ 2,166	$ 940
Research and development	787	600
	$ 2,953	$ 1,540

SUMMARY BALANCE SHEET DATA
(in thousands)

	March 31, 2019	December 31, 2018 [1]
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 127,923	$ 128,537
Total assets	172,784	139,109
Stockholders' equity	95,315	109,877

(1) Derived from audited financial statements

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