November 5, 2019

Rigel Announces Third Quarter 2019 Financial Results

Net sales of TAVALISSE® increased 15% quarter over quarter to $11.7 million

Advances development pipeline with new RIP1 inhibitor program initiating a Phase 1 study and positive in-human data from IRAK1/4 inhibitor program

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

SOUTH SAN FRANCISCO, Calif., Nov. 5, 2019 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the third quarter ended September 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.

"We continue to demonstrate progress in all of the key value drivers for Rigel," said Raul Rodriguez, Rigel's president and CEO. "Our commercial business continues to expand with U.S. sales increasing 15% quarter over quarter. We are moving forward with regulatory and collaborative efforts in Europe, Japan, and Canada to potentially make fostamatinib available to ITP patients globally; our Phase 3 trial for fostamatinib in warm autoimmune hemolytic anemia is enrolling; and we have strengthened our pipeline with progress in our IRAK1/4 and RIP1 programs. All of these achievements create valuable opportunities for Rigel both in the near and long term."

Financial Update

For the third quarter of 2019, Rigel reported a net loss of $11.5 million, or $0.07 per share, compared to a net loss of $23.8 million, or $0.14 per share, in the same period of 2018.

For the third quarter of 2019, Rigel reported net product sales from TAVALISSE of $11.7 million, compared to $4.9 million in the same period of 2018. The increase in net product sales reflects the continued expansion of TAVALISSE use since its commercial launch in May 2018.

Contract revenues from collaborations were $9.1 million for the three months ended September 30, 2019, of which $4.0 million related to a development milestone from Aclaris Therapeutics, Inc., $3.8 million related to a commercial launch milestone from Impact Biomedicines, Inc., which was subsequently acquired by Celgene Corp., and $1.3 million from its collaboration agreements with Grifols, S.A. and Kissei Pharmaceutical Co., Ltd. related to performance of certain research and development services. There were no contract revenues from collaborations during the three months ended September 30, 2018.

Rigel reported total costs and expenses of $32.9 million in the third quarter of 2019, compared to $29.2 million for the same period in 2018. The increase in costs and expenses was primarily due to increased research and development costs related to its ongoing Phase 3 study in warm autoimmune hemolytic anemia (AIHA).

For the nine months ended September 30, 2019, Rigel reported a net loss of $49.7 million, or $0.30 per share, compared to a net loss of $73.7 million, or $0.47 per share, for the same period of 2018.

Rigel reported total revenues of $43.9 million for the nine months ended September 30, 2019, compared to $6.7 million for the same period in 2018. Total revenues for the nine months ended September 30, 2019, consisted of $29.9 million in net product sales and $14.0 million in revenues related to Rigel's collaboration agreements with Grifols, S.A., Kissei Pharmaceutical Co., Ltd., Aclaris Therapeutics, Inc., and Impact Biomedicines, Inc. Total revenues for the nine months ended September 30, 2018 consisted of $6.7 million in net product sales.

Total costs and expenses for the nine months ended September 30, 2019, were $95.6 million, compared to $81.9 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 adult chronic ITP, and research and development costs related to its ongoing Phase 3 study in warm AIHA.

As of September 30, 2019, Rigel had cash, cash equivalents and short-term investments of $107.5 million, compared to $128.5 million as of December 31, 2018.

Business Update

- Increased net product sales by 15% to $11.7 million from $10.2 million in the second quarter of 2019.
- Received positive trend vote from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on the Marketing Authorization Application (MAA) for fostamatinib indicated for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments.
- Entered into exclusive license agreements with Medison Pharma to commercialize fostamatinib in Canada and Israel. Rigel received an upfront payment of $5 million, which included an advanced royalty payment, with the potential for approximately $35 million in regulatory and commercial milestones. In addition, Rigel will receive royalty payments beginning at 30% of net sales after credit for the advanced royalty payment is fulfilled.
- Began enrollment of a Phase 3 clinical trial of TAVALISSE in patients with warm

antibody AIHA. Enrollment is expected to complete in mid-2020 with topline results in mid-2021.

- Completed a Phase 1 clinical trial of its IRAK1/4 inhibitor, R835, which showed inhibition of cytokine production in a proof-of-mechanism study done in humans. R835 showed tolerability and a positive PK profile, supporting continued development of the molecule.
- Initiated a Phase 1 clinical trial of R552, a receptor-interacting protein kinase (RIP1) inhibitor. RIP1 is a key driver of necroptosis, a form of cell death that is implicated in a broad range of inflammatory processes.
- Appointed Wolfgang Dummer, MD, PhD to the role of Chief Medical Officer. Dr. Dummer has more than 20 years of clinical and drug development experience with companies such as Genentech, Inc., Biomarin Pharmaceuticals, Inc., and Aridis Pharmaceuticals, Inc., as well as an extensive academic history.

About ITP

In patients with ITP (immune thrombocytopenia), 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 (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 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.

About R552[1]

The investigational candidate, R552, is an orally available, potent and selective inhibitor of receptor-interacting protein kinase (RIP1). RIP1 is believed to play a critical role in necroptosis. Necroptosis is a form of regulated cell death where the rupturing of cells leads to the dispersion of their inner contents, which induces immune responses and enhances inflammation. In preclinical studies, R552 prevented joint and skin inflammation in a RIP1-mediated murine model of inflammation and tissue damage. The safety and efficacy of R552 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) 407-3088 (domestic) or (201) 389-0927 (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 (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 is a 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); a recently completed Phase 1 study of R835, a proprietary molecule from its interleukin receptor associated kinase (IRAK) program; and an ongoing Phase 1 study of R552, a proprietary molecule from its receptor-interacting protein kinase (RIP1) inhibitor program. In addition, Rigel has product candidates in clinical development with partners Aclaris Therapeutics, AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

[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, the commercial success of TAVALISSE in the U.S.; Rigel's ability to broaden its pipeline of assets targeting immune-mediated diseases; Rigel's regulatory and collaborative efforts in Europe, Japan, and Canada to make fostamatinib available to ITP patients globally; the

utility of fostamatinib in other indications, including warm autoimmune hemolytic anemia and other indications; Rigel's ability to achieve development and commercial milestones; the sufficiency of Rigel's cash, cash equivalents and short-term investments and the timing of its current cash runway; 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", "expects", "anticipates", "estimates", "hopes", "believes" 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 June 30, 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.

IR Contact: David Burke
Phone: 650.624.1232
Email: dburke@rigel.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)			
Revenues:				
Product sales, net	$ 11,716	$ 4,865	$ 29,943	$ 6,652
Contract revenues from collaborations	9,141	—	13,945	—
Total revenues	20,857	4,865	43,888	6,652
Costs and expenses:				
Cost of product sales	310	69	728	99
Research and development (see Note A)	14,463	11,097	38,638	33,136
Selling, general and administrative (see Note A)	18,121	18,069	56,276	48,632
Total costs and expenses	32,894	29,235	95,642	81,867
Loss from operations	(12,037)	(24,370)	(51,754)	(75,215)
Interest income	555	604	2,068	1,507
Interest expense	(8)	-	(8)	-
Net loss	$ (11,490)	$ (23,766)	$ (49,694)	$ (73,708)
Net loss per share, basic and diluted	$ (0.07)	$ (0.14)	$ (0.30)	$ (0.47)
Weighted-average shares used in computing net loss per share, basic and diluted	167,609	166,464	167,326	158,456

Note A

Stock-based compensation expense included in:				
Selling, general and administrative	$ 1,611	$ 2,194	$ 5,519	$ 3,913
Research and development	487	801	2,185	1,734
	$ 2,098	$ 2,995	$ 7,704	$ 5,647

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30, 2019	December 31, 2018 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 107,480	$ 128,537
Total assets	156,061	139,109
Stockholders' equity	68,911	109,877

(1) Derived from audited financial statements

View original content to download multimedia:http://www.prnewswire.com/news-releases/rigel-announces-third-quarter-2019-financial-results-300952176.html

SOURCE Rigel Pharmaceuticals, Inc.