November 23, 2020

Rigel and Medison Announce Health Canada Approval of TAVALISSE®, an Oral Medication for the Treatment of Adults with Chronic Immune Thrombocytopenia

SOUTH SAN FRANCISCO, Calif. and PETACH TIKVA, Israel, Nov. 23, 2020 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) and Medison Pharma (Medison) today announced that Health Canada has approved the new drug submission (NDS) for TAVALISSE® (fostamatinib disodium hexahydrate) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to other treatments.

"This approval of TAVALISSE provides ITP patients and physicians in Canada with a new oral treatment option, the only therapy to address the underlying platelet destruction that causes ITP," said Raul Rodriguez, Rigel's president and CEO. "With Medison as our collaborative partner, we believe TAVALISSE is well positioned for commercial success in the Canadian market."

In October 2019, Rigel entered into exclusive license agreements with Medison to commercialize TAVALISSE in Canada and Israel. With the approval from Health Canada, Medison intends to launch TAVALISSE in Canada in Q1 2021. In Israel, a decision on the new drug application (NDA) is anticipated during Q2 2021.

"Our multiregional partnership with Rigel to deliver TAVALISSE in Canada and Israel is a testament to our ongoing efforts to extend the reach of highly innovative therapies to patients across international markets," said Meir Jakobsohn, founder and CEO of Medison Pharma.

"Given our specialization in delivering cutting-edge therapeutics, TAVALISSE is a natural fit for Medison's expertise and will enable us to bring a much-needed treatment option to Canadian ITP patients," said Joe O'Neill, GM of Medison Canada.

Fostamatinib is commercially available in the U.S. under the brand name TAVALISSE® (fostamatinib disodium hexahydrate) tablets, which is the first and only spleen tyrosine kinase (SYK) inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic ITP who have had an insufficient response to a previous treatment.

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 include fatigue, 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. In addition to fostamatinib, 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 Medison Pharma

Medison is one of the world's largest commercial partners of leading global biotech companies. Medison is uniquely qualified to provide the complete spectrum of integrated services for international companies looking to enter or expand their presence in international markets, focusing on Canada, Israel, and Central Eastern Europe. Medison runs a corporate venture arm with a dedicated research and evaluation team boasting deep scientific and commercial backgrounds. Medison also operates a scouting program to cater its partners and is an active investor in life science projects around drug development and digital health. For more information, visit www.medison.co.il and follow Medison on LinkedIn.

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) tablets, 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. The product has been approved by the European Commission for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments and is marketed in Europe under the name TAVLESSE® (fostamatinib).

Fostamatinib[1] is currently being studied in a Phase 3 trial for the treatment of warm autoimmune hemolytic anemia (AIHA); an NIH/NHLBI-Sponsored Phase 2 trial for the treatment of hospitalized COVID-19 patients, in collaboration with Inova Health System; and a Phase 2 trial for the treatment of COVID-19 being conducted by Imperial College London. Additionally, Rigel plans to launch a Phase 3 clinical trial of fostamatinib for the treatment of hospitalized COVID-19 patients in the fourth quarter of 2020.

Rigel's other clinical programs include an ongoing Phase 1 study of R835[1], a proprietary molecule from its interleukin receptor associated kinase (IRAK) inhibitor program, and an ongoing Phase 1 study of R552[1], a proprietary molecule from its receptor-interacting protein kinase (RIP) inhibitor program. In addition, Rigel has product candidates in clinical development with partners AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

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

[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 potential future commercial success of TAVALISSE in the Canadian market, Rigel's ability to receive further payments under the Medison agreement, the timing of a launch of TAVALISSE in Canada, the timing for a decision on the NDA in Israel, and the expansion of the global opportunity for TAVALISSE through more marketing authorizations and launches. 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 "plans," "may," "anticipates," "believe," "expects" 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 fostamatinib in the U.S. and Europe; risks that the FDA, European Medicines Agency (EMA) or other regulatory authorities may make adverse decisions regarding fostamatinib or any of Rigel's product candidates; risks that clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; the availability of resources to develop and, if approved, commercialize fostamatinib or any other of Rigel's product candidates; the progress of our and our collaborators' product development programs, including clinical testing, and the timing of results thereof; our expectations with respect to regulatory submissions and approvals; our research and development expenses; protection of our intellectual property; 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 quarter ended September 30, 2020. In addition, the ongoing COVID-19 pandemic may result in further delays in Rigel's studies and trials, or impact Rigel's sales and ability to obtain supply of fostamatinib. 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.

Medison Contact
Maya Nix
Corporate Communications Lead
Phone: +972.3.925.0260
Email: mayan@medison.co.il

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

View original content to download multimedia:http://www.prnewswire.com/news-releases/rigel-and-medison-announce-health-canada-approval-of-tavalisse-an-oral-medication-for-the-treatment-of-adults-with-chronic-immune-thrombocytopenia-301178615.html

SOURCE Rigel Pharmaceuticals, Inc.; Medison Pharma