



October 1, 2014

IntelGenx and RedHill Biopharma Submit European Marketing Authorization Application for Migraine Drug RIZAPORT(R)

SAINT LAURENT, Quebec, Oct. 1, 2014 (GLOBE NEWSWIRE) -- IntelGenx Corp. (TSX-V:IGX) (OTCQX:IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, today announced, together with RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) ("RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, that they have submitted a Marketing Authorization Application ("MAA") to the German Federal Institute for Drugs and Medical Devices ("BfArM") seeking European marketing approval of their oral thin film formulation of rizatriptan for acute migraines, under the brand name RIZAPORT®. The brand name RIZAPORT® was also conditionally approved by the U.S. Food and Drug Administration ("FDA") as part of the New Drug Application ("NDA") review process in the U.S., subject to a Complete Response Letter ("CRL") received from the FDA in February 2014 and currently under discussions with the FDA.

The MAA was submitted under the European Mutual Recognition Procedure (MRP) with Germany as the reference member state. The submission is supported by several studies, including a recently completed comparative bioavailability study which successfully established the bioequivalence between RIZAPORT® and the European reference drug, Maxalt® Lingua, and follows a positive scientific advice meeting with the BfArM. RIZAPORT® oral thin film does not require the patient to swallow a pill or consume water and presents a potentially attractive therapeutic alternative for many migraine patients, including those who suffer from migraine-related nausea estimated to be approximately 80% of the total migraine patient population¹.

IntelGenx and RedHill previously conducted a successful bioavailability study which demonstrated the required FDA criteria for therapeutic bioequivalence between the RIZAPORT® soluble oral thin film and the U.S. reference drug, Maxalt-MLT®. Following the successful bioequivalence study, IntelGenx and RedHill announced in March 2013 the submission to the FDA and acceptance for review of an NDA seeking marketing approval of the product in the U.S., also under the brand name RIZAPORT®. Following a CRL received from the FDA in February 2014, which raised questions primarily related to Chemistry, Manufacturing and Controls ("CMC"), IntelGenx and RedHill reported that they believe that FDA approval of the RIZAPORT® NDA is subject to the satisfactory resolution of the remaining CMC questions, as well as securing a compliant source of the raw material. Accordingly, the companies continue to work with the FDA in order to address and resolve all remaining CMC questions and to secure a compliant source of the raw material.

"We are very pleased with the submission of a European marketing application for RIZAPORT®, which follows our submission of a U.S. New Drug Application currently under discussions with the FDA," **said Dr. Elkan Gamzu PhD, RedHill's RIZAPORT® Product Manager.** "This regulatory submission in Europe brings us closer to offering a new and potentially advantageous therapeutic alternative for patients suffering from migraines, including those who suffer from migraines with nausea and vomiting. We believe that RIZAPORT® oral thin film's rapid dissolution, pleasant flavoring and ease of use from the ability to administer without water, potentially improves compliance and adherence, and we look forward to making the product available to patients in Europe."

"From a commercial perspective, obtaining marketing authorization in Europe would expand the commercialization of RIZAPORT® into the second largest market of Maxalt®," **said Dr. Horst G. Zerbe, President and CEO of IntelGenx.**

"Pursuing development activities in Europe demonstrates our commitment to bring RIZAPORT® to migraine patients across the world and maximize the value of this asset."

About RIZAPORT®:

RIZAPORT® is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT₁ receptor agonist and the active drug in Merck & Co.'s Maxalt®. Marketing applications for RIZAPORT® have been filed both in the U.S. (NDA filed in March 2013) and in Europe (MAA filed in October 2014). Rizatriptan is considered one of the most effective oral triptans, a class of molecules that constrict blood vessels in the brain to relieve swelling and other migraine symptoms. The worldwide annual sales of triptans were estimated to have exceeded \$1 billion in 2013².

RIZAPORT[®] is based on IntelGenx' proprietary "VersaFilm[™]" technology. RIZAPORT[®] dissolves rapidly and releases its active ingredient in the mouth, leading to an efficient absorption of the drug through the gastro intestinal tract. The administration method of the RIZAPORT[®] oral thin film does not require the patient to swallow a pill or consume water and presents a potentially attractive therapeutic alternative for many migraine patients, including those who suffer from migraine-related nausea estimated to be approximately 80% of the total migraine patient population³.

About IntelGenx:

IntelGenx is a drug delivery company focused on the development of oral controlled-release products as well as novel rapidly disintegrating delivery systems. IntelGenx uses its unique multiple layer delivery system to provide zero-order release of active drugs in the gastrointestinal tract. IntelGenx has also developed novel delivery technologies for the rapid delivery of pharmaceutically active substances in the oral cavity based on its experience with rapidly disintegrating films. IntelGenx' development pipeline includes products for the treatment of indications such as severe depression, hypertension, erectile dysfunction, migraine, insomnia, CNS indications, idiopathic pulmonary fibrosis, oncology and pain, as well as animal health products. More information is available about the company at www.intelgenx.com.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-102** - a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and a planned European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting (iv) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON[®]** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT[®] (formerly RHB-103)** - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit www.redhillbio.com.

¹ Lipton RB, Buse DC, Saiers J, Fanning KM, Serrano D, Reed ML. (2013) Frequency and burden of headache-related nausea: results from the American Migraine Prevalence and Prevention (AMPP) study, Headache. 2013 Jan;53(1):93-103

² EvaluatePharma, 2013 WW annual sales by pharmacological class, 5-HT1B (serotonin) & 5HT1D (serotonin) agonist

³ Lipton RB, Buse DC, Saiers J, Fanning KM, Serrano D, Reed ML. (2013) Frequency and burden of headache-related nausea: results from the American Migraine Prevalence and Prevention (AMPP) study, Headache. 2013 Jan;53(1):93-103

Forward Looking Statements:

This document may contain forward-looking information about IntelGenx' operating results and business prospects that involve substantial risks and uncertainties. Statements that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These statements include, but are not limited to, statements about IntelGenx' plans, objectives, expectations, strategies, intentions or other characterizations of future events or circumstances and are generally identified by the words "may," "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "could," "would," and similar expressions. All forward looking statements are expressly qualified in their entirety by this cautionary statement. Because these forward-looking statements are subject to a number of risks and uncertainties, IntelGenx' actual results could differ materially from those expressed or implied by these forward looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the heading "Risk Factors" in IntelGenx' annual report on Form 10-K for the fiscal year ended December 31, 2013, filed with the United States Securities and Exchange Commission and available at www.sec.gov, and also filed with Canadian securities regulatory authorities and www.sedar.com. IntelGenx assumes no obligation to update any such forward-looking statements.

Each of the TSX Venture Exchange and OTCQX has neither approved nor disapproved the contents of this press release.

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Source: IntelGenx Corp.

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