



May 21, 2014

IntelGenx and RedHill Biopharma Report Positive Bioavailability Study Results in Support of Planned European Marketing Application in Q3/2014 for Anti-Migraine VersaFilm(TM) Product

SAINT LAURENT, Quebec, May 21, 2014 (GLOBE NEWSWIRE) -- IntelGenx Corp. (TSX-V:IGX) (OTCQX:IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, today reported, together with RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) ("RedHill"), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage proprietary drugs, positive results from a comparative bioavailability study with their anti-migraine VersaFilm™ product, an oral thin film formulation of rizatriptan for acute migraines. The study compared the anti-migraine VersaFilm™ product to the European reference drug Maxalt® lingua, marketed in Germany by MSD SHARP & DOHME GMBH, to support the planned submission of a European Marketing Authorization Application ("MAA") for the anti-migraine VersaFilm™ product during the third quarter of 2014.

The results of the study are subject to final quality assurance and an independent study report by the Canadian clinical research organization ("CRO") that conducted the study. The final independent report from the CRO is expected in the coming weeks.

The single-dose, crossover, comparative bioavailability study conducted in Canada followed a positive scientific advice meeting with the German Federal Institute for Drugs and Medical Devices (BfArM) previously announced by RedHill in November 2013. The study, which included 26 healthy volunteers, established the bioequivalence of the anti-migraine VersaFilm™ product and the European reference drug, Maxalt® lingua.

In light of the positive results from the bioavailability study and data from prior clinical studies conducted with the anti-migraine VersaFilm™ product, and subject to various regulatory requirements, IntelGenx and RedHill plan to submit a European MAA during the third quarter of 2014.

IntelGenx and RedHill previously conducted a successful bioavailability study which demonstrated the required U.S. Food and Drug Administration ("FDA") criteria for therapeutic bioequivalence between the anti-migraine VersaFilm™ soluble oral thin film product and the U.S. reference drug, Maxalt-MLT®. Following the successful bioequivalence study, IntelGenx and RedHill announced in 2013 the submission to the FDA and acceptance for review of a New Drug Application ("NDA") seeking marketing approval of the anti-migraine VersaFilm™ product. Following a Complete Response Letter received from the FDA in February 2014, which raised questions primarily related to Chemistry, Manufacturing and Controls ("CMC"), IntelGenx and RedHill recently reported that they believe that FDA approval of the anti-migraine VersaFilm™ product 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.

About the VersaFilm™ Oral Film Product:

The product is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT₁ receptor agonist and the active drug in Merck & Co.'s Maxalt®. 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 2013¹.

The product is based on IntelGenx' proprietary "VersaFilm™" technology. It dissolves rapidly in the mouth, leading to the absorption of the drug through the gastro intestinal track and into the bloodstream. The administration method of the 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 at approximately 80% of the total migraine patient population².

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 primarily on the development and acquisition of late clinical-stage, proprietary formulations and combinations of existing drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer and related conditions. 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 Helicobacter pylori infection, with an ongoing Phase III study; (iii) RHB-106 - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals Ltd.; (iv) RHB-103 - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned to be filed during Q3, 2014; (v) RHB-102 - a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting, in advanced development stages for multiple indications and, (vi) RHB-101 - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit: www.redhillbio.com

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.

¹ EvaluatePharma, 2013, WW annual sales by pharmacological class, 5-HT1B (serotonin) & 5HT1D (serotonin) agonist

² [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. doi: 10.1111/j.1526-4610.2012.02292.x. Epub 2012 Nov 13

CONTACT: Dr. Rajiv Khosla

President and CEO

IntelGenx Corp.

T: +1 514-331-7440

F: +1 514-331-0436

www.intelgenx.com

Source: IntelGenx Corp.

News Provided by Acquire Media