April 28, 2014

RedHill Biopharma and IntelGenx Announce Commencement of a Bioavailability Study With RHB-103 (Migraine) to Support European Marketing Application Planned for Q3/2014

TEL-AVIV, Israel, April 28, 2014 (GLOBE NEWSWIRE) -- 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, together with IntelGenx Corp. (TSXV:IGX) (OTCQX:IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, today announced the commencement of a comparative bioavailability clinical study comparing RHB-103 to the European reference drug. The study is intended to support the planned submission of a European Marketing Authorization Application ("MAA") for RHB-103, a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraines.

The comparative bioavailability study follows a positive scientific advice meeting with the German Federal Institute for Drugs and Medical Devices ("BfArM") announced by RedHill in November 2013. This single-dose, crossover, comparative bioavailability study includes 26 healthy volunteers and is intended to evaluate and compare the relative bioavailability and to assess the bioequivalence of RHB-103 and the reference drug, Maxalt® lingua, marketed in Germany by MSD SHARP & DOHME GMBH.

Results of the bioavailability study are anticipated by June 2014. Subject to the results of the study and to the required regulatory process, and in light of the data from prior successful studies conducted with RHB-103, RedHill and IntelGenx plan to submit a European MAA in the third quarter of 2014, with Germany as the reference member state, under the European Mutual Recognition Procedure ("MRP").

RedHill and IntelGenx previously conducted a successful bioavailability study which demonstrated the required U.S. Food and Drug Administration ("FDA") criteria for therapeutic bioequivalence between the RHB-103 soluble oral thin film and the U.S. reference drug, Maxalt-MLT®. Following the successful bioequivalence study, RedHill and IntelGenx announced in 2013 the submission to the FDA and acceptance for review of a New Drug Application ("NDA") seeking marketing approval of RHB-103. Following a Complete Response Letter ("CRL") received from the FDA in February 2014, which raised questions primarily related to Chemistry, Manufacturing and Controls ("CMC"), RedHill and IntelGenx recently reported that they believe that FDA approval of the RHB-103 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 RHB-103:

RHB-103 is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT_1 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 2013[1].

RHB-103 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 RHB-103 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 population[2].

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; (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.

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.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; (iv) the clinical development, commercialization, and market acceptance of the Company's therapeutic candidates; (v) the Company's ability to establish and maintain corporate collaborations; (vi) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi) competitive companies, technologies and the Company's industry. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on February 25, 2014. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

[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: Adi Frish

Senior VP Business Development & Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

PR contact (U.S.):

Lauren Glaser

Vice President

The Trout Group

+1-646-378-2972

lglaser@troutgroup.com

Source: RedHill Biopharma Ltd.

News Provided by Acquire Media