August 13, 2014

RedHill Biopharma Acquires Option for Phase II Pancreatic Cancer Drug RP101

- **Potentially expanding its gastrointestinal-focused pipeline, RedHill has secured an option to acquire RP101 from Dresden-based RESprotect GmbH, a spin-off from the Fraunhofer-Society**
- **RP101 has completed several Phase I and Phase II clinical studies**
- **RP101 has been granted Orphan Drug designation for the adjunct treatment of pancreatic cancer by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)**

TEL-AVIV, Israel, Aug. 13, 2014 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) (the "Company" or "RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, and RESprotect GmbH ("RESprotect"), a privately-held biotech company located in Dresden, Germany, today announced that they have entered into a binding exclusive option agreement for the acquisition of the oncology drug candidate RP101 and next generation compounds. RP101 is a proprietary, first-in-class, heat shock protein 27 (Hsp27) inhibitor, administered orally, which may prevent the induction of resistance to chemotherapy (chemoresistance), thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival.

Under the terms of the agreement, RedHill has the option to acquire the worldwide exclusive rights to RP101 for all indications, other than to the pancreatic cancer indication in South Korea. RedHill has agreed to pay RESprotect for a one year option, which may be extended by RedHill under certain agreed terms. During the option period, RedHill may, at its discretion, conduct development activities with RP101. If RedHill elects to exercise the option, it will acquire the exclusive rights to RP101 for a total payment, for both the option and the acquisition of the rights, of $100,000, as well as potential milestone payments and tiered royalties on net revenues, ranging from single-digit to mid-teens.

RP101 is an orally administered, patent-protected small molecule which binds to Hsp27, a chaperone protein which is found in abnormally high levels in cancer cells, and inhibits its activity. The overexpression of Hsp27, which results in the amplification of a multidrug-resistance (MDR) gene, has been linked to tumor resistance to cytotoxic drugs and the development of metastasis. Chemoresistance limits the effectiveness of chemotherapy and can ultimately lead to treatment failure. By inhibiting Hsp27, RP101 may prevent chemoresistance and enhance the sensitivity of tumors to chemotherapy. RP101 is based on a new mechanism of action of the anti-viral drug brivudine, a nucleoside analogue approved and marketed in several European countries for the treatment of herpes zoster. RP101 has completed several clinical studies, including Phase II studies in pancreatic cancer. RP101 has been granted Orphan Drug designation for the adjunct treatment of pancreatic cancer by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Dror Ben-Asher, RedHill's CEO, said: "Today's acquisition of an option for the Hsp27 inhibitor RP101 reflects RedHill's increasing strategic focus on new, clinical-stage, orally-administered treatments for patients suffering from gastrointestinal and inflammatory diseases, including pancreatic cancer and other gastrointestinal cancers, where there is a particularly strong need for better therapeutic options. Across several clinical studies, pancreatic cancer patients co-treated with RP101 and one or more chemotherapy agents were found to have longer overall survival than historical control pancreatic cancer patients treated with chemotherapy alone. In a randomized, placebo-controlled Phase II pancreatic cancer study, median overall survival was longer in patients receiving chemotherapy plus RP101 than in those receiving chemotherapy plus placebo in a subset of patients with high body surface area in the U.S. A scientific advice meeting with Germany's BfArM provided a possible pathway forward for the development of RP101." **Mr. Ben-Asher added:** "there are many government and other research and development grants available for gastrointestinal cancers and specifically for pancreatic cancer which we could potentially pursue, and there is also potential for regulatory designation of RP101 as an expedited program for a serious condition and unmet medical need. We are looking forward to exploring further development of RP101 with our new partners at RESprotect."

Prof. Rudolf Fahrig, RESprotect's CEO said: "We are delighted to sign this option agreement with RedHill Biopharma and look forward to work with our new partners at RedHill on the development of RP101."

About RP101:

RP101, invented by Prof. Rudolf Fahrig at the Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM) in Hannover, Germany, is an orally administered, patent-protected small molecule which binds to heat shock protein 27 (Hsp27) and inhibits its multidrug-resistance gene amplification activity. Hsp27 is a chaperone protein which is found in abnormally high levels in cancer cells and plays a key role in the development of therapy resistance and metastases. By inhibiting Hsp27, RP101 may prevent the induction of resistance to chemotherapy (chemoresistance) and maintain sensitivity of tumors to chemotherapy, thus potentially enhancing patient survival. RP101 has completed several Phase I and Phase II clinical studies

with a total of 249 subjects treated, including Phase II studies in pancreatic cancer. RP101 has been granted Orphan Drug designation for the adjunct treatment of pancreatic cancer by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 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 *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-102 -** a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting in advanced stages of development for multiple indications, including a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting planned for the third quarter of 2014. In addition, a Phase III study for an undisclosed indication is planned to commence in the third quarter of 2014, (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) **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 for the third quarter of 2014; and (viii) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit www.redhillbio.com

About RESprotect:

RESprotect GmbH is a Dresden-based, privately-held biotech company specializing in the development of drugs for the prevention and treatment of chemotherapeutic drug resistance and radiation therapy resistance. For more information, please visit www.resprotect.de

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.

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Source: RedHill Biopharma Ltd.