



Press Release

RedHill Biopharma Announces Collaboration with Germany's Fraunhofer Institute for Oncology Drug RP101

TEL-AVIV, Israel, February 8, 2016 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) (“RedHill” or the “Company”), an Israeli biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced a research collaboration with Leipzig-based Fraunhofer Institute for Cell Therapy and Immunology (IZI), a research unit of the Fraunhofer Society, one of the largest and most prominent applied research organizations in the world, for the evaluation of RedHill’s Phase II-stage oncology drug candidate, RP101.

The research collaboration tests RP101 in pre-clinical oncology models, including pancreatic cancer, in combination with standard-of-care chemotherapies to support existing Phase I and Phase II clinical data. RP101 is a proprietary, first-in-class, orally-administered, heat shock protein 27 (Hsp27) inhibitor intended to prevent the induction of resistance to chemotherapy (chemoresistance), thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival. RP101 has completed several clinical studies, including a Phase II study in pancreatic cancer and 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).

As part of the collaboration, Fraunhofer IZI is conducting real-time monitoring of tumor engraftment, tumoricidal efficacy, and response to treatment with RP101 in combination with standard-of-care chemotherapies. Results from the studies are expected during the first half of 2016. The preclinical program is intended to support the existing Phase I and Phase II clinical data with RP101 and to assess the drug’s clinical development path.

In August 2014, RedHill entered into an exclusive option agreement with RESprotect GmbH, a privately-held Germany-based biotech company, under which RedHill obtained the option to acquire the worldwide exclusive rights to RP101 for all indications, other than for the pancreatic cancer indication in South Korea. RedHill announced in July 2015 that it had extended the term of the exclusive option agreement for an additional year.

About RP101:

RP101 is a nucleoside analogue found by Prof. Rudolf Fahrig at the Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM) in Hannover, Germany, to inhibit

development of chemoresistance in various cancer models. It is an orally-administered, patent-protected small molecule which binds to heat shock protein 27 (Hsp27) and inhibits its anti-apoptotic effects. Hsp27 is a chaperone protein which is found in abnormally high levels in cancer cells. The overexpression of Hsp27, which results in anti-apoptotic effects, has been linked to tumor resistance to cytotoxic drugs and the development of metastasis. 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 been studied in several Phase I and Phase II clinical studies with a total of 249 subjects treated, including a Phase II study 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/TASE: RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful top-line results from a first Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study; (iii) **BEKINDA™ (RHB-102)** - a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis; (iv) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640)** - an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103)** - an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol.

About Fraunhofer IZI:

The Fraunhofer Institute for Cell Therapy and Immunology IZI investigates and develops specific problem solutions at the interfaces of medicine, life sciences and engineering. The Institute practices contract research for biotechnological, pharmaceutical and medical-technological companies, hospitals, diagnostic laboratories and research facilities. The Institute's core competencies are located in the field of Regenerative Medicine, in particular in the indication areas of oncology, ischemia and autoimmune, inflammatory and infectious diseases. The Institute is clinically oriented and conducts quality checks and the GMP-compliant manufacture of investigational medicinal products. Moreover, the Institute

provides support in obtaining manufacturing authorizations and approvals.
www.izi.fraunhofer.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 research, manufacturing, 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, approvals and feedback; (iv) the manufacturing, 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 research, 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; (xi) competitive companies and technologies within the Company’s industry; and (xii) the impact of the political and security situation in Israel on the Company’s business. 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 26, 2015. 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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