



RedHill Biopharma Regains Rights to its Proprietary Bowel Preparation RHB-106

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TEL-AVIV, Israel and RALEIGH, N.C., Jan. 02, 2020 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](#) (Nasdaq: [RDHL](#)) (Tel-Aviv Stock Exchange: [RDHL](#)) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases, today announced that it has provided Salix Pharmaceuticals Ltd. (Salix) with a notice of termination of their 2014 license agreement and has regained the worldwide exclusive rights to RHB-106, a proprietary encapsulated formulation for bowel preparation, currently under development.

"We are pleased to regain the rights to RHB-106, which aligns well with our expanded gastrointestinal-focused commercial activities in the U.S., and to pursue its development toward potential U.S. FDA approval," said **Dror Ben-Asher, RedHill's CEO**. "The quality of a bowel preparation, defined by its safety, palatability and efficacy, directly impacts the success of a colonoscopy. We believe RHB-106's novel flavorless solid oral pill formulation holds significant potential advantages over current bowel preparations and could ease patient burden and improve the likelihood of a successful outcome."

It is estimated that approximately 19 million colonoscopies are performed annually in the U.S.¹ The annual number of procedures in the U.S. is increasing, presumably due to the rising awareness of colorectal cancer. The 2019 sales of bowel preparations in the U.S. are estimated at approximately \$580 million².

About RHB-106

RHB-106 is a proprietary, flavorless, odorless, solid oral encapsulated formulation intended for the preparation and cleansing of the gastrointestinal tract prior to the performance of abdominal procedures and diagnostic tests, such as colonoscopies, barium enemas or virtual colonoscopies, as well as surgical interventions, such as laparotomies. RHB-106 can be taken with water and avoids patient exposure to the often unpalatable taste of current products. A Phase 2a study with a previous formulation of the RHB-106 actives was concluded in Australia with 62 patients demonstrating significantly improved patient response and comparable bowel cleansing, potentially allowing for an unobstructed procedure with reduced side-effects and improved compliance.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: [RDHL](#)) (Tel-Aviv Stock Exchange: [RDHL](#)) is a specialty biopharmaceutical company, primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S., **Aemcolo**[®], **Donnatal**[®], **EnteraGam**[®], and **Mytesi**[®], and is planning to launch **Talicia**[®] in the U.S. for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults³. RedHill's key clinical late-stage development programs include: (i) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102 (Bekinda**[®]), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **ABC294640 (Yeliva**[®]), a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation, and (vi) **RHB-107**, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at www.redhillbio.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 related to the commencement or timing of our clinical trials with RHB-106, as well as 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, and the timing of the commercial launch of its therapeutic candidates and its FDA-approved products; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (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 and Talicia[®]; (v) the Company's ability to successfully commercialize and promote Talicia[®], Aemcolo[®], Donnatal[®], EnteraGam[®] and Mytesi[®]; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. 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,

2019, as amended on May 15, 2019. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise unless required by law.

¹iDATA Research, August 2018

²Foster-Rosenblatt, December 2019

³For full prescribing information see: Aemcolo[®]: www.Aemcolo.com; Mytesi[®]: www.Mytesi.com; EnteraGam[®] <https://bit.ly/2N3q7DW>; Talicia[®]: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213004lbl.pdf.

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