Press Release

RedHill Biopharma Elaborates on Its Announced Positive Top-Line Results from Phase III Study of RHB-104 in Crohn's Disease

TEL-AVIV, Israel / RALEIGH, N.C., August 1, 2018 -- RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal (GI) diseases, today elaborated on the previously announced positive top-line results from the first Phase III study with orally-administered RHB-104 for Crohn's disease (the MAP US study).

"Based on the feedback from our shareholders, stakeholders and other market participants, we believe certain aspects of our MAP US Phase III study top-line results may not have been sufficiently clear, particularly in relation to the secondary endpoint of standalone week 52 remission. Therefore, we believe it is necessary to provide the following supporting context around the very strong data achieved in our Phase III study and its positive impact on our development path towards potential approval of RHB-104," **said Dror Ben-Asher, RedHill's CEO.**

The Company reiterates that its MAP US first Phase III study with RHB-104 successfully met its primary endpoint, as well as key secondary endpoints, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104.

The MAP US Phase III study was designed and powered to investigate the ability of RHB-104 to induce remission in Crohn's disease patients at week 26. This primary endpoint showed a clinically meaningful benefit with significantly greater remission in the RHB-104 group compared to placebo at week 26 (37% vs. 23%, p= 0.013). Moreover, while the secondary endpoints were not powered for significance in this induction of remission trial, key secondary endpoints were nevertheless met with statistically and clinically meaningful outcomes, including early remission at week 16 (42% vs. 29%, p= 0.019). The study achieved its primary objectives - demonstrating the efficacy and safety of RHB-104 in the induction of remission in Crohn's disease.

Importantly, the MAP US Phase III study results for week 26 and week 16 induction of remission are comparable to those of leading standard-of-care therapies, as shown in the table below, further supporting its potential to be a novel orally-administered treatment option in Crohn's disease[1]:

[1] The comparison to standard-of-care should not be construed as a direct and/or equal comparison given that studies were not identical in design, patient population and treatment period and were not conducted head-to-head. These studies utilized re-randomization of responders and MAP US study was a treat-through study.

Study	Administration	Endpoint	Placebo	Active Drug	Treatment Effect
RedHill's RHB-104 MAP US	Oral	Remission at week 26	23% (38/165)	37% (61/166)	14%
RedHill's RHB-104 MAP US	Oral	Remission at week 16	29% (48/165)	42% (73/166)	13%
Vedolizumab (Entyvio ®) CD1	Intravenous	Remission at week 6	7% (10/148)	15% (32/220)	8%
Vedolizumab (Entyvio®) CD2	Intravenous	Remission at week 6	12% (19/157)	15% (24/158)	3%
Adalimumab (Humira®) CD1	Subcutaneous	Remission at week 4	12% (9/74)	36% (27/76)	24%
Adalimumab (Humira®) CD2	Subcutaneous	Remission at week 4	7% (12/166)	21% (33/159)	14%
Ustekinumab (Stelara®) CD1	Subcutaneous	Remission at week 8	7% (18/247)	21% (52/249)	14%
Ustekinumab (Stelara®) CD2	Subcutaneous	Remission at week 8	20% (41/209)	40% (84/209)	21%

Regarding the standalone week 52 remission secondary endpoint, we believe there may have been some confusion. The standalone week 52 remission endpoint measures "late induction of remission" and does not evaluate preservation of remission over time. As such, this specific endpoint is neither a clinical nor a regulatory relevant endpoint. The standalone week 52 remission secondary endpoint was merely included by RedHill in the study to investigate whether certain individual patients might require more than 26 weeks of therapy for initial induction of remission. Accordingly, the analysis of standalone week 52 remission is an isolated exploratory outcome.

To emphasize, the clinically and regulatory relevant endpoint pertaining to week 52 is "maintenance of remission", which by definition evaluates the maintenance (preservation) of remission from the induction of remission or response at an earlier time point to week 52. This "maintenance of remission" endpoint, in conjunction with a separate early "induction of remission" endpoint, has served as the basis for approval of current standard-of-care therapies for Crohn's disease. In this endpoint, maintenance of remission from the induction of remission at week 16 to week 52, RHB-104 was twice as effective as placebo with high statistical significance (25% vs. 12%, RHB-104 and placebo, respectively, p= 0.007).

These MAP US Phase III results compare favorably to the data for maintenance of remission from other trials with standard-of-care therapies when analyzed similarly and calculated on the basis of the entire study population, rather than from the selected population that earlier achieved induction of response, as demonstrated in the following table:

Drug	Induction of Response or Remission	Maintenance of Remission (in responders)	Calculated Maintenance of Remission*[2]
RedHill's RHB-104	42% (week 16)[3]	59% (week 52) [4]	**25% (week 52)**
Infliximab (Remicade®)	57% (week 2)	39% (week 30)	**22% (week 30)**
Adalimumab (Humira®)	58% (week 4)	36% (week 56)	**21% (week 56)**
Ustekinumab (Stelara®)	48% (week 8)	53% (week 52)	**25% (week 52)**
Vedolizumab (Entyvio®)	31% (week 6)	39% (week 52)	**12% (week 52)**

* The percent of subjects in remission at end of study out of all patients enrolled, whether or not response or remission was achieved in a lead-in induction phase or trial. The Calculated Maintenance of Remission equals the percentage of patients who achieved Induction of Response or Remission multiplied by the percentage of patients who achieved Maintenance of Remission in responders.

The MAP US study also demonstrated that RHB-104 was twice as effective as placebo even in the more rigorous endpoint of durable remission defined as 100% remission from early remission at week 16 through weeks 20, 26, 35, and 44 and study completion at week 52 (18% vs. 9%, p= 0.038).

M. Scott Harris, M.D.[5], Adjunct Professor of Medicine, Georgetown University School of Medicine, Principal, Middleburg Consultants, stated: "The positive results of RedHill's MAP US study certainly met my expectations. The standalone week 52 remission endpoint must be considered exploratory and should not be expected to play any role in the future development of RHB-104 towards approval. The MAP US study was designed as an induction of remission and not as a maintenance of remission trial. Nonetheless, there are clear signs from the data that the drug is also effective for the maintenance of remission in Crohn's disease which could be confirmed in a future trial. This orally administered drug under development showed significant clinical benefit to Crohn's patients in need of new therapeutic options and I look forward to its addition to the Crohn's disease treatment armamentarium."

Ira Kalfus, M.D., RedHill's medical director, said: "The successful induction of remission at week 16 and week 26, coupled with the positive maintenance of remission and durable remission results from week 16 to 52 in our MAP US study, are very promising and provide RedHill with an excellent opportunity to pursue further development and potential approval of RHB-104 in Crohn's disease with an early week 16 induction of remission to week 52 maintenance endpoint. We look forward to discussing the results of the MAP US study and the path for approval with the FDA."

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[2] The comparison to standard-of-care should not be construed as a direct and/or equal comparison given that studies were not identical in design, patient population and treatment period and were not conducted head-to-head. These studies utilized re-randomization of responders and MAP US study was a treat-through study. Calculated Maintenance of Remission figures are based on the Company's calculations derived from individual product prescriber information. Data from standard-of-care therapies may be derived from different studies conducted per each therapy.

[3] Induction of remission.

[4] Company calculation from study data.

[5] Member of RedHill's Advisory Board and Consultant

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes four gastrointestinal products in the U.S.: **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi®** - an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg** - a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions, and **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104,** with positive top-line results from a first Phase III study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102),** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (v) **YELIVA® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107 (formerly MESUPRON),** a Phase II-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, 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 Company's reliance on third parties to conduct key portions of its clinical trials, including data management services, and the potential for those third parties to not perform satisfactorily; (iv) 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; (v) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates; (vi) the Company's ability to successfully promote Donnatal® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam®; (vii) 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; (ix) 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; (x) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (xi) 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; (xii) parties from whom the Company licenses its intellectual

property defaulting in their obligations to the Company; (xiii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (iv) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other companies and technologies within 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 22, 2018. 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.

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