March 2, 2015

Positive Bioavailability Studies of RedHill's BEKINDA(TM) to be Presented at the 2015 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Meeting

- **The results from two positive bioavailability studies, previously reported by the Company, demonstrate the safety and tolerability of BEKINDA™ and support the European marketing application submitted for BEKINDA™ and the planned submission of a U.S. New Drug Application (NDA) for oncology support**
- **A European Marketing Authorization Application (MAA) for BEKINDA™ for oncology support is currently under review by the UK MHRA, with feedback expected during H2/2015**
- **Top-line results from the ongoing Phase III study with BEKINDA™ (RHB-102) for acute gastroenteritis and gastritis (the GUARD study) are expected in Q4/2015**

TEL-AVIV, Israel, March 2, 2015 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) ("RedHill"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today reported the presentation of two posters at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2015 Annual Meeting, to be held between March 3-7, 2015 in New Orleans. The posters describe two previously reported comparative bioavailability studies for BEKINDA™ (RHB-102), a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron. RedHill is developing BEKINDA™ for the indications of gastroenteritis and gastritis as well as chemotherapy and radiotherapy-induced nausea and vomiting. The posters will be presented at the ASCPT meeting by the Canadian Contract Research Organization (CRO) who conducted the bioavailability studies for RedHill.

The first study compared the plasma levels of the active ingredient ondansetron after a dose of BEKINDA™ versus FDA-approved regimens of either Zofran® (ondansetron immediate release tablets) 8 mg given twice daily or as a single 24 mg dose (3 tablets). The randomized, crossover study in 18 healthy volunteers also assessed the accumulation of ondansetron in plasma after administering five consecutive daily doses of BEKINDA™ under fasting conditions, as well as the safety and tolerability of BEKINDA™. The results of the study demonstrated that the plasma levels of ondansetron after BEKINDA™ were similar or higher than the plasma levels after Zofran® 8 mg b.i.d, thus indicating that the efficacy of BEKINDA™ is at least as good as Zofran® 8 mg b.i.d. The study further demonstrated that the safety and tolerability of BEKINDA™ were similar to the safety profile of the FDA-approved regimens of ondansetron.

The second comparative bioavailability study evaluated the influence of food on the pharmacokinetics of BEKINDA™ in healthy volunteers. The randomized, crossover study demonstrated that, consistent with the commercially available Zofran® 8 mg immediate-release formulation, food delayed the absorption of BEKINDA™ and increased the maximal concentrations and extent of absorption of the ondansetron. Despite these increases, which are not expected to have clinical significance, the number and severity of adverse events were lower under fed conditions.

RedHill submitted a European Marketing Authorization Application (MAA) to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) in December 2014 seeking approval of BEKINDA™ for the indications of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively). The MAA was validated by the MHRA and RedHill expects to receive feedback during the second half of 2015. RedHill is also pursuing marketing approval for BEKINDA™ in the U.S. for CINV prevention. Following a pre-NDA with the FDA, and in light of the FDA's feedback, RedHill intends to use post-marketing data, along with data generated from prior studies, to further support a potential New Drug Application (NDA) in the U.S.

RedHill is pursuing an additional indication for BEKINDA™, as a treatment for acute gastroenteritis and gastritis - inflammations of the gastrointestinal tract which cause, among other symptoms, nausea and vomiting. A Phase III clinical study with BEKINDA™ is ongoing in the U.S. for this indication (the GUARD study), with top-line data expected during the fourth quarter of 2015. If approved for marketing for the treatment of acute gastroenteritis and gastritis, BEKINDA™ could become the first-ever 5-HT3 antiemetic drug approved for this indication, targeting an annual potential worldwide market estimated to exceed $650 million[1].

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing 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 a Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 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) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit 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 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; 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 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.

[1] Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727-741 and Company analysis.

CONTACT: Company contact:

Adi Frish

Senior VP Business Development & Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

IR contact (U.S.):

Lauren Kwiecinski

Vice President

The Trout Group

+1-646-378-2934

lkwiecinski@troutgroup.com

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