



## Press Release

### **RedHill Biopharma Announces Settlement of Movantik® Patent Litigation with Aurobindo**

*The settlement agreement with Aurobindo brings closure to all presently pending Movantik® patent litigation brought pursuant to The Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act)*

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*The earliest licensed entry date of any generic naloxegol in the U.S. is October 1, 2030*

**TEL AVIV, Israel and RALEIGH, NC, September 23, 2021,** [RedHill Biopharma Ltd.](#) (Nasdaq: [RDHL](#)) (“RedHill” or the “Company”), a specialty biopharmaceutical company, today announced that RedHill Biopharma Inc., AstraZeneca AB and AstraZeneca Pharmaceuticals LP (“AstraZeneca”) and Nektar Therapeutics have entered into a settlement and license agreement with Aurobindo Pharma USA, Inc. resolving their patent litigation in the U.S. in response to Aurobindo’s Abbreviated New Drug Application (“ANDA”) seeking approval by the U.S. Food and Drug Administration (“FDA”) to market a generic version of Movantik® (naloxegol).

RedHill acquired from AstraZeneca in April 2020 the global rights to Movantik, excluding Europe and Canada.

Under the terms of the settlement agreement, Aurobindo may not sell a generic version of Movantik in the U.S. until April 1, 2031 (subject to U.S. FDA approval) or earlier under certain circumstances.

The parties to the settlement agreement have also agreed to file a stipulation and order of dismissal with the U.S. District Court for the District of Delaware which will conclude this litigation with respect to Aurobindo. As required by law, the parties will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. Upon entry of the stipulation and order of dismissal, this settlement agreement will conclude all Hatch-Waxman Act

patent litigation brought to date against ANDA filers prior to the expiration of the patents listed in the Orange Book.

### **About RedHill Biopharma**

RedHill Biopharma Ltd. (Nasdaq: [RDHL](#)) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs, **Movantik®** for opioid-induced constipation in adults<sup>1</sup>, **Talicia®** for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults<sup>2</sup>, and **Aemcolo®** for the treatment of travelers' diarrhea in adults<sup>3</sup>. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (ABC294640)**, a first-in-class oral SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and Phase 2 studies for prostate cancer and cholangiocarcinoma ongoing; (iii) **RHB-107 (upamostat)**, an oral serine protease inhibitor in a U.S. Phase 2/3 study as treatment for symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (v) **RHB-102**, with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at [www.redhillbio.com](http://www.redhillbio.com) / <https://twitter.com/RedHillBio>.

*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 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 commercial products and ones it may acquire or develop in the future; (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 and type 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 risk that the Company will not succeed to complete the patient recruitment; the risk that the Company will not receive the relevant data required for benefiting from the Fast Track designation; the risk that the U.S. Phase 3 clinical study evaluating RHB-204 will not be successful or, if successful, will not suffice for regulatory marketing approval without the need for additional clinical and/or other studies; (v) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and*

*Talicia®; (vi) the Company's ability to successfully commercialize and promote Movantik®, Talicia® and Aemcolo®; (vii) the Company's ability to establish and maintain corporate collaborations; (viii) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build and sustain 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 commercial products 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; (xiv) the effect of patients suffering adverse events using investigative drugs under the Company's Expanded Access Program; and (xv) 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 March 18, 2021. 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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<sup>1</sup> Full prescribing information for Movantik® (naloxegol) is available at: [www.Movantik.com](http://www.Movantik.com).

<sup>2</sup> Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: [www.Talicia.com](http://www.Talicia.com).

<sup>3</sup> Full prescribing information for Aemcolo® (rifamycin) is available at: [www.Aemcolo.com](http://www.Aemcolo.com).