



NEWS RELEASE

\$2.9 Million NCI Grant Awarded for Clinical Development of RedHill's Opaganib and CAR T-Cell Combination in Ultra-High-Risk Multiple Myeloma

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TEL AVIV, Israel and RALEIGH, N.C., Oct. 19, 2026 /PRNewswire/ -- RedHill Biopharma Ltd. (Nasdaq: **RDHL**) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that its partner, the University of Oklahoma (OU), has received \$2.9 million in funding from the National Cancer Institute (NCI) to study, in clinical trials, whether RedHill's opaganib[1], given after CAR (chimeric antigen receptor) T-cell therapy, may help immune cells fight cancer more effectively.

The five-year, \$2.9 million grant from the NCI is planned to fund two phases of clinical trials. A Phase 1b trial plans to enroll up to 18 patients to evaluate the safety of the treatment combination of CAR T-cell therapy and opaganib and determine the appropriate dosage of opaganib. A subsequent Phase 2 trial plans to enroll up to 21 additional patients to seek preliminary evidence of effectiveness.

CAR T-cell therapy takes a patient's immune cells, genetically modifies them so they can recognize and attack cancer cells, and then returns them to the patient. In a first for Oklahoma, the CAR T cells will be manufactured on the OU campus rather than being sent to a commercial manufacturer, potentially saving both time and money.

"We need to find a novel, more effective treatment option for patients with ultra-high-risk multiple myeloma as they continue to have poor outcomes despite current treatments," said grant awardee, Yubin Kang, M.D., OU Health

hematologist-oncologist, division chief of Hematology, Bone Marrow Transplant and Cellular Therapy at OU Health Stephenson Cancer Center, and a professor at the OU College of Medicine. "With 10 years of preclinical studies on CAR T-cell therapy and opaganib, we believe the findings suggest that opaganib may help the modified immune cells remain active and continue attacking myeloma for longer. Opaganib works by blocking a protein called sphingosine kinase-2 (SPHK2), which appears to act as a kind of brake on the immune system's cancer-fighting T cells. When SPHK2 was absent or blocked in mice, T cells multiplied more effectively and became better at killing myeloma cells. When combining opaganib with CAR T-cell therapy in vivo in mice, the results were encouraging, with tumor growth controlled for a longer period of time[2]. I am excited to see whether combining CAR T-cell therapy with opaganib can produce longer-lasting responses and improve outcomes for these high-risk patients."

Dr. Mark Levitt, RedHill's Chief Scientific Officer said: "Opaganib has shown promise in preclinical studies as a potential combination therapy in a number of oncology and other indications. Prior preclinical and clinical work has shown that through a reduction of cancer cell survival proteins like c-Myc and Mcl-1[3], opaganib can potentially play a role in the treatment of multiple myeloma. We congratulate Dr. Kang and OU on this grant, which has the potential to be an important step to determine through clinical trials, whether these preclinical findings can turn into reality."

For patients with ultra-high-risk multiple myeloma, cancer often returns despite treatment, including bone marrow transplantation. CAR T-cell therapy is already an option for some patients whose cancer has returned.

The clinical trials will be conducted in partnership with RedHill, which is expected to provide opaganib, and Lentigen Technology, Inc., a Miltenyi Biotec, which developed the CAR construct. Miltenyi Biotec is enabling clinical translation by producing GMP-grade lentiviral vector for CAR T manufacturing on the CliniMACs Prodigy.

About the project

Research reported in this press release is supported by the National Cancer Institute of the National Institutes of Health under award No. R01CA293516-01A1.

About Opaganib (ABC294640)

Opaganib is a proprietary first-in-class investigational, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor drug. Potentially broad-acting, it is in development for multiple oncology, viral, inflammatory, metabolic (diabetes and obesity) and additional indications.

Opaganib's suggested mechanism of action, **published** in the journal Drug Design, Development and Therapy, is host-directed and potentially broad-acting and is expected to maintain its effect against emerging viral variants.

Opaganib is thought to work through the inhibition of multiple pathways, the induction of autophagy and apoptosis, and disruption of viral replication, through simultaneous inhibition of three sphingolipid-metabolizing enzymes in human cells (SPHK2, DES1 and GCS).

Opaganib has received Orphan Drug designation from the FDA for the treatment of neuroblastoma and cholangiocarcinoma. A Bayer-supported placebo-controlled randomized Phase 2 study is ongoing to evaluate the efficacy of opaganib in combination with Bayer's darolutamide in men with metastatic castrate-resistant prostate cancer (mCRPC), testing the potentially enhancing effect of opaganib in patients with a poor prognosis^[4]. Opaganib also has a Phase 1 chemoradiotherapy study protocol ready for FDA-IND submission.

Opaganib has demonstrated its safety and tolerability profile in more than 470 participants in multiple clinical studies and expanded access use, including a large global Phase 2/3 study in hospitalized patients with moderate to severe COVID-19, published in **Microorganisms**².

About the University of Oklahoma

Founded in 1890, the University of Oklahoma is a public research university with campuses in Norman, Oklahoma City and Tulsa. As the state's flagship university, OU serves the educational, cultural, economic and healthcare needs of the state, region and nation. In Oklahoma City, the Harold Hamm Health Campus is one of the nation's few academic health centers with seven health profession colleges located on the same campus. The Harold Hamm Health Campus serves approximately 4,000 students in more than 70 undergraduate and graduate degree programs spanning Oklahoma City and Tulsa and is the leading research institution in Oklahoma. For more information about the Harold Hamm Health Campus, visit www.ouhsc.edu.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: **RDHL**) is a U.S. specialty biopharmaceutical company primarily focused on the development and commercialization of proprietary drugs for gastrointestinal diseases, infectious diseases and oncology. RedHill promotes the FDA-approved gastrointestinal therapies Rebyota®, for the prevention of recurrent C. diff infection (rCDI), and the bowel preparation treatment, Clenpiq®. RedHill's key clinical late-stage development programs include: (i) opaganib (ABC294640), a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anti-inflammatory, antiviral, metabolic and anticancer activity, targeting multiple indications with a track record of U.S. government and academic collaborations intended for medical countermeasure development including for Ebola virus disease, radiation exposure indications such as GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and an ongoing Phase 2 study in prostate cancer in combination with darolutamide; (ii) RHB-102 (Bekinda), with a Phase 2-ready proof-of-concept study for GLP-1/GIP receptor agonist-associated GI intolerance, positive results from a first U.S. Phase 3 study for acute gastroenteritis

and gastritis, positive results from a U.S. Phase 2 study for IBS-D and potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting. RHB-102 is partnered with Hyloris Pharmaceuticals (EBR: HYL) for worldwide development and commercialization outside North America; (iii) RHB-204, a next-generation optimized formulation of RHB-104, with a Phase 2-ready study for Crohn's disease (based on RHB-104's positive U.S. Phase 3 Crohn's disease study results); and (iv) RHB-107 (upamostat), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, including COVID-19 and influenza and also targeting multiple cancer and inflammatory gastrointestinal diseases.

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Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and may discuss investment opportunities, stock analysis, financial performance, investor relations, and market trends. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words, and include, among others, statements regarding the NCI grant awarded to OU; the anticipated use of grant funding for the planned Phase 1b and Phase 2 trials; planned enrollment, timing and design of those trials and the potential benefits, if any, of opaganib in combination with CAR T-cell therapy. 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: the risk that the NCI funding may be reduced, delayed or terminated, or may be affected by broader uncertainty regarding government funding; the risks arising with trials conducted by a third party not controlled by RedHill; the risk that the trials may be delayed or may not demonstrate safety or efficacy; the risk that the acquisition of commercialization rights for Rebyota® and Clenpiq does not result in the planned commercial growth; the risk that opaganib is not accepted into Ebola virus disease control programs, or if accepted, that it does not demonstrate efficacy; the risk that development of RHB-204 for Crohn's disease may not be completed, or if completed may not be approved or may not achieve commercial success; the risk that opaganib is not effective against the indications for which we develop our products; the risk that RHB-102 (Bekinda) does not effectively reduce GLP-1/GIP-related nausea, vomiting and diarrhea; the risk regarding the Company's ability to regain and maintain compliance with Nasdaq's listing requirements, including the minimum bid price requirement; the risk that the addition of new revenue generating products or out-licensing transactions will not occur; the risk that the Company will not receive future milestone payments under its existing agreements or that they will be less than anticipated; the risk of current uncertainty regarding U.S. government research and development funding and that the U.S. government is under no obligation to continue to support development of our products and can cease

such support at any time; the risk that acceptance onto the RNCP Product Development Pipeline or other governmental and non-governmental development programs will not guarantee ongoing development or that any such development will not be completed or successful; the risk that the FDA does not agree with the Company's proposed development plans for its programs; the risk that the Company's development programs and studies may not be successful and, even if successful, such studies and results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional studies may be required; the risk that the Company will not successfully commercialize its products; as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical 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 pre-clinical studies or clinical trials or the development of any necessary commercial companion diagnostics; (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 manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia; (v) the Company's ability to establish and maintain corporate collaborations; (vi) 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; (vii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, pre-clinical studies or clinical trials; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) the Company's ability to collect on its judgement against Kukbo; (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 April 27, 2026. 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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