

PRESS RELEASE

RedHill Biopharma Appoints Key Opinion Leader Professor David Y. Graham from Baylor College of Medicine, Houston, Texas, as Lead Investigator for the US Pivotal Clinical Trial with RedHill's Crohn's Drug – RHB-104

The Company is Preparing Two Parallel Placebo-Controlled, Double-Blind Clinical Trials with RHB-104 for the Treatment of Crohn's Disease in Patients who are MAP-Infected (a Phase II/III Trial in the US, to be lead by Prof. Graham, and a European Phase III Trial) and has Recently Announced the Acquisition of Exclusive Rights to a MAP Bacterium Companion Diagnostic Test for RHB-104

Tel Aviv, October 5, 2011 - RedHill Biopharma Ltd. (TASE: RDHL), an emerging Israeli biopharmaceutical company focusing primarily on development and acquisition of late clinical-stage patented new formulations and combinations of existing drugs, announced the appointment of Professor David Y. Graham, MD, as the lead investigator of the Company's planned pivotal US clinical trial with RHB-104, its proprietary therapy for Crohn's disease. In this role, Prof. Graham will have broad responsibilities in the design of the clinical trial and will be actively involved in its execution and in the publication of its results.

Prof. Graham is an internationally renowned researcher and physician and is recognized as one of the most prominent gastroenterologists in the USA. He is currently a professor at the Baylor College of Medicine Departments of Medicine and Molecular Virology and Microbiology, Houston, Texas.

Prof. Graham is internationally recognized for his expertise in Medicine and Gastroenterology and is the author of more than 800 scientific papers, several books, and 100 chapters in medical text books. He is a Master of the American College of Gastroenterology and a Fellow of the American College of Physicians, the American Academy of Microbiology, the American Association for the Advancement of Science, the Infectious Diseases Society of America, and World Innovation Foundation. He is a former president of the American College of Gastroenterology and the winner of many prestigious awards. He was a physician to NASA astronauts during the Apollo program. He is listed among the Top 50 Most Influential Gastroenterology Professionals of the 20th Century by Gastroenterology.com, one of ISI's Highly Cited Researcher in Clinical Medicine¹, and one of the Best Doctors in America. Prof. Graham's research activities include widely diverse topics with particular

¹ <http://www.isihighlycited.com/>

focus on acid-peptic diseases and *Helicobacter pylori*, viral gastroenteritis, and the possible infectious etiology of inflammatory bowel disease (Crohn's Disease and Ulcerative Colitis).

RedHill's RHB-104 drug is intended to treat Crohn's patients who are infected with MAP bacterium (*Mycobacterium avium paratuberculosis*), which is considered to be one of the possible causes for the disease. MAP is believed to be found in 40%-50% of patients who suffer from Crohn's disease - an inflammatory disorder of the gastrointestinal tract, affecting approximately 700,000 patients in the US alone, currently with no available cure.

Following the recent announcements of RedHill's acquisition from the University of Central Florida of exclusive rights to a MAP bacterium companion diagnostic test for RHB-104, its engagement in a manufacturing agreement with a Canadian manufacturer and an engagement with a global Clinical Research Organization (CRO), the Company is currently preparing two parallel placebo-controlled, double-blind clinical trials with RHB-104 for the treatment of Crohn's patients who are MAP-infected (a Phase II/III trial in the US to be lead by Prof. Graham, and a European Phase III trial).

Ira Kalfus, MD, RedHill's VP Medical Affairs said today: "We are very excited about having attracted someone of Prof. Graham's stature and qualifications. Professor Graham is one of the world's leaders in gastroenterology and a key opinion leader in the US. His remarkable scientific expertise and clinical experience in the treatment of Crohn's disease, as well as his outstanding reputation will be invaluable for the successful execution of the planned clinical trial with RHB-104."

Prof. David Graham, MD, RHB-104 Lead Investigator said today: "I am delighted to have been appointed as lead investigator for RedHill Biopharma's upcoming RHB-104 US pivotal trial. I am impressed with the Company's drug development team and enthusiastic about testing RHB-104 in the contemplated trial. For more than 25 years we have worked toward finding the cause of Crohn's disease. Finally, we will be able to directly test a drug which may prove the hypothesis that one of the causes for the disease is MAP infection. The opportunity to support the development of this revolutionary drug is extremely compelling and I am hopeful that RHB-104 will benefit Crohn's patients around the globe".

About Crohn's Disease:

Crohn's disease is an inflammatory disorder of the gastrointestinal tract that affects approximately 700,000 Americans. Common symptoms of Crohn's include severe abdominal pain, diarrhea and rectal bleeding. There is currently no cure for Crohn's disease and existing treatments aim at suppressing inflammation, thus offering symptomatic relief for a limited period of time. Consequently, it is estimated that two-thirds to three-quarters of patients with Crohn's disease will require surgery at some point during their lives².

About RedHill Biopharma Ltd.:

RedHill Biopharma is an emerging Israeli biopharmaceutical company focused primarily on development and acquisition of late clinical-stage patented new formulations and combinations of existing drugs. The Company's current product pipeline includes a once-daily formulation of a leading congestive heart failure and high blood pressure drug, a once-daily formulation of a leading chemotherapy induced nausea and vomiting prevention drug, an oral thin film formulation of a leading triptan for the treatment of acute migraine, a combination therapy for the treatment of MAP infection in Crohn's and two additional gastrointestinal

² See Crohn's & Colitis Foundation of America's website at <http://www.cdfa.org>.

drugs. The Company's team includes prominent pharmaceutical experts. For more information please visit: www.redhillbio.com

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