



## Press Release

### **RedHill Biopharma Acquires Phase II Oncology Drug MESUPRON<sup>®</sup> from WILEX AG**

- **RedHill expands its late clinical-stage gastrointestinal-focused pipeline with MESUPRON<sup>®</sup>, an oncology drug targeting gastrointestinal and other solid tumor cancers licensed from Wilex AG**
- **MESUPRON<sup>®</sup> completed several Phase I and Phase II clinical studies, including a Phase II proof of concept study in locally advanced non-metastatic pancreatic cancer, demonstrating safety and tolerability and suggesting activity as measured by both tumor response rate and overall survival when administered in combination with first-line chemotherapeutic agents**
- **MESUPRON<sup>®</sup>, a small molecule uPA inhibitor administered by oral capsule, presents a new non-cytotoxic approach to cancer therapy with several potential mechanisms of action to inhibit both tumor metastasis and growth**

**TEL-AVIV, Israel, June 30, 2014** RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including cancer, and WILEX AG (ISIN DE0006614720 / WL6 / FSE) ("WILEX"), a biopharmaceutical company focused on oncology, based in Munich, Germany, today announced that they have signed an exclusive license agreement for the oncology drug candidate MESUPRON<sup>®</sup>. The MESUPRON<sup>®</sup> small molecule (INN: Upamostat) is a proprietary, first-in-class, urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule. WILEX has completed several clinical studies with MESUPRON<sup>®</sup> in

different indications, including two Phase II proof of concept studies for pancreatic cancer and metastatic breast cancer.

Under the terms of the agreement, RedHill acquired the exclusive development and commercialization rights to MESUPRON<sup>®</sup>, excluding China, Hong Kong, Taiwan and Macao, for all indications. RedHill will pay WILEX an upfront payment of USD 1 million and potential tiered royalties on net revenues, ranging from mid-teens up to 30%. RedHill will be responsible for all development, regulatory and commercialization of MESUPRON<sup>®</sup>.

MESUPRON<sup>®</sup> inhibits the uPA system, which has been shown to play a key role in tumor cell growth, invasion and the metastasis process. High uPA levels are associated with poor prognosis in various solid tumor cancers, such as pancreatic, gastric, breast and prostate cancers. MESUPRON<sup>®</sup> presents a promising new non-cytotoxic approach to cancer therapy with several potential mechanisms of action to inhibit both tumor metastasis and growth. MESUPRON<sup>®</sup> has completed several Phase I studies and two Phase II proof of concept studies. The first Phase II study in locally advanced non-metastatic pancreatic cancer and the second study in metastatic breast cancer, established the drug's safety and tolerability profile. The Phase II studies with MESUPRON<sup>®</sup> in both indications suggested activity as measured by both tumor response rate and overall survival of patients when administered in combination with first-line chemotherapeutic agents.

**Dror Ben-Asher, RedHill's CEO, said:** "The acquisition of MESUPRON<sup>®</sup> reflects our commitment to patients suffering from gastrointestinal and inflammatory diseases, including related cancers such as pancreatic cancer, gastric cancer and colorectal cancer. It adds to RedHill's pipeline of six late clinical-stage drug candidates and fits well with our risk-mitigating business model. MESUPRON<sup>®</sup> is a unique non-cytotoxic approach targeting oncology indications where there is a very strong demand for better therapeutic options. Thanks to the development work conducted by WILEX, MESUPRON<sup>®</sup> is supported by extensive pre-clinical and clinical data, and we believe in its potential to become an important treatment option for cancer patients. Our experienced development team is enthusiastic to advance this important new drug. We look forward to collaborating with our new partner WILEX and would like to thank them for entrusting us with the development and commercialization of MESUPRON<sup>®</sup>."

**Dr. Paul Bevan, Head of R&D of WILEX, commented:** "We are very delighted about today's signing of the second license agreement for MESUPRON<sup>®</sup> within the last three months. With RedHill, we have now concluded the final step for the global out-licensing of our drug candidate MESUPRON<sup>®</sup>. RedHill is an experienced and knowledgeable partner and highly committed to further progressing MESUPRON<sup>®</sup> towards regulatory approval and commercialization."

**About MESUPRON<sup>®</sup>:**

MESUPRON<sup>®</sup> is a proprietary, first-in-class urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule. The uPA system has been shown to play a key role in tumor cell growth, invasion and the metastasis process. High uPA levels are associated with poor prognosis in various solid tumor cancers, such as pancreatic, gastric, breast and prostate cancers. MESUPRON<sup>®</sup>

presents a promising new non-cytotoxic approach to cancer therapy with several potential mechanisms of action to inhibit both tumor metastasis and growth. MESUPRON<sup>®</sup> has completed several Phase I studies and two Phase II proof of concept studies. The first Phase II study in locally advanced non-metastatic pancreatic cancer and the second study in metastatic breast cancer, established its safety and tolerability profile. The Phase II studies with MESUPRON<sup>®</sup> in both indications suggested activity as measured by both tumor response rate and overall survival of patients when administered in combination with first-line chemotherapeutic agents.

#### **About RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105** - an oral combination therapy for *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (iv) **MESUPRON<sup>®</sup>** - a Phase II uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (v) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting, in advanced development stages for multiple indications, including a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting planned for the third quarter of 2014 and a Phase III study for an undisclosed indication planned to commence in 2014, (vi) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned for the third quarter of 2014; and (vii) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit [www.redhillbio.com](http://www.redhillbio.com)

#### **About WILEX:**

WILEX AG is a biopharmaceutical company based in Munich, Germany. Focused on oncology, the Company's portfolio includes diagnostic and therapeutic product candidates for the specific detection and targeted treatment of various types of cancer based on antibodies and small molecules. The WILEX subsidiary Heidelberg Pharma GmbH in Ladenburg, Germany, offers preclinical contract research services and an antibody drug conjugate (ADC) technology platform. WILEX AG is listed on the Frankfurt Stock Exchange: ISIN DE0006614720 / WKN 661472 / Symbol WL6. More information is available at [www.wilex.com](http://www.wilex.com).

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