**FOR IMMEDIATE RELEASE**

# Veeva and Bioforum Partner with RedHill Biopharma to Maximize Value of Opaganib Phase 2/3 COVID-19 Clinical Data

*Veeva Vault CDMS and Bioforum selected to optimize clinical data management for RedHill's global Phase 2/3 clinical trial evaluating opaganib in patients with severe COVID-19*

**PLEASANTON, CA and NESS ZIONA, Israel — Sept. 23, 2020 —** Veeva Systems (NYSE: VEEV) ("Veeva") and Bioforum today announced their collaboration with RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill") on a global Phase 2/3 clinical study evaluating opaganib (Yeliva®, ABC294640),[1] a first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor, in patients hospitalized with severe COVID-19 pneumonia requiring treatment with supplemental oxygen.

The opaganib Phase 2/3 study is set to enroll up to 270 patients in up to 40 clinical sites around the world and collect broad and rigorous data in a short amount of time. To support the study, RedHill has adopted Veeva Vault CDMS, a modern cloud platform for electronic data capture (EDC), coding, data cleaning, and reporting. Vault CDMS provides RedHill with a flexible EDC that simplifies and streamlines processes for building and deploying clinical studies. Bioforum, a global data-focused contract research organization (CRO) and a certified Veeva partner, has been selected by RedHill, a long-time client, to implement and configure Vault CDMS for this COVID-19 study.

"With its unique dual anti-inflammatory and anti-viral mechanisms, opaganib has the potential to inhibit the key drivers of disease progression and address the serious unmet medical need for safe, effective, and life-saving treatments for patients with severe COVID-19," said Aida Bibliowicz, vice president of clinical affairs at RedHill. "Our immediate goal is to compile clinical data as early as the fourth quarter of 2020 to support potential applications for emergency use authorizations of opaganib. As such, efficiency in our studies and the quality and integrity of our trial data is absolutely critical, and we are pleased to partner with Bioforum and Veeva to help ensure this."

Vault CDMS enables trial sponsors and their CRO partners to manage studies collaboratively from build through execution. Veeva Vault EDC, part of Vault CDMS, provides an intuitive interface for capturing trial data and is designed for flexibility, enabling teams to create study builds faster and make mid-study changes with no downtime.

"RedHill's opaganib is an exciting, needed drug candidate to overcome the pandemic," said Henry Levy, general manager, Vault CDMS, sites and patients at Veeva Systems. "We're thrilled that our technology and partnership with Bioforum are helping to drive innovation and look forward to working alongside RedHill in advancing this important treatment with the potential to save lives and improve the health of COVID-19 patients."

Bioforum's co-founder and president Amir Malka added: "We're proud to be contributing to this important COVID-19 study. This continues our long-term partnership with RedHill, supporting their efforts to rapidly advance global clinical development programs and deliver therapies that make a meaningful difference in patients' lives. We're confident that together with Veeva, we can help clients like RedHill improve efficiencies in all stages of clinical development — from study design and start-up through execution and submission."

To learn more about opaganib (Yeliva®, ABC294640) clinical trials, please visit www.redhillbio.com.

**About Opaganib (ABC294640, Yeliva®)**
Opaganib, a new chemical entity, is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anticancer, anti-inflammatory, and anti-viral activities, targeting multiple oncology, viral, inflammatory, and gastrointestinal indications. By inhibiting SK2, opaganib

[1] Opaganib is an investigational new drug, not available for commercial distribution.

impacts multiple cellular pathways which are associated with cancer growth, viral replication, and pathological inflammation.

Opaganib received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of cholangiocarcinoma and is being evaluated in a Phase 2a study in advanced cholangiocarcinoma and in a Phase 2 study in prostate cancer. Opaganib is also being evaluated in a global Phase 2/3 study and a U.S. Phase 2 study for the treatment of coronavirus (COVID-19).

Pre-clinical data have demonstrated both anti-inflammatory and anti-viral activities of opaganib, with the potential to reduce lung inflammatory disorders, such as pneumonia, and mitigate pulmonary fibrotic damage. Opaganib demonstrated potent anti-viral activity against SARS-CoV-2, the virus that causes COVID-19, completely inhibiting viral replication in an *in vitro* model of human lung bronchial tissue. Additionally, pre-clinical *in vivo* studies[2] have demonstrated that opaganib decreased fatality rates from influenza virus infection and ameliorated Pseudomonas aeruginosa-induced lung injury by reducing the levels of IL-6 and TNF-alpha in bronchoalveolar lavage fluids.

Opaganib was originally developed by U.S.-based Apogee Biotechnology Corp. and completed multiple successful pre-clinical studies in oncology, inflammation, GI, and radioprotection models, as well as a Phase 1 clinical study in cancer patients with advanced solid tumors.

Under a compassionate use program, COVID-19 patients (as classified by the WHO ordinal scale) were treated with opaganib in a leading hospital in Israel. Data from the treatment of these first patients with severe COVID-19 with opaganib have recently been published.[3] Analysis of treatment outcomes suggested substantial benefit to patients treated with opaganib under compassionate use in both clinical outcomes and inflammatory markers as compared to a retrospective matched case-control group from the same hospital. All patients in the opaganib-treated group were discharged from hospital without requiring mechanical ventilation, whereas 33% of the matched case-control group required mechanical ventilation. Median time to weaning from high-flow nasal cannula was reduced to 10 days in the opaganib-treated group, as compared to 15 days in the matched case-control group. The development of opaganib has been supported by grants and contracts from U.S. federal and state government agencies awarded to Apogee Biotechnology Corp., including from the NCI, BARDA, the U.S. Department of Defense, and the FDA Office of Orphan Products Development.

The ongoing studies with opaganib are registered on www.clinicaltrials.gov, a web-based service by the U.S. National Institute of Health, which provides public access to information on publicly and privately supported clinical studies.

**About RedHill Biopharma**
RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal diseases. RedHill promotes the gastrointestinal drugs, Movantik® for opioid-induced constipation in adults,[i] Talicia® for the treatment of *Helicobacter pylori (H. pylori)* infection in adults,[ii] and Aemcolo® for the treatment of travelers' diarrhea in adults.[iii] RedHill's key clinical late-stage development programs include: (i) RHB-204, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (ii) opaganib (Yeliva®), a first-in-class 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-104, with positive results from a first Phase 3 study for Crohn's disease; (iv) RHB-102 (Bekinda®), with positive results from a Phase 3 study for acute gastroenteritis and gastritis, and positive results from a Phase 2 study for IBS-D; (v) RHB-107, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases and is also being evaluated for COVID-19 and (vi) RHB-106, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com.

**About Bioforum the Data Masters**
Bioforum is a data-focused contract research organization (CRO), serving clients worldwide in

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[2] Antiviral Res., Transient inhibition of sphingosine kinases confers protection to influenza A virus infected mice, 2018
[3] MedRxRiv, Compassionate Use of Opaganib For Patients with Severe COVID-19, 2020

optimizing the collection, standardization, and reporting of clinical research data. We strive to consistently improve and innovate data processes, enabling the most efficient data submissions for our clients across the life sciences industry worldwide. From our offices in Israel, the U.S., Australia, and South Africa, our multidisciplinary team provides in-depth expertise and delivers high-quality solutions, including medical writing, data management, clinical programming, biostatistics, and pharmacovigilance. To learn more about us and our services, visit bioforumgroup.com or find us on LinkedIn at linkedin.com/company/bioforum-ltd.

**Additional Information**
For more on Veeva Vault CDMS, visit: veeva.com/cdms
Connect with Veeva on LinkedIn: linkedin.com/company/veeva-systems
Follow @veevasystems on Twitter: twitter.com/veevasystems
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**About Veeva Systems**
Veeva Systems Inc. is a leader in cloud solutions—including data, software, and services—for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 900 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. The company is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit veeva.com.

**Forward-looking Statements Regarding Veeva and its Products**
This release contains forward-looking statements, including the market demand for and acceptance of Veeva's products and services, the results from use of Veeva's products and services, and general business conditions (including the on-going impact of COVID-19), particularly within the life sciences industry. Any forward-looking statements contained in this press release are based upon Veeva's historical performance and its current plans, estimates, and expectations, and are not a representation that such plans, estimates, or expectations will be achieved. These forward-looking statements represent Veeva's expectations as of the date of this press announcement. Subsequent events may cause these expectations to change, and Veeva disclaims any obligation to update the forward-looking statements in the future. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially. Additional risks and uncertainties that could affect Veeva's financial results are included under the captions, "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the company's filing on Form 10-Q for the period ended July 31, 2020. This is available on the company's website at veeva.com under the Investors section and on the SEC's website at sec.gov. Further information on potential risks that could affect actual results will be included in other filings Veeva makes with the SEC from time to time.

**Forward-looking Statements Regarding RedHill and Opaganib**
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, the risk of a delay in compiling clinical data to support potential applications for emergency use authorizations of opaganib; the risk that the antiviral activity in the *in vitro* study will not be demonstrated in clinical trials; the risk that the U.S. Phase 2 clinical study evaluating opaganib will not be successful and the risk that completion of enrollment for this clinical study will be delayed; the risk that the Company will not initiate the Phase 2/3 study for opaganib in certain geographies, will not expand this study in additional countries and that it will not be successful; the risk that other COVID-19 patients treated with opaganib will not show any clinical improvement; the risk of a delay in applying for emergency use authorizations; the development risks of early-stage discovery efforts for a disease that is still little understood, including difficulty in

assessing the efficacy of opaganib for the treatment of COVID-19, if at all; intense competition from other companies developing potential treatments and vaccines for COVID-19; the effect of a potential occurrence of patients suffering serious adverse events using opaganib under compassionate use programs, as well as 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 manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia®; (v) the Company's ability to successfully commercialize and promote Movantik®, Talicia® and Aemcolo®; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) 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; (viii) 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; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements, and needs for additional financing; (xiii) the effect of patients suffering adverse events using investigative drugs under the Company's Expanded Access Program; and (xiv) 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 4, 2020. 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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[i] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.
[ii] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.
[iii] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.