Press release 26 April, 2019

RhoVac reports positive written response from the FDA regarding recently completed pre-IND meeting

RhoVac AB ("RhoVac") reports today, on April 26, 2019, that the company has received a written response from the Food and Drug Administration (FDA), USA regarding to the recently completed pre-IND meeting on development of the company's drug candidate RV001. The subject of the meeting was to obtain agreement with the Agency regarding the scope of currently available data and the necessary data to support an IND submission for the clinical phase 2 trial in prostate cancer patients. Furthermore, the purpose of the meeting was to discuss with the agency and reach concurrence regarding the initial IND study protocol in the identified study population, the proposed endpoints along with the proposed safety monitoring. The FDA has confirmed that no further preclinical studies are required to support clinical development of the company's clinical phase II trial in USA and that the design and the defined end-points in the study are relevant to document clinical proof of concept in treatment of prostate cancer patients with the company's drug candidate RV001.

In alignment with the company's original development schedule, RhoVac contacted the FDA in early 2019, and in March the company announced that FDA had accepted RhoVac's request for a pre-IND meeting. A pre-IND meeting is comparable to a *Scientific Advice Procedure* in the EU, which RhoVac concluded in mid-2018. Following confirmation of the pre-IND meeting, the company submitted a Briefing Package which FDA has now evaluated and the response to our questions is based on this background information.

In conclusion, the FDA agrees that, in relation to USA, no further preclinical studies are required in support of a clinical phase II trial in prostate cancer patients. The identical study protocol is currently under review in Denmark with subsequent review in other European countries. The FDA also commented that the company's approach in developing the quality specification for the drug candidate RV001 complies with relevant regulatory guidelines. In the response relating to the proposed clinical trial, the FDA agrees that the definition of the patient population, which we plan to recruit for the clinical study, is well-defined and that the clinical end-points set in the study are relevant in order to document clinical proof on concept.

Comments from RhoVac´s CEO, Anders Ljungqvist
-A pre-IND meeting may be a face-to-face meeting at FDA in Washington DC, a telephone conference or a written response. Based on the questions and the background information we forwarded the FDA, FDA assessed to have adequate background to be able to respond in writing. It is gratifying that the FDA confirms that we have correctly interpreted the regulatory guidelines in USA enabling us to continue our clinical development of RV001 based on the same strategy as used within the EU. A big thank you to employees and external consultants for a very professional and valuable work.

For more information. Please contact:
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This information is such that RhoVac AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on 26 April 2019.

About RhoVac AB
RhoVac AB conducts research and development of immunotherapeutic drugs. The Company's main focus is the development of a therapeutic cancer vaccine with the potential to prevent or limit metastasis in cancer. RhoVac's first drug candidate has completed pre-clinical and clinical phase I/II. RhoVac has its headquarters at Medicon Village in Lund, Sweden. Since 2007, research is conducted primarily at the University Hospital in Herlev, Denmark and at University of Tübingen by research teams of world-class in their field. RhoVac is listed on Spotlight Stock Market, Sweden, a Multilateral Trading Facility (MTF), since March 2016. The share is traded under the ticker RHOVAC. Learn more at www.rhovac.com.