Press Release, November 25. 2020

RhoVac's Prostate Cancer Drug Candidate, RV001, is granted Fast Track Designation by the FDA

Lund, Sweden, November 25, 2020: RhoVac, a clinical stage company today announced that the American FDA has granted Fast Track Designation to the company's drug candidate, RV001. Fast Track Designation is granted to investigational drugs for expedited review by the FDA, to facilitate development of drugs aimed at treating serious or life-threatening conditions and fill unmet medical needs.

The granted Fast Track Designation means that Rhovac and RV001 are eligible for the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, provided relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

RhoVac filed its Fast Track Designation application at the end of September, and the company is pleased to learn less than 60 days later that the FDA has granted Fast Track Designation to RhoVac's drug candidate, RV001. The drug candidate is currently engaged in a phase IIb clinical trial in prostate cancer, a study that aims to recruit more than 175 patients and that involves centres both in Europe and in the US. The study aims to conclude in the beginning of 2022. In prostate cancer there is currently no other therapy available for patients to prevent cancer recurrence. Currently, these patients undergo only surveillance and have no access to preventive therapy. Only when patients are diagnosed with recurring and now metastatic cancer, are they again eligible for therapy such as hormone therapy. The aim of RV001 development is to ensure that fewer patients will have to experience recurring cancer and that progression is delayed in those that do. If a Proof of Concept (PoC) for the use of RV001 in prostate cancer is obtained, it is highly likely that the drug will also be tried in other cancer forms, as there is nothing prostate specific about the scientific rationale for the drug candidate per se.

RhoVac's CEO, Anders Månsson, comments: "We are extremely pleased and proud that our drug candidate, RV001, has earned Fast Track Designation by the FDA. We obviously appreciate the benefits that this might entail in terms of access to FDA advice and an accelerated approval process. But also the fact that the FDA has reviewed our data, and found our drug candidate worthy of this level of priority, obviously sends a clear signal of recognition of the drug's potential to all our would-be partners, which is something of great importance to us."

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 November 25 2020 at 08:20.

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On RhoVac AB

RhoVac was established as a private company in Denmark in 2007. Under this company, the basic development steps for the drug candidate RV001 were undertaken. In 2015 the Swedish RhoVac AB was formed, which is now headquartered and in 2016 the company was listed on the then Aktietorget in Sweden (now Spotlight Stock Market). RhoVac has passed the early stages of development. In 2018, the first clinical trial (phase I / II) was completed in prostate cancer, demonstrating that RV001 has good safety and is well tolerated, and that the drug provides the expected immune response that will exert its effect on the cancer cells. The strong immune response has also been shown to last over time. Therefore, RhoVac is launching a clinical phase IIb trial that will include at least 175 prostate cancer patients. The study is designed to show, with statistical significance, the effect of RV001 in preventing disease progression in prostate cancer after surgery or radiation to the primary tumour. RhoVac is listed on Spotlight, Sweden, a Multilateral Trading Facility (MTF) since March 2016. The share is traded under the ticker RHOVAC. Read more at www.rhovac.com.