



2018-07-09

## Summer greetings from RhoVac

In 2015, RhoVac AB ("RhoVac") launched a focused three-year plan aimed at developing the company's drug candidate RV001, an immuno-oncology treatment, with the potential to prevent or limit the spread of cancer (metastasis). The current treatments (surgery, radiation and / or chemotherapy) of the mother tumor are relatively effective, but many of the patients experience serious side effects and the disease has a high risk of relapse. RhoVac's focus is on preventing this relapse for which, the company is investing in the development of the drug candidate RV001. Today, three years later, we are in the final phase of this development plan and are waiting for the report of the results of the first clinical study with RV001. At the same time, we have started preparations for the next phase, which aims at a clinical phase IIb development.

In February 2018, the treatment of the 22 patients taking part in the phase I/II study of treatment with RhoVac's drug candidate RV001 completed. In March the last blood samples for immunological analysis were drawn. The purpose of this clinical study is to evaluate the safety and tolerability of patients, and to investigate the RV001 mediated immune response before, during and after treatment of the patients. The results of this clinical trial are expected around mid-2018 and the clinical final report is expected to be completed by the end of Q3 2018. In order to find out how long the established immune response lasts after the treatment has been completed, RhoVac is now running a follow-up of the patients in the study. We aim to report the results of this follow-up study during Q1/Q2 2019.

As part of the preparations for the next clinical phase, we submitted a briefing package for the Scientific Advice procedure at the European Medicines Agency (EMA) in January 2018. The submitted document contained about 50 pages description of RhoVac's operations and the planned execution of the forthcoming clinical trial. During this procedure, the company has the opportunity to ask specific questions to EMA. In their response, EMA can confirm that RhoVac's documentation is in compliance with the regulatory framework in the EU and that they have a consensus on the continued work. EMA can also highlight weaknesses in the plans, thus underlining the company's needs for consideration or improvement for the formal application of the Phase II clinical trial. The reply from EMA is not a formal approval for the next phase, but should be seen as valuable scientific and regulatory advice, which will be the basis for the continued planning of the study. Knowing and following the advice given by EMA significantly increases the probability of approval for the next phase of the clinical trial. In further preparation for the forthcoming clinical study, RhoVac has secured the access of the study medicine needed for the study from company's French partner, Carbogen Amcis.

In July 2018, the US Food and Drug Administration (FDA) has invited for an open workshop in Washington DC, USA. The workshop aims at discussing active measures for development of products for the early treatment of prostate cancer in patients. We will attend this workshop, which will provide a good base for preparing for a pre-IND meeting at the FDA for the upcoming Phase IIb clinical trial.

On the R&D side of the business, research collaboration with the University of Tübingen has been fruitful and successful. Therefore, RhoVac has extended the collaboration agreement with Dr. Gouttefangeas at the Department of Immunology regarding the characterization and analysis of immunological response when patients are treated with RV001. Another research collaboration which will be continued, is the collaboration with Lund University, where Dr. Ceder and his colleagues looking at overexpression of protein RhoC in prostate cancer stem cells. We aim to report the results of this collaboration in autumn 2018.

In April, RhoVac received recognition from the EU through receiving a grant of €50,000 for the Phase 1 application of the Horizon 2020 program with a significant excellent score (13.8 out of 15). Horizon 2020 supports SMEs by financing innovations with high potential in the EU. The calls for proposals tend to be highly competitive; last spring, the success rate was 12.6% with 2009 proposals submitted. The money will be used for preparation for the Horizon 2020 phase 2 application, which is expected to be submitted in Q3/Q4 2018.

Just before the summer, the company completed a rights issue to secure funding with the main purpose being business development: identifying outlicensing opportunities or potential partners. Part of this money will also be used for follow-up of the phase I/II study, regulatory preparations for future phase IIb study and also financing of working capital. During the subscription period, the company was presented at several investment meetings in Stockholm, Malmö and Gothenburg. The rights issue was welcomed by 196% oversubscription. This significant number shows that investors believe the company is in

an exciting phase. We would like to take the opportunity to thank our investors for the interest in the company and for their confidence in us.

As a step in RhoVac's increased focus on business development, we have strengthened this part of the organization during the spring by employing Colpman Consulting Ltd. David Colpman has a long experience of business development from major pharmaceutical companies and has also been involved as adviser in several business deals, both in the Nordics and international life science market. On the other side, at the annual general meeting, Gunnar Gårdemyr was elected to the Board. Gunnar has a solid experience and has worked with business development, strategic planning, export sales and sales of major international companies. We are excited to have Gunnar for the rest of our journey.

Updating you with our recent achievements, now we wish you all a nice and beautiful summer.

RhoVac AB

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**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 phase and clinical phase I / II study has started spring 2017. RhoVac has its head office at Medicon Village in Lund, Sweden. The research has been conducted since 2007 primarily at the University Hospital in Herlev, Denmark, by a world-class research team in its niche. RhoVac is listed on AktieTorget, Sweden, a Multilateral Trading Facility (MTF), since March 2016. The share is traded under the ticker RHOVAC. Read more at [www.rhovac.com](http://www.rhovac.com)*