Intervacc identifies a potential short out-of-stock situation regarding Strangvac

Stockholm, September 20, 2024 - Intervacc AB (publ) predicts that the vaccine Strangvac®, which is approved for sale in Europe and the UK, may be out-of-stock for a short period from the 1st October 2024. The doses of vaccine that are currently available for sale have a shelf-life that expires on the 30th September 2024 and Intervacc expects the out-of-stock situation in Sweden to be resolved during the first half of October. The out-of-stock situation is caused by the implementation of improved analytical methods that are used during the manufacturing process which, following their successful validation, must be approved by the competent regulatory authorities before the new batches of vaccine can be released for sale.

The manufacture of biological medicines is a complex process and Intervacc has worked closely with our partners to develop improved analytical methods that provide greater robustness and flexibility, whilst ensuring that the vaccine is manufactured and controlled according to the highest quality standards by our contract manufacturers. This work has resulted in the development of improved validated methods and processes for which the company is seeking approval through so-called variation applications, in order to replace the previous methods and processes stated in the market approval. Based on these new manufacturing processes and analytical methods, the company has manufactured new batches of vaccine that can be made available for sale immediately after approval of the variation applications.

Whilst awaiting approval, and in order to minimize the duration of a potential out-of-stock period, the company will request the authorities to consider a Special Batch Release (SBR). Strangvac® was approved via a central procedure and Intervacc has been granted a sales license by the European Commission, which is valid in all EU member states, Iceland, Norway and Liechtenstein, and is also approved in Great Britain by the VMD. However, whilst Strangvac® is approved centrally, the application for SBR will be made to the competent authority in each country where Strangvac® has been launched and the time required for approval of each SBR is expected to vary between countries.

The company assesses that it is likely to obtain approval for SBR before the company receives approval for the variation applications, and that the submission of the variation applications is aligned with the SBR process. An approval for a SBR means that the company can immediately make the new manufactured batches of Strangvac® available to resolve the potential out-of-stock situation quickly.

Preventing, limiting and remedying potential shortage and out-of-stock situations is a priority for pharmaceutical companies and authorities. The SBR procedure varies in different countries, and, in Sweden, Intervacc has updated the Swedish Medicines Agency on the forecasted duration of the potential out-of-stock situation, which the Swedish Medicines Agency makes public through their e-service "Search rest-announced drugs".

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This information is information that Intervacc AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for immediate publication, through the agency of the contact person set out above on September 20, 2024.

About Strangvac
Strangvac®, a vaccine against equine strangles, is approved for sale and marketing in the EU, as well as in the United Kingdom, Iceland, Norway, and Liechtenstein. It has been launched in Sweden, Denmark, the United Kingdom, France, Germany, Belgium, the Netherlands, Austria, Ireland, Poland, and Italy.

About Intervacc
Intervacc AB is a Swedish company within animal health developing vaccines for animals. The Company's vaccine and vaccine candidates are based on several years of research at Karolinska Institutet and Swedish University of Agricultural Research where the foundation was laid for the Company´s research and development work. The Intervacc share has been listed on the Nasdaq First North Growth Market since April 2017.

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