Intervacc announces submission of the Marketing Authorization Application for Strangvac to the European Medicines Agency

Stockholm February 26, 2020 – Intervacc AB (publ) announces that the Company's Marketing Authorization Application (MAA) for review of Strangvac® has been submitted today to the European Medicines Agency (EMA). Intervacc is seeking approval for Strangvac® as a vaccine against equine strangles, a highly contagious infectious disease that affects horses globally.

"The MAA filing represents a significant milestone for Intervacc. We are now submitting a regulatory application for marketing authorization for our first in-house developed vaccine and take a major step toward preventing outbreaks and suffering in horses by making Strangvac® available to the equine veterinarian community. A vaccine against Equine Strangles is an important tool in the fight against the highly contagious disease. Strangles is the most frequently diagnosed contagious equine disease in the world and in the case of an outbreak, stables must be quarantined and often face great difficulties and costs." said Andreas Andersson, Chief Executive Officer of Intervacc.

After accepting the submission of the dossier, an opinion from the Committee for Medicinal Products for Veterinary Use (CVMP) at EMA is expected within 210 days, with the addition of clock-stops for the applicant to provide answers to questions which may arise during the review. The Company estimates that the total processing time will be about one year.

The vaccine has been developed with an innovative technology and is based on fusions of recombinant proteins. The research behind the vaccine's technical platform has been done together with researchers at Karolinska Institute and the Swedish University of Agricultural Sciences, SLU.

"Upon approval, Strangvac® will be the first Swedish Animal Health Vaccine to receive marketing authorization by the centralised EMA procedure covering all 28 member states of the European Union (E.U.), as well as Iceland, Liechtenstein and Norway" stated professor Jan-Ingmar Flock, Cheif Scientific Office at Intervacc who together with Bengt Guss, professor at SLU, has worked with the project since its inception.

The MAA for Strangvac® is based on a successful series of clinical studies demonstrating the safety, immune response, efficacy and DIVA capability. DIVA (Differentiation of Infected from Vaccinated Animals) capability is a key feature during epidemics in order to distinguish vaccinated animals from asymptomatic carriers.

For more information please contact:
Andreas Andersson, CEO
Phone: +46 (0)8 120 10 601
Cell: +46 (0)73 335 99 70
E-mail: andreas.andersson@intervacc.com

This information is information that Intervacc 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 February 26, 2020.

About Intervacc
Intervacc AB (publ) is a company within the Biotechnology sector. The Company´s main area is to develop modern sub-unit vaccines against economically important bacterial infections, within animal health. The company´s 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 with Eminova Fondkommission AB, adviser@eminova.se, +46 (0)8–684 211 10 as Certified Adviser.

About Strangvac®
Strangvac®, a modern vaccine against Strangles, a highly contagious and serious infection in horses caused by the bacterium Streptococcus equi. Strangvac® consists of only soluble recombinant proteins, is injected intramuscularly and totally devoid of any living infectious agent. This results in a well-tolerated vaccine with excellent safety profile, as expected of a modern vaccine.

Contact information for Certified Adviser
Eminova Fondkommission AB
E-mail: adviser@eminova.se, Phone: +46 (0)8 – 684 211 10

Date Created
2020-02-26