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Moredun Research Institute, Pentlands Science Park,
Bush Loan, Penicuik, Midlothian, EH26 0PZ

Tel: 0131 445 5111 Email: info@moredun.org.uk

Louping Ill is a neurological disease caused by the tick-borne Louping Ill virus (LIV). It is transmitted by the sheep tick and can infect livestock (principally sheep) wildlife species and humans. The disease is associated with high mortality in sheep and represents a huge issue in areas of the UK where ticks carry the virus. Currently, these geographical areas are spreading.

Following the discontinuation of an inactivated whole virus Louping Ill vaccine (marketed by MSD) due to difficulties with manufacturing, Moredun Research Institute (MRI) has developed a new class of vaccine against Louping Ill in sheep. This vaccine has been shown, in laboratory trials, to protect sheep from Louping Ill. Importantly, the vaccine is simpler to manufacture, meaning a more reliable supply to farmers. MRI have partnered with Kernfarm B. V., a veterinary pharmaceutical supplier based in The Netherlands, with the aim of bringing this new vaccine to market.

Photo: www.shutterstock.com

BENEFIT TO FARMERS

There are no other vaccines available against Louping Ill and other control methods (tick treatments and management) are not sustainable due to many factors, including increasing requirements for highly frequent treatments, which is likely to lead to resistance. Given the recent trend of longer tick seasons and the subsequent increasing spread of Louping Ill, a vaccine will be of great benefit to sheep farmers in the UK, reducing the incidence of disease with a benefit in both animal welfare and economic impact.

DEVELOPMENT

The development plan for bringing this vaccine to market will be carried out in three phases. It should be noted that each phase is sequential and relies on the success of the previous phase(s). Whilst we are confident of a successful outcome from all three phases, as with any vaccine development there is an element of risk - therefore success, and the timelines, cannot be guaranteed.

PHASE 1: MANUFACTURING TRANSFER (£720,000, ~ 9 months)

In the first phase, the aim is to establish large-scale production of the vaccine. At present we know that the vaccine can be made in the laboratory and that this laboratory produced vaccine works well. However, to produce large quantities of the vaccine for commercial use, the scale of production needs to be vastly increased. This process will be subcontracted to a Contract Development and Manufacturing Organisation (CDMO) and involves a great deal of work to transfer the production method to an industrial scale and to validate the process so that it is sufficiently robust for commercial production going forward.

At the end of this phase we anticipate having a scaled up vaccine production process in place that will be used for commercial manufacture for many years.

PHASE 2: REGULATORY DOSSIER (£1,470,000, ~16 months)

The second phase involves essential studies at MRI to test the safety and effectiveness of the vaccine produced using the scaled-up process developed in Phase 1. Although we know that the laboratory produced vaccine works in protecting sheep from Louping Ill, we need to ensure that a vaccine made using our manufacturing-scale process will also be protective. Data from these trials will be used to prepare a comprehensive regulatory proposal, which will be submitted to the UK regulator, Veterinary Medicines Directorate (VMD), for market registration of the vaccine, which will allow it to be sold commercially. We have already been in dialogue with the VMD who have agreed to the data which will be required for registration of the vaccine (which is less than other vaccines, due to the limited size of the market for Louping Ill vaccines).

At the end of this phase we anticipate having detailed information on the safety and effectiveness of the vaccine produced at large scale and also a comprehensive regulatory proposal ready for submission to the VMD.

PHASE 3: COMMERCIAL MANUFACTURE (£2,820,000, ~12 months)

The third and final phase will involve submission and subsequent assessment of the regulatory proposal by the VMD, which could take up to nine months or longer. Concurrently, commercial manufacture will commence, so that stock is available for sale immediately once regulatory approval has been granted.

At the end of this phase, we anticipate having a VMD registered vaccine against Louping Ill ready for sale within the UK.