



BioNet's Recombinant Pertussis Vaccine Submitted to European Medicines Agency (EMA)

"Monovalent recombinant acellular pertussis vaccine proven to significantly boost immunity against pertussis"

Lyon, France – July 31, 2024, BioNet Europe, the French subsidiary of BioNet, a vaccine manufacturer specializing in the development of genetically engineered vaccines, has announced the submission of a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its monovalent Recombinant Pertussis Vaccine (RPV).

BioNet's stand-alone vaccine targets whooping cough, a highly contagious respiratory disease on the steep rise across Europe. This non-combined vaccine is tailored to the persons who require pertussis-only booster vaccination and are up-to-date with their diphtheria and tetanus immunizations.

Dr Giuseppe Del Giudice, Director Translational Research at BioNet, stated: *"BioNet's recombinant vaccine is designed to provide more effective and longer-lasting immune protection against pertussis than traditional acellular pertussis vaccines. It contains a Pertussis Toxin (PT), the main component responsible for severe pertussis disease, which is inactivated by recombinant technologies rather than chemicals."*

These recombinant technologies allow for the preservation of the native structure of the PT, fundamental for the induction of higher immune protection. Currently, no other monovalent or recombinant pertussis vaccines are available in Europe, making BioNet's RPV a best-in-class vaccine driving significant advancement in public health with the potential to improve acceptance for pertussis immunization.

Phillippe Guillot-Chene, CEO of BioNet Europe, added, *"We believe that BioNet's RPV represents a transformative vaccine for preventing pertussis disease. After receiving the positive feedback from EMA Scientific Advice, we are honored to have our MAA submission validated by the EMA as well."*

The safety, immunogenicity and antibody persistence induced after one single booster dose of BioNet's RPV were demonstrated in numerous randomized clinical trials, notably amongst adults in Australia, adolescents in Switzerland, as well as vulnerable populations such as pregnant women and elderly in Thailand.

The vaccine is licensed in Asia (under the Pertagen® trademark) and is included in the pertussis maternal immunization program for pregnant women in Thailand. The MAA of Pertagen® has also been submitted to the Australian Therapeutic Goods Administration.

About BioNet

BioNet is a vaccine manufacturer specializing in the development of recombinant and mRNA vaccines against respiratory diseases and other global public health threats. BioNet has a strong track record with development and biomanufacturing, having advanced over three proprietary recombinant pertussis vaccines from early R&D to licensure. It currently markets multiple vaccines through its established commercial network. BioNet has been rapidly expanding its operations across Asia, Europe and North America.

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Forward-Looking Statements

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