Company Announcement

Bavarian Nordic's Chikungunya Vaccine Candidate Granted Accelerated Assessment by European Medicines Agency

- Accelerated assessment allows for a shorter review period with EMA.
- Bavarian Nordic is on track to submit its Marketing Authorisation Application for CHIKV VLP to EMA during H1 2024.

COPENHAGEN, Denmark, February 23, 2024 – Bavarian Nordic A/S (OMX: BAVA) ("the Company") today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted accelerated assessment for the upcoming Marketing Authorisation Application (MAA) for CHIKV VLP, the Company's investigational chikungunya vaccine.

The accelerated assessment, which is granted based upon CHMP's decision that the vaccine candidate is of major interest for public health and therapeutic innovation, may reduce the timeframe for the review of the MAA from 210 days under the standard review procedure to 150 days, not counting clock stops when applicants must provide additional information[1].

Bavarian Nordic is on track and plans to submit its MAA for CHIKV VLP to the EMA during H1 2024.

"We are pleased to receive the accelerated assessment in recognition of our chikungunya vaccine candidate and our efforts to bring this novel product to the market. With this, we have the ability to accelerate the approval and our launch timelines for the vaccine in Europe. As part of our global strategy, we also plan to submit our biologics license application (BLA) for the vaccine candidate to the U.S. Food and Drug Administration later this year," said Paul Chaplin, President and CEO of Bavarian Nordic.

In 2023, Bavarian Nordic successfully completed two Phase 3 studies of CHIKV VLP. Both studies met their primary endpoints, demonstrating that CHIKV VLP induced high levels of neutralizing antibodies against chikungunya in individuals 12 years and above, with antibody titers equal to or above the threshold agreed with authorities as a marker of seroprotection.

One study (NCT05072080) enrolled 3,254 healthy adults and adolescents aged 12 to 64 years of age, who were randomized to receive either a single intramuscular injection of CHIKV VLP, or placebo. The results up to day 22 post vaccination showed that CHIKV VLP was highly immunogenic, as demonstrated by the strong induction of chikungunya neutralizing antibodies in 98% of vaccinees in the active group.

Importantly, CHIKV VLP induced significant neutralizing antibodies in 47% and 97% of the subjects after 8 days and 15 days post vaccination respectively. These responses were robust and durable, as 86% of the subjects had seroprotective levels of neutralizing antibodies 6 months post vaccination.

A similar study, which enrolled 413 healthy adults ≥65 years of age (NCT05349617), showed neutralizing antibodies in 87% of the vaccinees 22 days after a single vaccination. Seroprotective antibodies were confirmed in 82% of the individuals at day 15.

CHIKV VLP was well-tolerated across both studies and vaccine-related adverse events were mainly mild or moderate in nature.

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccine company with a mission to protect and save lives through innovative vaccines. We are a global leader in smallpox and mpox vaccines, supplied to governments to enhance public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. For more information visit www.bavarian-nordic.com.

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Forward-looking statements
This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control, that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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[1] https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/accelerated-assessment