

Bavarian Nordic Announces Positive Data from Phase 2 Extension Study of its Universal RSV Vaccine

- Broad antibody and T cell responses against RSV remained durable 1 year post a single vaccination with MVA-BN® RSV in the majority of subjects
- An annual booster of MVA-BN-RSV induced a broad and robust immune response, particularly in subjects with waning immunity one year after first vaccination, demonstrated by fast post-vaccination increases of neutralizing and total antibodies against both RSV subtypes (A & B); increases in mucosal RSV specific IgA and a broad, robust, and cellular immune response to all 5 RSV proteins encoded in the vaccine.

COPENHAGEN, Denmark, August 8, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced positive data from the extension study of its Phase 2 study investigating the safety and immune responses of its universal RSV vaccine, MVA-BN® RSV in an older adult population.

In 2017, the Company reported data from a Phase 2 study that investigated various schedules and doses of the MVA-BN RSV vaccine in 421 subjects aged 55 and older. This study demonstrated that the vaccine induced robust antibody and T cell responses against RSV with only a single booster vaccination and these responses remained elevated for an entire RSV season (6 months post vaccination). The extension study re-enrolled 88 subjects one year later, after having received a single vaccination with either a low or high dose of the vaccine in the Phase 2 study and were further boosted with the same vaccine dose; mimicking an annual booster regime.

The extension study demonstrated that in at least 60% of the subjects the broad antibody responses against RSV were durable and remained elevated compared to baseline, one year after receiving a single booster vaccination. Similarly, the T cell responses against RSV also remained elevated one year post vaccination in half of the subjects re-enrolled, depending on which the RSV protein encoded in the vaccine was evaluated (ranging from 27% to 72% of the subjects). Following a further annual booster with MVA-BN RSV, there was a rapid and significant increase in serum antibody responses, including neutralizing antibodies against both RSV subtypes (A & B) and total IgG and IgA antibodies against RSV. This effect was most notable in subjects with the weakest immunity at the baseline (week 56) prior to the second vaccination. Compared to pre-vaccination levels 1 year before, the boost effect was in the range of a 1.5 to 3-fold increase depending the antibody parameter, however the increases were in the range of 1.3 to 2-fold when compared to the week 56 levels (baseline for the annual boost), as the antibody responses remained elevated one year post the first vaccination. These were also supported by a significant boost in the mucosal IgA responses measured from nasal swabs that has been reported to be an important correlate of protection against RSV. The T cell responses against all five RSV encoded proteins were also significantly boosted following the annual vaccination. Again, this effect was most prevalent in subjects with the weakest immunity prior to the second vaccination.

These positive clinical results will be key in discussing the design of the Phase 3 study with the FDA at a meeting planned for later this year.

“We are exceptionally happy to share these data, which show the ability of our vaccine to provide broad RSV specific immunity over multiple seasons. This establishes our hypothesis that MVA-BN RSV is an annual booster vaccine, and is the only RSV candidate vaccine in development that has been able to demonstrate the induction of a broad immune response targeting not only antibodies, but T cells and mucosal immunity. Showing that the administration of a live virus vaccine over multiple seasons is both safe and immunogenic is a significant piece of data, which we know both KOLs and potential partners will be excited to see.” said Paul Chaplin, President and CEO of Bavarian Nordic.

About MVA-BN RSV

MVA-BN RSV has been specifically designed to mimic a natural RSV infection, and can boost the body's memory response against RSV. The vaccine has been shown to elicit T-cells and humoral antibodies against each of the 5 targets encoded in the vaccine, as well as the whole virus. Additionally, increased IgA antibodies were detected in the nasal mucosa of vaccinated subjects. Previously published studies have shown that in RSV human challenge studies, the presence of IgA antibodies in the mucosa is highly correlated with immune protection in subjects who do not develop symptoms of RSV. In those studies, the level of IgA expression seen was similar to the levels of expression detected post-vaccination with MVA-BN RSV.

About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safe therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to improve the health and quality of life for children and adults. We supply our IMVAMUNE® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union (under the trade name IMVANEX®) and in Canada. Registration studies are currently underway in the U.S. In addition to our long-standing collaboration with the U.S. government on the development of IMVAMUNE® and other medical countermeasures, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, in collaboration with the National Cancer Institute, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors. For more information visit www.bavarian-nordic.com or follow us on Twitter [@bavariannordic](https://twitter.com/bavariannordic).

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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