Company Announcement

Bavarian Nordic Announces Marketing and Distribution Agreement with Dynavax to Launch HEPLISAV B® Hepatitis B Vaccine in Germany

COPENHAGEN, Denmark, May 27 2021 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) has entered a partnership with Dynavax Technologies Corporation (Nasdaq: DVAX) a biopharmaceutical company focused on developing and commercializing novel vaccines for the marketing and distribution of their HEPLISAV B® [Hepatitis B Vaccine (Recombinant), Adjuvanted] Hepatitis B vaccine in Germany with an expected launch in the fourth quarter of 2021.

In February 2021, the European Commission (EC) granted marketing authorization for HEPLISAV B for the active immunization against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older. HEPLISAV B is the only FDA- and EC-approved hepatitis B vaccine with a two-dose schedule for adults that is completed in one month.

HEPLISAV B will complement and strengthen Bavarian Nordic's commercial portfolio by leveraging its existing marketing and distribution network in Germany, which, in addition to the Company's own vaccines for rabies and tick-borne encephalitis, also will include Valneva's vaccines for Japanese Encephalitis and cholera as part of the mutual marketing and distribution agreement entered last year. The strong overlap with the existing target audience within general practitioners, occupational health groups and travel medicine specialists provides a good strategic fit and clear commercial synergies for the dedicated sales force, Bavarian Nordic has established in Germany.

Ryan Spencer, Chief Executive Officer of Dynavax, commented: "We are excited to work with Bavarian Nordic on the commercialization of HEPLISAV B in Germany. Hepatitis B is a highly infectious and potentially deadly virus with increasing infection rates, and over 250 million people infected worldwide. Thankfully, hepatitis B can be prevented with effective vaccination. With a two-dose regimen that takes only one month to complete and a statistically significantly higher seroprotection rate in head-to-head clinical trials, HEPLISAV B provides a unique opportunity to address known challenges with compliance, while delivering higher levels of protection compared to the three-dose regimen of the comparator vaccine."

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "We are pleased to expand our commercial footprint in the largest EU market by adding a complementary product to our marketing and distribution and we look forward to assisting Dynavax in a successful market entry in Europe later this year."

About Hepatitis B

Hepatitis B is a viral disease of the liver that can become chronic and lead to cirrhosis, liver cancer and death. The hepatitis B virus is 50 to 100 times more infectious than HIV,[i] and transmission is on the rise. There is no cure for hepatitis B, but effective vaccination can prevent the disease.

In adults, hepatitis B is spread through contact with infected blood and through unprotected sex with an infected person. The U.S. Centers for Disease Control (CDC) recommends vaccination for those at high risk for infection due to their jobs, lifestyle, living situations and travel to certain areas.[ii] Because people with diabetes are particularly vulnerable to infection, the CDC recommends vaccination for adults age 19 to 59 with diabetes as soon as possible after their diagnosis, and for people age 60 and older with diabetes at their physician's discretion.[iii] Approximately 20 million U.S. adults have diabetes, and 1.5 million new cases of diabetes are diagnosed each year.[iv]

About HEPLISAV B

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HEPLISAV B is an adult hepatitis B vaccine that combines hepatitis B surface antigen with Dynavax's proprietary Toll-like Receptor (TLR) 9 agonist CpG 1018 adjuvant to enhance the immune response. Dynavax has worldwide commercial rights to HEPLISAV B.

Important EU/EEA Product Information
HEPLISAV B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

The use of HEPLISAV B should be in accordance with official recommendations.
It can be expected that hepatitis D will also be prevented by immunisation with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

For full E.U. Prescribing Information for HEPLISAV B, click here.

Important EU/EEA Safety information
Do not receive HEPLISAV B if you have had a sudden life-threatening, allergic reaction after receiving HEPLISAV B in the past, or if you are allergic to any of components of this vaccine, including yeast. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.

Appropriate medical treatment and supervision should be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The administration of HEPLISAV B should be postponed in subjects suffering from acute severe febrile illness.
Immunocompromised persons may have a diminished immune response to HEPLISAV B.

Because of the long incubation period of hepatitis B, it is possible for unrecognised HBV infection to be present at the time of immunisation. HEPLISAV B may not prevent HBV infection in such cases.

There are very limited data on the immune response to HEPLISAV B in individuals who did not mount a protective immune response to another hepatitis B vaccine.

As a precautionary measure, it is preferable to avoid the use of HEPLISAV B during pregnancy. Vaccination during pregnancy should only be performed if the risk-benefit ratio at the individual level outweighs possible risks for the fetus.

The most common patient-reported side effects reported within 7 days of vaccination were pain, swelling or redness at the injection site, feeling tired, headache, muscle aches, feeling unwell and fever.

Important U.S. Product Information
HEPLISAV B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older.

For full U.S. Prescribing Information for HEPLISAV B, click here.

Important U.S. Safety Information (ISI)
Do not administer HEPLISAV B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV B, including yeast. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV B. Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV B. Hepatitis B has a long incubation period. HEPLISAV B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration. The most common patient reported adverse reactions reported within 7 days of vaccination were injection site pain (23% to 39%), fatigue (11% to 17%) and headache (8% to 17%).

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company's first commercial product, HEPLISAV B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], is approved in the U.S. and European Union for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18

years and older. Dynavax is also advancing its CpG 1018 adjuvant as a premier vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacture and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. government of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS®, also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Our commercial product portfolio furthermore contains the market-leading vaccine Rabipur®/RabAvert® against rabies and Encepur® against tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, MVABEA®, which is licensed to the Janssen Pharmaceutical Companies of Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine based on an in-licensed capsid virus-like particle technology. The vaccine candidate, ABNCoV2, is currently being investigated in clinical trials. For more information visit www.bavarian-nordic.com.

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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[i] CDC. https://www.cdc.gov/hepatitis/hbv/bfaq.htm
[ii] CDC. https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm
[iii] CDC. https://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf
[iv] CDC. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf