



LATE-CYCLE MEETING MATERIALS

November 25, 2024

Our STN: BLA 125820/0

Bavarian Nordic A/S
Attention: Todd Phillips
Bavarian Nordic Inc.
1005 Slater Road, Suite 101
Durham, NC 27703

Dear Dr. Phillips:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for VIMKUNYA, (Chikungunya Vaccine, Recombinant) injectable suspension, supplied as a single 0.8 mL dose pre-filled syringe.

Based on the progress of the review, we do not have any substantive review issues to discuss at this time. If you do not have any questions, additional data, or analyses to discuss for this application, the Late Cycle meeting may be cancelled upon your request. Please inform us in writing within two business days if you would like to cancel this meeting. If not, please identify your topics for discussion at the Late Cycle meeting, currently scheduled for December 4, 2024, 8:01 AM-9:31 AM.

If you have any questions, please contact the Regulatory Project Managers, Georgeta Crivat, Ph.D. (Georgeta.Crivat@fda.hhs.gov), Vera Stupina, Ph.D. (Vera.Stupina@fda.hhs.gov), and Ms. Katherine Berkhausen (Katherine.Berkhausen@fda.hhs.gov), by email.

Sincerely,

Loris D. McVittie, Ph.D.
Director
Division of Review Management and
Regulatory Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research