

MVA-BN[®] (IMVANEX[®]/IMVAMUNE[®]): A non-replicating, new generation smallpox vaccine available for updating smallpox preparedness plans

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Decades after its eradication, Variola virus still remains a threat due to its potential use in biological warfare and bioterrorism. Traditional replicating smallpox vaccines stockpiled for military use and post-outbreak mass vaccination are associated with rare, but potentially severe and even fatal adverse drug reactions. Moreover, their use is contraindicated in a considerable percentage of the population which is known to have an increased risk of serious adverse events, such as people with compromised immune systems and chronic skin conditions. MVA-BN[®] smallpox vaccine (IMVANEX[®] in Europe, IMVAMUNE[®] in the US and Canada), a live, highly attenuated vaccinia strain which does not replicate in human cells, is an alternative to traditional (replicating) smallpox vaccines. The safety database of MVA-BN[®] was recently enlarged to a total of more than 7, 300 subjects due to ongoing phase II and III trials. Although these trials are still blinded, the safety data confirm the excellent safety profile of MVA-BN[®], showing no relevant cardiac events, as well as none of the severe side effects associated with traditional smallpox vaccines due to their replicating nature. In the US, MVA-BN[®] obtained pre-Emergency Use Authorization (pre-EUA) for all populations with HIV and atopic dermatitis, which has led to stockpiling of 20 million doses of MVA-BN[®] for emergency use specifically in these populations. Recently, MVA-BN[®] has been granted marketing authorization in the European Union and in Canada. The acknowledged positive risk-benefit profile of MVA-BN[®] has opened up new opportunities for changing pre-event smallpox vaccination policies, but also for post-event preparedness plans such as stockpiling of MVA-BN[®], including use for people with contraindications to traditional vaccines.

Biography

Nathaly Arndtz-Wiedemann obtained her medical degree from the University of Munich in Germany. She has 18 years of experience in the pharmaceutical and biotech industry, particularly in the field of prophylactic vaccines and immunotherapeutic biologicals, working for companies like SmithKline Beecham, Berna Biotech and Bavarian Nordic. In her current position, she is leading the Clinical Department at Bavarian Nordic, being responsible for the overall clinical strategy and the planning and execution of all clinical programs for development of the company's preventive vaccines against infectious diseases.

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