RMP SUMMARY

JYNNEOS® (SMALLPOX AND MPOX VACCINE MODIFIED VACCINIA ANKARA-BAVARIAN NORDIC (MVA-BN®) (LIVE ATTENUATED, NON-REPLICATING))

Based on: EU RMP Version 9.3

Data lock point for this RMP	31-Jul-2022
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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of JYNNEOS® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of JYNNEOS® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Bavarian Nordic Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of JYNNEOS®.

SUMMARY OF RISK MANAGEMENT PLAN FOR JYNNEOS® (SMALLPOX AND MPOX VACCINE MODIFIED VACCINIA ANKARA-BAVARIAN NORDIC (MVA-BN®) (LIVE ATTENUATED, NON-REPLICATING))

This is a summary of the risk management plan (RMP) for JYNNEOS. The RMP details important risks of JYNNEOS, and how more information will be obtained about JYNNEOS's risks and uncertainties (missing information).

JYNNEOS's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how JYNNEOS should be used.

This summary of the RMP for JYNNEOS should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).
Important new concerns or changes to the current ones will be included in updates of JYNNEOS's RMP.

I THE MEDICINE AND WHAT IT IS USED FOR

JYNNEOS is authorised for active immunisation against smallpox, mpox and disease caused by vaccinia virus in adults (see SmPC for the full indications). It contains smallpox vaccine live Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN®) (live attenuated, non-replicating) as the active substance and it is given by subcutaneous (SC) injection.
Further information about the evaluation of JYNNEOS's benefits can be found in IMVANEX*'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/Imvanex.

*IMVANEX® is the EU brand name of MVA-BN, called JYNNEOS® in Switzerland

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of JYNNEOS, together with measures to minimise such risks and the proposed studies for learning more about JYNNEOS's risks, are outlined below.
Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of JYNNEOS is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of JYNNEOS are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of JYNNEOS. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

As of the date of this report, BN oversees 8992 subjects exposed with JYNNEOS, including at-risk populations for which replicating smallpox vaccines such as Dryvax and ACAM2000 are contraindicated, e.g. individuals with AD or HIV infected subjects. (late breaking: more than 900.000 doses have been administered in the US in the ongoing mpox outbreak as of 11-Oct-2022, numbers from other countries are still being compiled).

No trends for unexpected and/or serious adverse reactions were detected and no difference in the safety profile has been observed between vaccinia-naïve and vaccinia-experienced subjects receiving JYNNEOS.

Important identified risks	None
Important potential risks	Myo-/pericarditis Postvaccinal encephalitis
Important missing information	Use during pregnancy and breastfeeding Elderly subjects Individuals with organ impairment Immunocompromised patients Interactions with other vaccines and concomitantly

II.B Summary of Important Risks

Important potential risk: Myo-/pericarditis	
Evidence for linking the risk to the medicine	Pharmacological class effect, US Department of Defense Smallpox Vaccination Program (US DoD 2007); ACAM2000 package information leaflet
Risk factors and risk groups	No risk factors identified;
Risk minimisation measures	Routine risk minimisation measures • All cases of suspected/possible myo-/pericarditis will be followed-up according to the case definitions as published by the Centers of Disease Control and Prevention • As no confirmed cases of myo-/pericarditis have been reported for JYNNEOS, no additional risk minimisation activities are considered necessary. Additional risk minimisation measures None proposed
Additional pharmacovigilance activities	Additional pharmacovigilance activities: POX-MVA-039 SEMVAc study See section II.C of this summary for an overview of the post-authorisation development plan.

Important potential risk: Postvaccinal encephalitis	
Evidence for linking the risk to the medicine	Pharmacological class effect, US Department of Defense Smallpox Vaccination Program (US DoD 2007); ACAM2000 package information leaflet
Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures • All cases of suspected/possible postvaccinal encephalitis will be followed-up • As postvaccinal encephalitis has not been reported for JYNNEOS, no additional risk minimisation activities are considered necessary. Additional risk minimisation measures None proposed
Additional pharmacovigilance activities	Additional pharmacovigilance activities: POX-MVA-039 SEMVAc study See section II.C of this summary for an overview of the post-authorisation development plan.
Missing information: Use during pregnancy and breastfeeding	
Risk minimisation measures	Routine risk minimisation measures SmPC Section 4.6 '**Fertility, pregnancy and lactation** clearly points out that use during pregnancy and breastfeeding is not recommended. Additional risk minimisation measures None proposed
Additional pharmacovigilance activities	Additional pharmacovigilance activities: POX-MVA-039
Missing information: Interactions with other vaccines and concomitantly administered immunoglobulins	

Risk minimisation measures	Routine risk minimisation measures SmPC section Interaction with other medicinal products and other forms of interaction states: 'No interaction studies with other vaccines or medicinal products have been performed. Therefore, concomitant administration of JYNNEOS with other vaccines should be avoided. The concomitant administration of the vaccine with any immunoglobulin including Vaccinia Immune Globulin (VIG) has not been studied and should be avoided' Additional risk minimisation measures None proposed

No table is applicable for important missing information on elderly subjects, on individuals with organ impairment, and on immunocompromised patients, as no risk minimization measures are proposed.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorization

Study short name: PASS/PAES POX-MVA-039: An observational post-authorization safety and efficacy study for the prophylactic vaccination with JYNNEOS following re-emergence of circulating smallpox infections
Purpose of the study: The primary objective of the study will be to monitor and characterise incidence of serious adverse events and/or medically attended adverse events in patients exposed to JYNNEOS in accordance with a national public health vaccination program and/or other real-life use.
Effectiveness endpoints will also be included in the PASS/PAES.

The POX-MVA-039 study is not designed or operationally feasible to adapt during current mpox outbreak, due to the difference between smallpox and mpox mode of transmission and the present implementation of vaccination campaigns to target a limited number of people in close contact with mpox cases and people at high risk of exposure.

Study short name: SEMVAc (Sicherheit und Effektivität der MVA-BN Impfung gegen MPXV-Infektion bei Risikopersonen in Deutschland) (Safety and Effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany)
Purpose of the study: This is a prospective, non-interventional, multicentric cohort study. It is a non-BN sponsored clinical study. The primary outcome measure is vaccine effectiveness of JYNNEOS against symptomatic PCR-detected mpox disease, defined as reduction in risk of disease in vaccinated versus unvaccinated individuals. Safety and tolerability of JYNNEOS vaccination will be assessed through questionnaires as one of the secondary outcome measures.

The study has started on 07-Jul-2022.

II.C.2 Other Studies in Post-Authorisation Development Plan

NA