

**Teleconference with Bavarian Nordic (BN) to Discuss
Pediatric Requirements in Support of Monkeypox
Indication For JYNNEOS**

Date/Time:

April 15, 2019, 2:30 PM EST

CBER Attendees

Doran Fink, David Rouse, Bharat Khurana and Sudhakar Agnihothram

BN Attendees

Barbara Petzold, Heinz Weidenthaler, Jane MacLennan, Chris Heery and Renee Boerner

Discussion Points

- In response to BN's question regarding the origin of the request for the inclusion of an indication for the prevention of monkeypox infection for JYNNEOS, CBER indicated that the request came in from the government stakeholders external to the FDA and cannot provide any further details.
- BN indicated that since monkeypox infection is very rare in the US, BN currently considers no pediatric population to be at risk of monkeypox infection. BN considers the conduct of clinical trials in the pediatric population to be impossible or highly impractical, thereby supporting a full-waiver in all pediatric age groups. In support of this rationale, BN quoted data from literature noting that other than the 2003 outbreak of monkeypox infection in USA, no other cases have been reported, although cases related to travelers are always a possibility. Pediatric populations currently at risk or exposed to monkeypox virus are in Sub-Saharan Africa, where conducting clinical studies would be impractical.
- Given this rationale, BN wanted to understand why CBER considers it difficult to justify a full-waiver for the pediatric studies. CBER clarified that a PREA PMR study would not necessarily need to be conducted in the US. CBER also clarified the previously stated advice that considerations for granting a full-waiver for pediatric studies for a monkeypox indication are not as straightforward as for the smallpox indication, since small pox is completely eradicated worldwide. However, following further internal discussion CBER agrees that BN has made a compelling argument to support a full waiver for the monkeypox indication, since pediatric populations currently at risk of monkeypox infection are currently limited to those residing in deeply forested and remote areas of the Democratic Republic of Congo in Africa. Furthermore, use of JYNNEOS for prevention of monkeypox in the U.S. would be limited to adult laboratory workers who handle monkeypox virus and adult public health officials who might be asked to respond

to monkeypox outbreaks. CBER appreciated that BN provided their own assessment in support of the proposed waiver request.

- CBER advised BN to submit a waiver request that includes the justifications discussed during this teleconference. BN may follow the format of a Pediatric Study Plan and may submit a draft copy for CBER's review via email.
- Action Item – BN plans to submit a draft of a full-waiver request via email during the week of April 29, 2019 and FDA will review the request and provide feedback for a formal submission.