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Date: 26/08/2024 17:54:04
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Attachments: image001.png
CIOMS_2024000029.pdf

Dear team,

Please see below a proposal of sponsor assessment for the follow-up 1 NTEAE received on 03-Jul-2024 , for patient 01-01-089 from site # 01-01. The SAE term reported in this form is “Infusion related reaction” and the investigator assessed the relationship to ICT01 to be “related” and to pembrolizumab to be “unlikely” related.

Sponsor assessment:

"Infusion related reaction" is expected according to the current version of the ICT01 investigator's brochure.
"Infusion related reaction" is expected according to the current version of the PEMBROLIZUMAB SmPC.

"Infusion related reaction" occurred at the same date of the first administration of ICT01 and pembrolizumab. The chronology between the onset of event and ICT01/pembrolizumab administration is compatible. "Infusion related reaction" has been observed after the administration of ICT01 in monotherapy and also in combination with pembrolizumab, according to the most recent version of approved IB. In this context, the sponsor endorses the investigator's opinion that this event of "Infusion related reaction" is probably related to ICT01, and "unlikely" related to pembrolizumab.

Analysis of similar events:
Cumulatively, at the time of this reaction, this is the 29th case of "infusion related reaction" reported as SAE/AESI since start of ICT01 development. Among these cases, 3 (11%) were grade 1, 17 (60%) were grade 2 and 8 (29%) were grade 3. All cases were resolved/recovered, and only one recovered with sequelae.

"Infusion related reaction" is listed in the current version of ICT01 IB. Risk characterization is ongoing.

Please also find a draft CIOMS form for your review.

Please acknowledge via return e-mail if you agree with this evaluation and don’t hesitate to come back to us if you have any comments.

Best regards,

Maryna Neborachko
Clinical Safety Officer

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