25 June 2026
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Human Medicines Division

Assessment report for paediatric studies submitted according to Article 46 of the Regulation (EC) No 1901/2006

IXCHIQ

Chikungunya vaccine (live)

Procedure no: EMA/PAM/0000338015

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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Status of this report and steps taken for the assessment			
Current step	**Description**	**Planned date**	**Actual Date**
☐	CHMP Rapporteur AR	1 June 2026	28 May 2026
☐	CHMP comments	15 June 2026	n/a
☐	Updated CHMP Rapporteur AR	18 June 2026	n/a
☒	CHMP outcome	25 June 2026	25 June 2026

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1. Introduction

This report covers the following post-authorisation commitments undertaken by the MAH:

Submission of the response to Question 7d as committed to be provided under procedure EMA/PAM/0000264439 (original number) relatively to missing viraemia data at the time of submission of VLA1553-321 Part C.

Namely, as specified in question 7d: "*The Applicant commits to testing serum samples from participants with early-onset CHIK-like AR with missing viraemia data at Day 8 and Day 29. The respective results will be provided in tabular format, along with the additional information as requested*".

2. Summary of data submitted

Within this procedure, the MAH submitted viraemia results from participants with early-onset CHIK-like AR (early onset CLAR) that had missing viraemia data for plasma samples isolated at Day 8 and Day 29 at the time of submission of the completed data from the paediatric study VLA1553-321 (Part C).

In addition, as requested, the MAH submitted a consolidated table summarizing viraemia results from all the subjects of VLA1553-321 that experienced early onset CLAR and that includes preferred term, severity, if the subjects underwent acute visit (AC)/convalescent visits (CV) and if AESI criteria (both definitions separately) were met (listing 3).

In study VLA1553-321, 116/502 (23.1%) participants that were administered VLA1553 experienced early onset CLAR. Day 8 and Day 29 viraemia data from 38/116 participants were missing under procedure EMA/PAM/0000264439 and for 37/38 participants samples were retrospectively tested and results submitted within this procedure. Among these, one subject was baseline seropositive.

A quantifiable viraemia level was detected in the Day 8 sample of 1/37 subjects (plasma viral load of 9,138.6 GCE/mL). All the other Day 8 samples tested were either <LLOQ (2/37 subjects) or viraemia was not detectable or was <LOD (34/37 subjects, including the baseline seropositive subject). All Day 29 samples retrospectively tested for these 37 subjects were negative for viraemia.

<u>Summary of viraemia data for subjects of study VLA1553-321 that were administered VLA1553 and that experienced early onset CLAR (results submitted within different procedures):</u>

Of the 110 baseline seronegative participants with early onset CLAR in the VLA1553 group, at Day 8: 84/110 (76.4%) were non-viraemic; 16/110 (14.5%) were viraemic; 9/110 (8.2%) had inconclusive results; and 1/110 (0.9%) had no viraemia result available (samples not collected). No viraemia was detected at Day 29 in baseline seronegative participants with early onset CLAR.

Of the 16 viraemic participants at Day 8, 4 had viraemia levels <LLOQ, while 12 had quantifiable levels (mean plasma viral load: 44,331 GCE/mL; range: 5,511-138,492 GCE/mL). In viraemic participants, the occurrence of early onset CLAR and the severity of the CLAR were not linked to a specific viraemia level at Day 8, as viraemia levels varied considerably between participants. Similar early onset CLAR symptoms and longest CLAR symptom durations were observed in participants who were viraemic or non-viraemic at Day 8.

Of the 6-baseline seropositive VLA1553 participants with early onset CLAR, 5/6 participants had undetectable viraemia at Day 8 and Day 29, while one participant (REC01-035) had quantifiable viremia at Day 8 (12,518 GCE/mL) and was non-viraemic at Day 29. One subject that experienced severe pyrexia and

complied with the definition of CHIK-like AR but not of AESI - was already addressed in the response to Question 1d (EMEA/H/C/0005797/II/0001) and it was concluded that seropositive status was implausible.

The 116/502 participants in the VLA1553 group with early onset CLAR include the 17/502 participants of study VLA1553-321 that met the protocol definition of early onset AESI. For these subjects, available viraemia data have been previously assessed in procedure EMA/PAM/0000264439 and missing viraemia data for Day 8 and Day 29 have been submitted within this procedure.

Of the 116/502 participants in the VLA1553 group with early onset CLAR, 11/116 participants also met the protocol definition of late onset AESI, which was reported for 38/502 subjects administered VLA1553 in study VLA1553-321. For these subjects, viraemia data have been previously assessed in procedure EMA/PAM/0000264439.

3. Scientific discussion

In study VLA1553-321, 116/502 (23.1%) participants that were administered VLA1553 experienced early onset CLAR. Day 8 and Day 29 viraemia data from 38/116 participants were missing under procedure EMA/PAM/0000264439 and for 37/38 participants samples were retrospectively tested and results submitted within this procedure.

A quantifiable viraemia level was detected in the Day 8 sample of 1/37 subjects (subject MAO01-013, plasma viral load of 9,138.6 GCE/mL). All the other Day 8 samples tested were either <LLOQ (2/37 subjects) or viraemia was not detectable or was <LOD (34/37 subjects). All Day 29 samples retrospectively tested for these 37 subjects were negative for viraemia.

In the present procedure, the MAH provided missing Day 8 and Day 29 viraemia data for participants with early onset CLAR in the VLA1553 group. These additional data confirm that the majority of subjects experiencing early onset CLAR after IXCHIQ administration have undetectable viraemia at Day 8; that no differences in experienced CLAR symptoms are noted when comparing viraemic and non-viraemic participants; and that for participants who had positive viraemia at Day 8 and who experienced adverse event(s), their severity cannot be linked to a specific viraemia level.

4. Overall conclusion

The MAH submitted the requested missing viraemia data for subjects experiencing early-onset CHIK-like AR (CLAR) and a compiled table summarizing all the available data regarding viraemia tested in participants experiencing post-vaccination CLAR.

Missing data submitted do not contribute to identification of a potential link between vaccine viraemia levels detected early post-vaccination and reported adverse events (including their severity grading).

Overall and as previously already specified, with the available evidence generated in the context of the CDP of IXCHIQ, no conclusion can be drawn on the impact or absence of impact of vaccine viraemia on the safety of VLA1553.

☒ PAM fulfilled

No regulatory action required.