WHO Product Development for Vaccines Advisory Committee (PDVAC)

Meeting on Measles–Rubella Microarray patches

21 June 2023
Micron Biomedical announces positive measles and rubella vaccination results from first clinical trial of microarray injection-free vaccine delivery in children.

Successful Phase 1/2 study is the first clinical trial of any microarray technology in pediatric populations as the need for a pain-free, logistically simplified vaccine delivery option grows worldwide.

The study, which evaluated the safety, immunogenicity, and acceptability of the leading commercially available measles-rubella (MR) vaccine from the Serum Institute of India delivered by Micron’s microarray technology in adults, toddlers, and infants, was presented today at the Micron2023 conference in Seattle, Washington.

“Micron, with support from the Bill & Melinda Gates Foundation and the CDC, is thrilled to accomplish a major milestone in the future of injection-free administration of necessary and potentially life-saving vaccines and therapeutics,” said Steven Damon, CEO of Micron Biomedical. “With this completed Phase 1/2 clinical trial in children, in addition to other completed and ongoing Phase 1 and Phase 2 clinical trials, Micron remains at the forefront of the effort to bring microarray-based drug and vaccine products to market.”

Infants as young as 9 months old are among the first children in the world to be vaccinated via a microarray-based delivery system.


Funding accelerates Vaxxas’ clinical pipeline of innovative vaccines.

Accelerating the development of measles and rubella microarray patches to eliminate measles and rubella: recent progress, remaining challenges.

### Hypothetical timelines for Micron MR–MAP development

**please note: funding is currently not confirmed for manufacturing facility or phase III**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2021</td>
<td>Phase I/2</td>
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<tr>
<td>2022</td>
<td>Phase 2 Micron</td>
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<tr>
<td>2023</td>
<td>Phase 1/2 Vaxxas</td>
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<tr>
<td>2024</td>
<td>MAPs facility design, construction and scale up</td>
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<td>2025</td>
<td>Pilot-scale manufacturing</td>
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<td>2026</td>
<td>NRA Review</td>
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<td>2027</td>
<td>WHO PQ</td>
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<td>2028</td>
<td>Full-scale facility design, construction &amp; validation</td>
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<td>2034</td>
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The actual timelines may vary.

- Micron Phase 2 will be repeated in infants with greater number of participants and Vaxxas phase 1/2 will be conducted while the Micron pilot facility is being stood up – opportunity to refine **critical product attributes**
- Related to this, we need to understand how these vaccines will be prioritized for use in early introduction because initial supply will likely be limited.

**MR-MAP is ready to be used in LMICs.**
Objectives of this PDVAC meeting

- briefly review the status of the clinical and human factor studies for MR-MAPs and the phase 1/2 data from Micron Biomedical;
- consider the timeline and regulatory/WHO prequalification (PQ) implications for a MR-MAP with an additional MR antigen;
- review the anticipated priority use cases for introduction of MR-MAP, including findings from the WHO CAPACITI Innovation Framework, and discuss the implications on and remaining questions related to the critical product attributes;
- discuss the priority clinical and pre-implementation research questions that need to be conducted for MR-MAP in the next 2 years.

Please note: there are many moving parts that cannot be discussed today in an open forum so we will not be discussing funding, the manufacturing scale up strategy or the phase 3 clinical trial designs.

Also not in scope of discussion today: Vaxxas manufacturing scale up strategy.

We are focusing on the certainties (commitment to two phase 2 studies with each of Micron and Vaxxas) and seeking advice on critical questions and immediate next steps.
# Overview of the agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Proposed speaker</th>
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<tbody>
<tr>
<td>1.00 – 1.10pm</td>
<td>Welcome and opening remarks,</td>
<td>Ruth Karron &amp; Raman Rao</td>
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<td>Context for and objectives of the meeting</td>
<td>Birgitte Giersing</td>
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<td>1.10 – 1.35</td>
<td>Presentation of MR-MAP Phase 1/2 clinical study data, including</td>
<td>Ed Clarke (LSHTM) and Michael Royals (independent)</td>
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<td>15 + 10</td>
<td>acceptability findings of Micron MR-MAP</td>
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<td>1.35 – 1.50</td>
<td>Overview of MR-MAP candidates in product development</td>
<td>Courtney Jarrahian (PATH) (pre-recorded)</td>
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<td>10 + 5</td>
<td>o Plan for additional phase 2s and PATH human factors studies</td>
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<tr>
<td>1.50 – 2.05</td>
<td>Potential timeline and regulatory implications for development with</td>
<td>Birgitte Giersing (WHO)</td>
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<td>5 + 10</td>
<td>a different MR antigen</td>
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<td>2.05 – 2.30</td>
<td>MR-MAP priority use case analysis and critical product attributes</td>
<td>Mateusz Hasso-Agopsowicz (WHO) Anna-Lea Kahn (WHO) (pre-recorded)</td>
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<td>15 + 10</td>
<td>o Consideration of VVM30 and controlled temperature chain (CTC)</td>
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<td>2.30 – 3.00</td>
<td>Discussion on critical attributes and key clinical/product development</td>
<td>Ruth Karron &amp; Raman Rao to chair Birgitte Giersing (framing)</td>
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<td>(2’ framing)</td>
<td>research questions for MR-MAP</td>
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<td>3.00 – 4.00</td>
<td>PDVAC closed session</td>
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**Apologies**

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