WHO Product Development for Vaccines Advisory Committee (PDVAC)

Meeting on Measles-Rubella Microarray patches

21 June 2023

Recently announced phase 1/2 safety and immunogenicity data for MR-MAP

Micron Biomedical

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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.

ATLANTA, May 17, 2023 /PRNewswire/ — Micron Biomedical, a life science company developing first-in-class dissolvable microarray-based products that simplify and improve the administration, transport, and storage of drugs and vaccines, today announced positive Phase 1/2 data from the first-ever clinical trial of microarray technology in children including infants as young as 9 months old.

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 MICRONEEDLES 2023 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."

"This trial may help shape future approaches to reaching children and families with vaccines," said James Goodson, CDC.

Infants as young as 9 months old are among the first children in the world to be vaccinated via a

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Vaxxas Awarded US$5 million [AU$7.5 million] Grant for Clinical Study of Measles and Rubella Vaccination using Vaxxas' High Density Micro-Array Patch

Funding Accelerates Vaxxas' Clinical Pipeline of Innovative Vaccines

frontiers in Public Health

REVIEW
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Check for updates

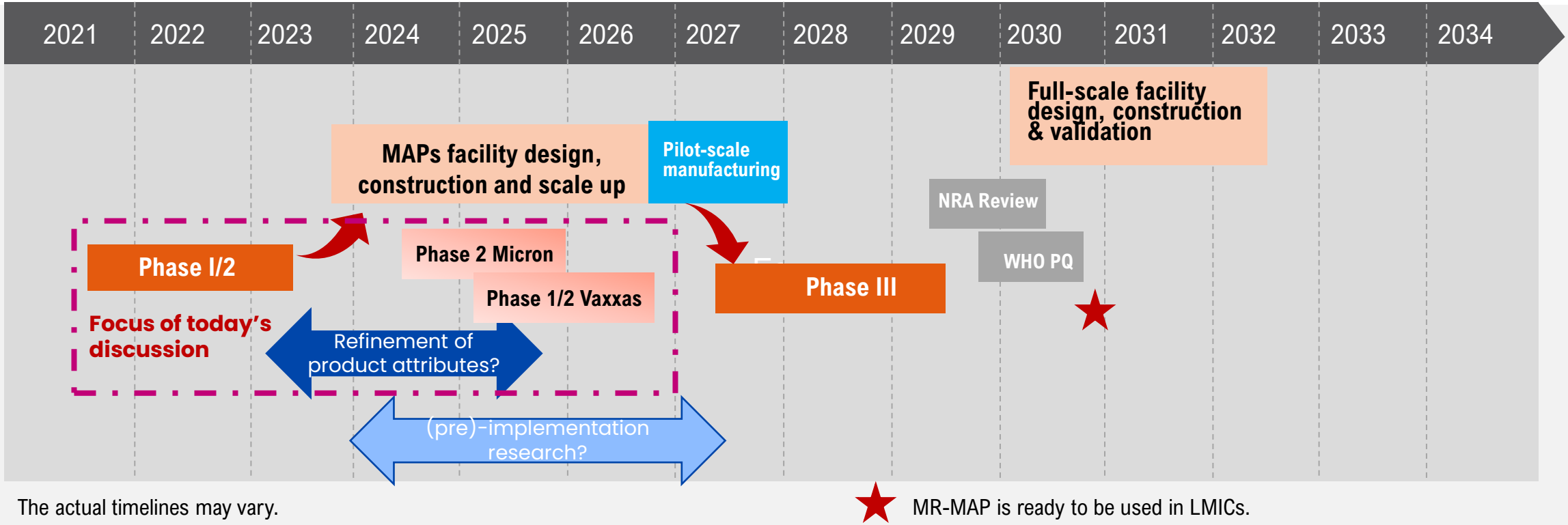
Accelerating the Development of Measles and Rubella Microarray Patches to Eliminate Measles and Rubella: Recent Progress, Remaining Challenges

Mateusz Hasso-Agopsowicz[1], Natasha Crowcroft[1], Robin Biellik[2], Christopher J. Gregory[3], Marion Menozzi-Arnaud[4], Jean-Pierre Amorij[5], Philippe-Alexandre Gilbert[6], Kristen Earle[6], Collrane Frivold[7], Courtney Jarrahian[7], Mercy Mvundura[7], Jessica J. Mistilis[7], David N. Durrheim[8] and Birgitte Giersing[1]*

OPEN ACCESS

https://micronbiomedical.com/micron-biomedical-announces-positive-measles-and-rubella-vaccination-results-from-first-clinical-trial-of-microarray-injection-free-vaccine-delivery-in-children/

Hypothetical timelines for Micron MR-MAP development
please note: funding is currently not confirmed for manufacturing facility or phase III



The actual timelines may vary.

★ MR-MAP is ready to be used in LMICs.

- 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.

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

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

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Apologies

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