Malaria monoclonal antibodies for malaria prevention: Preferred Product Characteristics and clinical development

3, 11, and 29 November 2021

Agenda time zone: Central European Time (CET) - Virtual meeting

Meeting Objectives:

1. Review the landscape of malaria mAbs and mAbs PPCs for other pathogens
2. Agree on a set of PPC criteria for malaria mAbs
3. Ensure alignment with WHO guidance on mAbs development and PPCs for mAbs for other pathogens (HIV, RSV, COVID) and complementarity with PPCs for malaria vaccines and chemoprevention.

PROVISIONAL PROGRAMME *(may be subject to change)*

Time	Topic	Speaker
Day 1, Nov 3	**Malaria mAbs pipeline: challenges and opportunities**	
12:20 – 12:30	**Call in period**	
12:30 – 12:40	**Welcome and introductions** **Opening remarks**	David Schellenberg, WHO GMP Pedro Alonso, Soumya Swaminathan
12:40 – 13:10	**Background on PPCs for malaria and mAbs** ▪ Summary of malaria PPCs and WHO framework for PPC development ▪ State of the art - mAbs for infectious diseases and WHO mAbs PPC development *Joint Q&A*	Lindsey Wu, WHO GMP Erin Sparrow, WHO IVB
13:10 – 13:20	*Break*	
13:20 - 15:30	**Overview of malaria mAbs development** ▪ Discovery and target identification ▪ Overview of malaria mAbs clinical development process and pipeline ▪ *Pf*CSP mAbs candidate CIS43 ▪ Clinical evaluation and manufacturing *Joint Q&A*	*Chair: Jean-Louis Ndiaye* Josh Tan, US NIAID Kayla Andrews, Gates Medical Research Institute Bob Seder, US NIAID Lisa Connell-Crowley, Just-Evotec Biologics
15:30 – 15:40	*Break*	

Time	Topic	Speaker
15:40-16:40	**Background on existing malaria mAb TPPs** ▪ Overview of BMGF TPps for mAbs ▪ The use of modelling to inform PPCs ▪ Technical criteria in BMGF mAbs TPPs *Joint Q&A*	*Chair: Kevin Marsh* Jean-Luc Bodmer BMGF Narimane Nekkab and Melissa Penny, STPH Jacqueline Kirchner, BMGF
16:40 – 16:50	**Closing remarks**	David Schellenberg
Day 2, Nov 11	**Use case scenarios and PPC review (closed session with scientific committee members only)**	
12:20 – 12:30	Call-in period	
12:30 – 12:40	**Plan for the day** SDC administration (DOIs), scene setting – epidemiological considerations	Lindsey Wu
12:40 – 13:50	**Discussion of use case scenarios** Potential discussion topics: development options that will affect PPC criteria, use in seasonal vs. perennial settings, prevention of infection vs. transmission, infants/children vs older children/adults, malaria in pregnancy, emergency situations, mAbs used in combination with other malaria interventions	*Chair: Francisco Saute*
13:50 – 14:00	*Break*	
14:00 – 16:15	**Review of PPC criteria for priority use cases** Potential discussion topics: detailed review of each PPC criteria description, need for additional use case scenarios and/or criteria	*Chair: Kevin Marsh*
16:15 – 16:25	**Building consensus**	TBD if needed
16:25 – 16:30	**Closing remarks**	David Schellenberg
Day 3, Nov 29	**Product development to implementation**	
13:20 – 13:30	Call-in period	
13:30 – 13:50	**Welcome and introduction** **Summary of SDC working session**	Chairs Lindsey Wu
13:50 – 14:50	**Session 1: Early clinical development** 3 discussion topics (20 min each) ○ Preclinical models ○ CHMI ○ Target life cycle stages	Chair: Francisco Saute
14:50 – 15:00	*Break*	
15:00 – 16:20	**Session 2: Late clinical development**	Chair: Kevin Marsh

Time	Topic	Speaker
	3 discussion topics (20-30 min each) ○ Standardising efficacy endpoints ○ ADAs, mAbs-vaccine interactions ○ Age de-escalation, pregnancy studies	
16:20 - 16:50	**Session 3: Phase 3 to implementation** ○ WHO PQ and CSA ○ WHO Evidence to Decision policy process ○ Manufacturing to meet supply/demand	Chair: Kevin Marsh
16:50 – 17:00	**Concluding remarks & next steps** **Closure**	Lindsey Wu