

International PfSPZ Consortium Meeting
University of Maryland Institute for Bioscience and Biotechnology Research
9600 Gudelsky Drive, Rockville, MD 20850

Day 1: Monday, November 18, 2019 - 8:30-18:00

Time	Subject	Presenter(s)
08:30	Arrival, Registration Coffee	
09:00	Welcome	Peter Billingsley
09:05	Welcome to IBBR	Tom Fuerst
09:15	Celebrating the life of Shahid Khan	All - led by Stephen Hoffman
09:35	Overview and expectations of the meeting	Stephen Hoffman, Peter Kremsner, Mitoha Ond'o Ayekaba
	Pathway to licensure for PfSPZ Vaccine	
09:45	Overview of Sanaria strategy	Stephen Hoffman
10:00	PEI-Sanaria meeting summary and outcomes	Stephen Hoffman, Peter Kremsner
10:15	The kENUP Foundation and EU Malaria Fund	Regina Rabinovich
	Regulatory	
10:25	The regulatory pathway to licensure of PfSPZ Vaccine	Tooba Murshedkar
	Safety	
10:35	Safety of PfSPZ Vaccine - an analysis from all trials	Preston Church
	Licensing PfSPZ Vaccine for protection of 18-50-year-old adults with little or no previous or recent exposure to malaria, who visit areas of Africa where malaria is transmitted.	
10:50	Heterologous (Pf7G8) CHMI is as stringent a test of vaccine efficacy as is field exposure	Thomas Richie
11:00	An explanation for stringency of heterologous CHMI based on genomic, proteomic, and predicted CD8 T cell epitope data	Joana Carneiro da Silva
11:10	Coffee	
11:25	Diagnostic qPCR for CHMI - to be covered tomorrow	Sean Murphy
11:25	Overview of studies to support licensure	Thomas Richie
11:30	Mali 1-4	Alassane Dicko, Sara Healy
11:45	LaSPZV1	Peter Kremsner
11:55	Warfighter 3: 1, 8, 29 day PfSPZ Vaccine regimen (9.0x10 ⁵ PfSPZ) with 7G8 CHMI on days 2, 7, 14 and	Judy Epstein
12:05	The 152 in Germany and US: 1, 8, 29 day PfSPZ Vaccine regimen (9.0x10 ⁵ PfSPZ) with 7G8 CHMI on	Peter Kremsner, Patrick Duffy
12:15	Discussion: focus on strategy, timeline and clinical trials	Peter Kremsner, Stephen Hoffman
12:45	Lunch	
	Licensing PfSPZ Vaccine for protection of 2-50-year-olds living in malaria endemic areas: Field trial with Phase 3 compliant vaccine	
13:30	Controversies (primary and secondary outcome variables, clearance of parasitemia)	Thomas Richie
13:40	Scientific Advisory Board perspective	Preston Church
13:50	Validation of TBS for field studies	Pete Billingsley
13:55	Confirmation of TBS by PCR: to be covered tomorrow	Sean Murphy
13:55	Confirmation by genomic sequencing	Joana Carneiro da Silva
14:00	Incidence study	Raul Chuquiyaury
14:10	EGSPZV4 trial	Said Jongu
	Structured discussion	
14:25	Summary of the plan as presented including short, medium and long term goals	Stephen Hoffman, Peter Kremsner
14:35	How do we improve the plan, especially EGSPZV4?	All
15:10	Coffee	
	PfSPZ Vaccine - addressing limitations	
15:25	Overview	Thomas Richie
15:35	Infants in Kenya: updated analysis	Thomas Richie
15:45	Infants in Kenya: lack of T cell responses	Phil Swanson
15:55	Discussion	
16:25	Plans for the first clinical trial of a PfCSP mAb and plans for further development of mAbs	Robert Seder
	Future work: the mid- and long-term timelines	
16:35	Expanding the use of PfSPZ Vaccine: mid- and long-term timelines	Thomas Richie
16:40	Update on Reprotox study in rabbits	Pete Billingsley
16:45	Women of childbearing potential	Alassane Dicko
16:55	Vaccinations for seasonal malaria prevention in children	Alassane Dicko
	Progress to elimination	
17:00	EG - BIMEP (paper, P3 award)	Mitoha Ondo'o Ayekaba/Chris Schwabe
17:15	Modeling vaccine strategies in EG	Daniel Citron
17:25	Current control and selection of locations for cluster randomized control	Guillermo Garcia/Carlos Cortes
17:35	Feasibility of elimination with PfSPZ Vaccine - cluster randomized and step-wedge studies (100&Change)	Pete Billingsley, Salim Abdulla (remotely)
17:45	Strategies for elimination elsewhere	Honorati Masanja
17:55	A ministry of health view of elimination	Mitoha Ondo'o Ayekaba
18:05	Finish for the day	
19:00	Dinner at Thai Tanium, Kentlands Market Square, Gaithersburg MD 20878	
18:05	Side meeting: sample finalization for EGSPZV4	By Invitation - you will know who you are

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Tuesday, 19 November 2019

Time	Subject	Presenter
08:30	Breakfast	
09:00	Introduction to the day	Stephen Hoffman
	PfSPZ-CVac Current and Planned Trials	
09:10	Overview of PfSPZ-CVac clinical development plan	Thomas Richie
09:20	PfSPZ-CVac (PYR/CQ) - results of LMIV clinical trials focusing on heterologous CHMI at 12-13 weeks	Agnes Mwakingwe
09:30	TÜCHMI-003 results, day 1, 6, and 29 reigmen heterologous CMMI at 12.5 weeks	Peter Kremsner
09:40	PfSPZ-CVac (PYR/CQ) - field trial in adults in Mali	Patrick Duffy/David Cook
09:50	IDSPZV1 - PfSPZ-CVac (CQ) field trial in soldiers in Indonesia	Thomas Richie
	Progress with genetically altered SPZ vaccines - the journey toward a mid- to late-arresting GAP	
10:00	Outline of PfSPZ-GAP strategy	Stephen Hoffman
10:10	PfSPZ-GAP3KO - final results of clinical trial in Seattle and manufacturing plans	Ashley Vaughan/Kim Lee Sim
10:20	Late arresting, replication competent (LARC) vaccines: Progress and plans for PfSPZ-LARC1 (MEI2 KO)	Ashley Vaughan
10:35	PbSPZ-PfCSP: results of clinical trial and future plans	Miguel Prudêncio
10:45	PfSPZ-PvCSP and other knock in parasites	Leiden team
10:50	Coffee	
11:05	Structured discussion: the future pathway for PfSPZ-CVac	Peter Kremsner, Patrick Duffy
	Improving efficacy and reducing cost of goods	
11:35	Overview	Kim Lee Sim
11:40	Progress and plans for multi-strain and hybrid PfSPZ vaccines	Ashley Vaughan/Kim Lee Sim
11:50	<i>In vitro</i> production of PfSPZ	Abraham Eappen
12:00	Status of 7DW8-5 adjuvant including GMP manufacture	Sumana Chakravarty, Moriya Tsuji
12:10	Immunocompromised mosquitoes	Ehud Inbar
12:20	Lunch	
	Optional tours of the insect transformation facility during lunch hour	Ehud Inbar/Robert Alford
	Immunology and human mAbs	
13:20	Introduction	Stephen Hoffman
13:25	Cellular immunological results in IMRAS	Ken Stuart
13:35	Cellular immunological results from PfSPZ vaccines studies in Mali and US	Irfan Zaidi
13:45	Cellular immunological results from studies in Tanzania and Equatorial Guinea	Claudia Daubenberger
13:55	Planned cellular immunological and systems biology studies	John Tsang
14:05	Initial results and planned antibody based studies	Jon Herman
14:15	Planned TCR studies	Moriya Tsuji
14:25	Discussion	Moderators: Sumana Chakravarty, Claudia Daubenberger
	Ongoing and Planned CHMI studies for next 12 months	
14:55	Lambaréné, Gabon: LACHMI2	Peter Kremsner
15:00	Kilifi, Kenya: Vac074 and TransMod	Melissa Kapulu (remotely)
15:10	Bethesda, USA: ECG study	Judy Epstein
15:15	PvSPZ Challenge: development and plans	Sumana Chakravarty
15:25	Confirmation of TBS and qPCR in CHMI and field studies using validated PCR markers	Sean Murphy
15:35	Discussion	
14:55	Coffee	
	Close-Out Session	
15:10	Funding opportunity: UO1	All - led by Stephen Hoffman
15:40	General discussion: consortium priorities for 2020	TBD
16:10	Close out	Stephen Hoffman
16:20	Optional tours of Sanaria	