CEPI

Portfolio Review Meeting with the CEPI Scientific Advisory Committee

9-10th November 2022

MEETING REPORT – EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

Since its launch in January 2017, CEPI has built a global portfolio of over 110 projects with more than 400 awardees and sub-awardees in over 50 countries, across vaccine development, enabling science, and cross-cutting activities for a broad range of emerging infectious diseases. On 9-10th November 2022, CEPI conducted a review of its Disease X, Lassa, Broadly Protective Coronaviruses (BPCV), and Nipah R&D and manufacturing portfolios, engaging its Scientific Advisory Committee (SAC) and key coalition partners in a technical review of portfolio targets and priorities to achieve the strategic objectives for CEPI's second five-year programme, "CEPI 2.0". Specific objectives for the Portfolio Review meeting were to:

1. Recap on CEPI 2.0 strategic targets and plans for each pathogen / area;
2. Review CEPI portfolio composition and performance for each pathogen / area;
3. Align on portfolio priorities and investment needs for each pathogen / area.

During the meeting, participants provided perspectives on CEPI's targets and strategy across the entire R&D investment portfolio. Acknowledging that CEPI activities have had a positive impact in the field globally, participants urged CEPI to continue to advance its R&D portfolio and strategy, including CEPI's 100 Day Mission, capitalizing on its unique skills and competencies while focusing investments where biggest needs in product development exist. Four broad areas were highlighted to ensure successful delivery of CEPI 2.0 portfolio targets:

(i) Actively monitoring prioritization efforts from both pathogen and platform specific perspectives, focusing on the balance between investing in platforms versus disease-specific vaccine development programmes;
(ii) Embedding a manufacturing strategy in platform and disease-specific initiatives and together with regional partnerships helping address anticipated equitable access issues anticipated to emerge through the successful implementation of vaccine development programmes;
(iii) Capitalizing on technical/scientific data across projects and programmes to improve decisions to advance CEPI's R&D portfolio, including risk assessments building on scenarios where projects shall be terminated;
(iv) Focusing on preparedness activities that fill gaps for outbreak response and continuing to nurture co-funding relationships to maintain momentum in epidemic and pandemic response, connecting key players and forming networks for a response, without major own investments.

For Disease X, participants recommended that CEPI advances at least one mRNA-based prototype vaccine through licensure submission and builds vaccine libraries through clinical proof of concept for up to four virus families, using multiple platform innovations. In doing so, they urged CEPI to:

(i) Continuously update and re-rank virus family priorities, based on evidence and modelling projections;
(ii) Continue to seek expert advice on immunogen design;
(iii) Explicitly consider data comparisons between RNA technologies and other platforms, to help expand the knowledge base on the potential of these;
(iv) Specify criteria for portfolio prioritization and ensure appropriate go/no-go stage gates are in place;
(v) Liaise with stakeholders to promote involvement of enabling science communities in target countries and to tackle perceived safety concerns with specific platforms.

For Lassa, participants recommended that CEPI continues support and prioritizes funding for Lassa vaccine candidates through phase 3 to licensure submission. To achieve this, they suggested that CEPI:

(i) Advances one vaccine candidate to phase 3, considering data from all programmes and using integrated prioritization criteria;
(ii) De-prioritizes further development of one candidate where anticipated advantages of the platform have not materialised;
(iii) Maintains critical mass and diversity in the portfolio to mitigate against risk of failure;
(iv) Finalizes internally desired Target Product Characteristics;
(v) Concludes epidemiological data collection and analysis to inform pivotal trial size and design;
(vi) Secures contractual commitments to allow tech transfer for manufacturing in Africa;
(vii) Continues to strengthen plans for manufacturing, clinical, regulatory and community engagement.

For BPCV, participants recommended that CEPI prioritizes demonstration of ≥1 variant proof broadly protective SARS-CoV-2 candidate through clinical proof of concept in the short-term and addresses scientific and technical concerns for the longer-term delivery of the broadly protective Betacoronavirus vaccine target. To do this, they noted that CEPI should:

(i) Develop standardized criteria for project prioritization;
(ii) Establish standardized stage gate review procedures and ensure standardized enablers are in place for comparing vaccine candidate performance;
(iii) Define virus panels and ensure strains are made available to assess breadth of protection;
(iv) Engage with scientific community to obtain consensus on definition of breadth of protection;
(v) Plan for biosafety risk assessments, which will require establishment of lab(s) (BSL3) for assessing candidates against panel of viruses.

For Nipah, participants recommended that CEPI prioritizes funding for vaccine candidates through late-stage development for licensure submission on an accelerated pathway, and that it continues support for mAb product development for outbreak use. To achieve this, they urged CEPI to:

(i) Advance one candidate to phase 2 studies while an additional candidate completes phase 1, with the vaccine candidate selection for phase 2/3 to be informed by clear criteria and models;
(ii) De-prioritize further development of one candidate where data suggest inferior performance;
(iii) Maintain critical mass and diversity in the portfolio to mitigate against risk of failure;
(iv) Continue to determine the use case (reactive vs. preventive) for Nipah vaccines and align Target Product Characteristics with the desired product profile for each use case;
(v) Consider clear criteria and models to support prioritization of vaccine candidates for late-stage development;
(vi) Continue to build interlinkages with Disease X for portfolio backup strategies and Chikungunya for data requirements to support accelerated approval pathways.

These recommendations will be incorporated into CEPI's portfolio planning activities over the coming months, to ensure successful implementation of the organization's R&D and Manufacturing & Supply Chain investment programmes.

APPENDIX I – AGENDA

November 9th 9.30am – 16.10pm BST:

Time	Session	
9:30-9:40	**Welcome** Richard Hatchett	
9:40-10:00	**Objectives for Day 1** Manu Hanon	
10:00-10:45	**Plenary Session: Overall portfolio overview** Melanie Saville	
10:45-11:00	*Break*	
11:00-12:30	**Day 1 Parallel Session: Disease X** Co-chairs: Alan Barrett *(SAC)* & Tim Endy *(CEPI)*	**Day 1 Parallel Session: Lassa** Co-chairs: Alash'le Abimiku *(SAC)* & Jakob Cramer *(CEPI)*
12:30-13:30	*Lunch*	
13:30-14.45	**Day 1 Parallel Session: Disease X** Co-chairs: Alan Barrett *(SAC)* & Tim Endy *(CEPI)*	**Day 1 Parallel Session: Lassa** Co-chairs: Alash'le Abimiku *(SAC)* & Jakob Cramer *(CEPI)*
14:45-15:00	*Break*	
15:00-15:50	**Plenary Session: Day 1 Playback Summaries** Alan Barrett & Alash'le Abimiku	
15:50-16:10	**Close** Manu Hanon	

November 10th 9.30am – 16.10pm BST:

Time	Session	
9:30-9:45	**Day 1 Recap & Objectives for Day 2** Manu Hanon	
9:45-10:45	**Plenary Session: Response activities** Melanie Saville and Nicole Lurie	
10:45-11:00	*Break*	
11:00-12:30	**Day 2 Parallel Session: BPCV** Co-chairs: Peter Paradiso *(SAC)* & Chris da Costa *(CEPI)*	**Day 2 Parallel Session: Nipah** Co-chairs: Paula Bryant *(SAC)* & Mike Whelan *(CEPI)*
12:30-13:30	*Lunch*	
13:30-14.45	**Day 2 Parallel Session: BPCV** Co-chairs: Peter Paradiso *(SAC)* & Chris da Costa *(CEPI)*	**Day 2 Parallel Session: Nipah** Co-chairs: Paula Bryant *(SAC)* & Mike Whelan *(CEPI)*
14:45-15:00	*Break*	
15:00-15:50	**Plenary Session: Day 2 Playback Summaries** Luciana Borio & Paula Bryant	
15:50-16:10	**Close** Manu Hanon	

APPENDIX 2 –PARTICIPANTS

SAC attendees

Chairs

- **Emmanuel Hanon,** Viome, BE (Chair)
- **Laura A. Palomares Aguilera,** Instituto de Biotecnología, Universidad Nacional Autónoma de México, MX (Vice-Chair)
- **Michael King,** University of Virginia, US (Vice-Chair)

Session Co-Chairs

- **Alash'le Abimiku,** International Research Center of Excellence, Institute of Human Virology, NG (Lassa)
- **Alan D. Barrett,** University of Texas, Medical Branch, US (Dis. X)
- **Paula Bryant,** National Institute of Allergy and Infectious Diseases, National Institutes of Health, US (Nipah)
- **Peter Paradiso,** Paradiso Biologics Consulting, LLC, US (BPCV)

Participants

- **Sani Aliyu,** Cambridge University Hospitals Foundation Trust, UK
- **Vineeta Bal,** Indian Institute of Science Education and Research, Pune, IN
- **Luciana Borio,** Arch Venture Partners, US
- **Inger Damon,** Centers for Disease Control and Prevention, US
- **Michel De Wilde,** MDW Consultants, LLC, US
- **Peter Dull,** Bill & Melinda Gates Foundation, US
- ***George Gao,** Chinese Center for Disease Control and Prevention, CN
- **Josie Golding,** Wellcome Trust, IE
- **Rebecca Grais,** Pasteur Network, FR
- **Ken J. Ishii,** International Vaccine Design Center, The University of Tokyo, JP
- **Kent Kester,** IAVI, US
- **Phil Krause,** Independent consultant, US
- **Marc Lipsitch,** Harvard T.H. Chan School of Public Health, US
- ***Dominique Maugeais,** Independent consultant, FR
- **Vasee Moorthy,** WHO, UK
- **Gary Nabel,** ModeX Therapeutics, US
- ***Stanley Plotkin,** University of Pennsylvania, US
- **Mahmudur Rahman,** GHD|EMPHNET, BD
- **Rino Rappuoli,** National Institute for Pandemic Preparedness (NIPP), IT
- **Peter Smith,** London School of Hygiene & Tropical Medicine, UK
- **Stephen Thomas,** SUNY Upstate Medical University, US
- ***Krishna Mohan Vadrevu,** Bharat Biotech International, IN

***Virtual attendance**

APPENDIX 2 –PARTICIPANTS (continued)

Guest observers

- **Minoru Tobiume,** SCARDA
- **Charlie Weller,** Wellcome
- **Mariagrazia Pizza,** TLS
- ***Christopher Houchens,** BARDA
- ***Christian Wimmer,** HERA
- ***Andreas Prenner,** HERA
- ***Angela Tessarolo,** HERA
- ***Patrick Lydon,** WHO
- ***Gary Disbrow,** BARDA
- ***Edit Zsepessy,** HERA

CEPI attendees

Speakers

- **Richard Hatchett,** CEO
- **Nicole Lurie,** Executive Director, Preparedness & Response
- **Melanie Saville,** Executive Director, Research and Development

Session Co-Chairs

- **Jakob Cramer,** Director Clinical Development (Lassa)
- ***Chris Da Costa,** Project Leader (BPCV)
- **Timothy Endy,** Project Leader (Dis. X)
- **Martina Ochs,** Project Leader (Dis. X)
- **Mike Whelan,** Project Leader (Nipah)
- **In-Kyu Yoon,** Director, Programmes and Innovative Technology (BPCV)

Observers/support

- **Kwasi Amfo,** Consultant
- **Mike Aviles,** IT Officer
- **Birgitte Booij,** Senior Portfolio Manager
- **Gabrielle Breugelmans,** Director, Epidemiology
- **Mariann Vaule Bringsvaerd,** Senior Project Manager, Co-Head, PMO
- **Lindi Dalland,** Senior Project Manager, Co-Head, PMO
- **Matthew Downham,** Director, Manufacturing Network and Supply Chain
- **Sarah Doyle,** SAC and JCG Officer
- **Anand Ekambaram,** Executive Director, Manufacturing Network and Supply Chain
- **Alice Fernandez,** Project Manager
- **Roice Fulton,** Consultant
- **Dimitrios Gouglas,** Senior Portfolio Manager
- **Adam Hacker,** Director and Global Head, Regulatory Affairs
- **Luz Hermida,** Project Manager
- **Joe Simmonds-Issler,** Chief of Staff
- **Frederik Kristensen,** Deputy CEO
- **Paul Kristiansen,** Director, Laboratory Research and Innovations
- **Ingrid Kromann,** Director, Manufacturing and QC Development
- **Stephen Mayhew,** Director of Strategy and Portfolio
- **Sheldon Poujade,** Business Development Lead
- **Kristine Rose,** R&D Chief of Staff
- **Tung Thanh Le,** Portfolio Manager
- **Ashley Tsai,** Portfolio Officer
- **Emma Wheatley,** Director, Access and Private Partnerships

Plus up to 40 virtual CEPI colleagues