COVID vaccines development & manufacturing

DCVMN 21st Annual General Meeting
4th November 2020

Richard Hatchett, MD
CEO, CEPI
CEPI has invested >$1.5bn in the COVAX R&D&M portfolio

- Portfolio objectives are to rapidly deliver sufficient vaccine for global use in emergency conditions at a scale, with a target to help COVAX secure 2 billion vaccine doses by end of 2021
- Current R&D portfolio has 9 candidate vaccines, with others in due diligence / negotiation
- Clear Go / No Go criteria to determine further investment
- “Wave 2” portfolio of translational candidates being established with investment from CEPI / BMGF / others
- Enabling science projects are funded to accelerate vaccine development
COVAX: an end-to-end solution

Bold ideas and brilliant innovation for the worst global health crisis in 100 years

- World’s largest and most diverse portfolio of Vx candidates
- Accelerated scale-up of manufacturing
- Equitable access & fair allocation
- Delivery at Scale
# COVID-19 Vx landscape - 44 candidates in human clinical trials

<table>
<thead>
<tr>
<th>Technology platform</th>
<th>Phase I</th>
<th>Phase I/II</th>
<th>Phase II</th>
<th>Phase IIb/III and III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral vectors</td>
<td>Shenzhen GIMI aAPC</td>
<td>Vxaart VXA-CoV2-1</td>
<td>ImmunityBio / NantKwest nAd5-S-Fusion</td>
<td>Shenzhen GIMI LV-SMENP-DC</td>
</tr>
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<td>Viral vectors</td>
<td>ReiThera GRAd-COV2</td>
<td>Wantai / Xiamen DeiNS1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mRNA</td>
<td>Walvax Biotech ARCoV</td>
<td></td>
<td>Imperial LNP-nCoV/AdVEnv</td>
<td>CureVac CVnCoV</td>
</tr>
<tr>
<td>DNA</td>
<td></td>
<td></td>
<td>Arcturus Arct-021</td>
<td></td>
</tr>
<tr>
<td>Protein-based</td>
<td>Medicago / GSK VLP</td>
<td>West China Hospital / U. of Sichuan</td>
<td>Vaxine / Medytox COVAX-19</td>
<td>Medigen MVC-COV1901</td>
</tr>
<tr>
<td>Protein-based</td>
<td>CSL / Queensland</td>
<td>Covaxx UB-612</td>
<td></td>
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<tr>
<td>Protein-based</td>
<td></td>
<td></td>
<td>Clover SCB-2019</td>
<td></td>
</tr>
<tr>
<td>Inactivated</td>
<td>Shenzhen Kangtai</td>
<td></td>
<td>Bharat Biotech COVAXIN</td>
<td>Inst. of Medical Biology / CAMS</td>
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<tr>
<td>Inactivated</td>
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<td>RIBSP OAZCOVID-IN</td>
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1. For advanced purchase agreement (APA); 2. For tech transfer, scale-out and reservation fees

Source: CEPI Vx landscape

COVAX MoU signed
COVAX deal signed
CEPI agreement signed
COVAX R&D candidate
CEPI funded candidate for R&D outside COVAX R&D portfolio
# COVAX R&D portfolio – 9 assets, 8 in clinical trials

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<th>Viral vectors</th>
<th>Protein-based</th>
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<tr>
<td>Candidate</td>
<td>Merck / Themis V591</td>
<td>Novavax NVX-CoV2373</td>
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<td>Inovio INO-4800</td>
<td>AstraZeneca ChAdOx1-S</td>
<td>Clover SCB-2019</td>
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<tr>
<td>Moderna mRNA-1273</td>
<td>U. of Hong Kong</td>
<td>CSL / Queensland</td>
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<td>CureVac CVnCoV</td>
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<th>UK</th>
<th>China</th>
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<td>Phase III</td>
<td>Phase II</td>
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- **Speed**
- **Scale**
- **Access**
Building Capacity at Risk – Drug substance

The most productive platforms will be scaled-out to multiple countries/regions (Expression of Interest for expanding capacity)

CEPI executed a global capacity survey (EOI) and found enough capacity for >10BN doses

- 52 Manufacturers Reviewed
- 20 Groups Contacted
- 1 Reservation agreement signed with SK Bio in Korea
- 6 deals signed between manufacturers and vaccine developers based upon CEPI introduction

- Scale-up at risk (before clinical proof of concept)
- Scale-out at risk
- Final dose will not be known until Q3-Q4 2020 (some even later)
- Bulk vaccine is stockpiled in anticipation of dose level definition
- The impact of the dose and yield information can change predicted outcome by >10-fold.
Building Capacity at Risk – Drug product

Drug Product capacity and vial procured in advance of knowing which products advance

CEPI executed a global capacity survey (EOI) and found capacity for >2BN doses of vaccine

- 89 Manufacturers Reviewed
- 23 Groups Contacted
- 7 Companies shortlisted
- 2 Reservation agreements signed with GC Pharma in Korea and BioFabri in Spain

- Vials secured at risk
- DP strategy developed
- Scale-up at risk (before clinical proof of concept)
- Scale-out at risk
- Each product is scaled-out in different countries to expand capacity
PART 2 – future trends we are seeing
Preparing for the next pandemic

COVID-19 provides an opportunity to think about how we systematically reduce the risk of naturally occurring threats.

Trends are converging in a way that could make the world better prepared for the next pandemic:

- **Political will** to invest in health security
- **Revolution in vaccinology**, with multiple new platforms approved
- **Global desire** to reduce pandemic risk

Viruses are collective, transnational threats. They should be tackled collaboratively in future.
Expanding the R&D agenda

An **expanded R&D agenda** focused on global risk reduction.

**Rapid response platforms** – multiple platforms will be validated for the first time during this pandemic, and ready to use.

**Candidate vaccines against every class of viral threat** – experience of developing MERS vaccines sped up work on COVID-19.

**Validating platforms across multiple pathogens** will considerably accelerate vaccine development.
Collaboration opportunities with DCVMs in COVID-19 response and beyond

We still have major gaps in our EoI when it comes to understanding the capacity of the DCVMN and would benefit from having the individual organizations share their data for both DS (by platform – recombinant protein, LVV (adherent and suspension), RNA, DNA) and DP

Leveraging organizations that already work through WHO PQ for supplying the Gavi AMC92
Vision for the future

COVID-19 can inspire us to assemble a global network to combat other epidemic disease threats.

COVAX can be a model for a multilateral, multisectoral collaborative approach to global risk reduction.

Requires recognition that national health security and global health security are interdependent.