COVAX Facility update

Dr Richard Hatchett (CEPI), CEO
Dr Seth Berkley (GAVI), CEO
Dr Soumya Swaminathan (WHO), Chief Scientist
### Technology platform

#### Viral vectors
- **Shenzhen GIMI**, sAPC
- **Merck / Themis**
- **Vaxart**, VXA-CoV2-1
- **ImmunityBio**, hAd5-S-Fusion
- **Merck / JAVI**, rSVV

#### mRNA
- **Walvax Biotech**, ARCoV

#### DNA
- **Symvivo**, bacTETRI-Spike

#### Protein-based
- **Medicago**, VLP
- **Finlay**, FINLAY-FR-2
- **Vaxine / Medytox**, COVAX-19
- **Medigen**, MVC-COV1901
- **City of Hope**, COH0451
- **Bio E**, BEOV2C
- **SpyBio**, RBD
- **Finlay**, FINLAY-FR-1
- **Sanofi / GSK**, Rec.Pro
- **Sichuan**, RBD
- **FBRI.SRC**, EpiVac

#### Inactivated
- **CSL / U.Q.**, UB-612
- **Clover**, SCB-2019
- **Adimmune**, AdimiSC-2f

### Phase I

#### Phase I/II
- Imperial
- Arcturus
- Genexine
- Osaka / AnGes
- Zydus Cadila
- Inovio

#### Phase II
- CureVac
- Pfizer / BioNTech
- Moderna
- ImmunityBio

#### Phase IIb/III and III
- CanSino
- AstraZeneca
- Gamaleya
- Janssen

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**COVID-19 R&D portfolio – 49 candidates in human clinical trials¹**

1 Candidates which have not been able to confirm the dosing of the first subject have not been included on this mapping (e.g. Providence, Kentucky, U.Tuebingen)

2 For Advance Purchase Commitment (APC)

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**Source:** CEPI Vx landscape

**UPDATED ON DECEMBER 10, 2020**

**Presenter:** Richard H.
First efficacy data available: overview of latest results from Pfizer/BioNTech, Moderna, AstraZeneca, Gamaleya and Sinopharm

<table>
<thead>
<tr>
<th>Platform</th>
<th>mRNA</th>
<th>mRNA</th>
<th>ChadOx 1 vector</th>
<th>Ad26 &gt;&gt; Ad5 prime-boost</th>
<th>Inactivated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary point estimate of vaccine efficacy</td>
<td>95% (p&lt;0.0001)</td>
<td>94.1% (p&lt;0.0001)</td>
<td>70% (p&lt;=0.0001) (pooled)</td>
<td>91.4% 28 days post dose 1 (7days post dose 2)</td>
<td>86% effective</td>
</tr>
<tr>
<td>90% and 62% (LH and HH regimens¹)</td>
<td>Statistical significance not reported</td>
<td>91.4% 28 days post dose 1 (7days post dose 2)</td>
<td>Statistical significance not reported</td>
<td>91.4% 28 days post dose 1 (7days post dose 2)</td>
<td>86% effective</td>
</tr>
<tr>
<td>Phase 3 study enrollment</td>
<td>43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate</td>
<td>&gt;30,000 participants</td>
<td>UK trial - 12,390 subjects, 2,742 with LH (90% efficacy) UK/Brazil trial – 10,300 HH 62% efficacy</td>
<td>40,000 participants</td>
<td>31,000 participants</td>
</tr>
<tr>
<td>Total number of cases</td>
<td>170 cases (8 in vaccine group) 10 severe cases (9 in placebo, 1 in vaccine group)</td>
<td>196 cases (11 in vaccine group) 30 severe cases (incl. 1 death), all in placebo group</td>
<td>131 cases across 2 trials No severe or hospitalized cases among patients who received vaccine</td>
<td>39 cases</td>
<td>No case reported</td>
</tr>
<tr>
<td>Cold chain</td>
<td>-80°C, 2-8°C for up to 5 days</td>
<td>-20°C, 2-8°C for up to 30 days</td>
<td>Storage, transport and handled 2-8°C for up to 6 months</td>
<td>2 versions: • Lyo 2-8°C • Liquid Frozen -20°C</td>
<td>2-8°C for up to 30 days</td>
</tr>
<tr>
<td>Plans for licensure</td>
<td>Submitted to US FDA for EUA, EMA and WHO EUL/PQ, Temp Authorization UK MHRA</td>
<td>Rolling submissions to US FDA for EUA, EMA and plan to WHO for EUL/PQ</td>
<td>Rolling submissions to EMA, MHRA, PQ</td>
<td>Emergency authorization in Russia Timeline for non-Russian submissions under assessment</td>
<td>-</td>
</tr>
</tbody>
</table>

¹ LH – Low dose followed by High dose, HH – 2 doses of high dose formulation
Overview of COVID-19 vaccine landscape

49 candidates currently in human clinical trials\(^1\)

8 of 9 candidates in CEPI’s COVAX R&D portfolio are in human clinical trials

12 candidates are currently in Phase IIb/III and III

**Nov 2020**
First efficacy readouts from four candidates (Pfizer, Moderna, AstraZeneca, Gamaleya Institute), which enabled some manufacturers to start the process for emergency use authorizations (EUA) / emergency use licensure (EUL)

**Dec 2020**
First emergency approval in UK, 1st injection of participant; emergency approval granted in Canada with vaccine rolling out next week; efficacy readout from Sinopharm

**Q1/Q2 2021**
expected dates for first licenses and start date for commercial distribution

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\(^1\) 52 candidates if candidates that have not been able to confirm the dosing of the first subject (e.g. Providence, Kentucky, U.Tuebingen) are included
COVAX Facility portfolio candidates are selected based on several criteria

- Portfolio diversity
- Regional scope & scalability
- Pricing
- Timing of doses
- Deal terms
- Efficacy and immunogenicity
- Safety
- Probability of success
- Programmatic feasibility
- Delivery considerations

Presenter: Seth B.
Candidates to be included in the COVAX Facility portfolio are being selected from the COVAX R&D portfolio and other clinical candidates.

**COVAX CEPI R&D portfolio**
CEPI invests in R&D for selected promising candidates to accelerate vaccine availability.

**COVID-19 Vx pipeline candidates**
All candidates\(^1\) in the COVID-19 vaccine landscape in clinical development stages.

**COVAX Facility portfolio**
Selected candidates from the COVAX R&D portfolio and other clinical candidates from the Vx landscape (*pending regulatory approval and policy recommendation)*.

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1. Excluding those in COVAX R&D Portfolio

**COVAX portfolio will include selected promising candidates across different technologies and geographies**
Final COVAX Facility portfolio is expected to have around 10 or more candidates across 4-5 technology platforms, with early doses available in Q1 2021.

The COVAX Facility aims for a diverse and actively managed portfolio of around 10 or more vaccine candidates to achieve 2 billion doses by the end of 2021:

- Diversifying technologies
- Diversifying geographies
- Diversifying vaccine characteristics
- Accounting for attrition
COVAX Facility portfolio currently includes 4 candidates with several expected near-term agreements

To date, the COVAX Facility has signed...

- Deal with SII to provide doses for AMC92 economies
  
  SII / AstraZeneca collaboration announced on Aug 7, 2020
  SII / Novavax collaboration announced on Sep 29, 2020

- MoU with AstraZeneca
  Announced on Jun 4, 2020

- Statement of Intent with Sanofi / GSK
  Announced on October 28, 2020

Several candidates are in near-term MoU agreements

# COVAX Facility Portfolio – expected regulatory, supply timelines

<table>
<thead>
<tr>
<th>Vaccine candidates</th>
<th>Q1 2021</th>
<th>Q2 2021</th>
<th>Q3 2021</th>
<th>Q4 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca (IND)</td>
<td></td>
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<tr>
<td>Novavax (IND)</td>
<td></td>
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<tr>
<td>Sanofi Flex (FR)</td>
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<tr>
<td>Candidate 1</td>
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<tr>
<td>Candidate 2</td>
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<tr>
<td>Candidate 3</td>
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<tr>
<td>Other Candidates</td>
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</tbody>
</table>

- **Expected regulatory & WHO PQ timeframe**
- **Expected supply timeframe**

Presenter: Seth B.
COVAX is negotiating with ~10 suppliers with the ambition of contracting enough volumes to deliver 2bn doses in 2021.

**COVAX Facility volumes to be contracted over time**, doses per quarter (by candidate and in total, 2021)

- **Q1 2021**: ~2,040M
- **Q2 2021**: ~500M
- **Q3 2021**: Total expected attrition
- **Q4 2021**: ~2,040M

**Total end-2021**: ~2,540M

**Expected attrition**: ~500M

- **AstraZeneca**
- **SII (AstraZeneca and Novavax)**
- **Sanofi-GSK**
- **Candidate 1**
- **Candidate 2**
- **Candidate 3**
- **Others (x3)**

In Q1/2, we are focused on early, equitable access.

In Q3/4, we are focused on delivering large volumes for participants.
Speed and equity are the focus

- 100 country applications for WB loans in 100 days
- Release of 1st efficacy results (Pfizer, Moderna, AZ, Gamaleya, Sinopharm)
- 1st use of vaccine in HICs (8 Dec, UK)
- 1st use of vaccine in a LMIC (as simultaneous as possible)
- Broader deployment / delivery of Covid-19 vaccines

Presenter: Seth B.
What we are doing to prepare for arrival of vaccine...

- **Engaging with manufacturers and securing supply** from a large, diversified portfolio
- **Standing up a fair and equitable allocation mechanism** that ensures all participants get vaccine from the COVAX Facility at the same time
- **Raising funding** for the COVAX AMC financial instrument to support AMC eligible participants
- **Developing a No-Fault Compensation Scheme** to ensure Indemnification and Liability issues do not delay delivery of doses to AMC economies
- **Implementing a governance mechanism** to ensure the voices of all participants are heard
- **Engaging with participants** to support COVAX and preparing for the arrival of doses

...and what you can be doing

1. **Build A National Task Force** - Form a group responsible for putting the planning together; assign a leader/focal point.
2. **Develop a national plan** - Use all partners and planning tools available
3. **Secure any necessary financing** - Work with the World Bank and other MDB financing teams to confirm eligibility, apply for financial resources if necessary
4. **Prepare for delivery now** – Focus on indemnification and liability, prime your regulatory processes, and prepare any needed infrastructure
5. **Communicate actively** - Keep an open line with the COVAX Facility
AMC92 Participants would be supported by global partners throughout their journey

<table>
<thead>
<tr>
<th>Some of the steps along the journey</th>
<th>Support provided</th>
<th>Pillar partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of national plan &amp; strategy (incl., programmatic readiness)</td>
<td>Provision of guidelines, planning tools</td>
<td>WHO, Gavi, UNICEF, PAHO</td>
</tr>
<tr>
<td></td>
<td>Decision making / application support</td>
<td></td>
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<tr>
<td></td>
<td>CCE / TA support</td>
<td></td>
</tr>
<tr>
<td>Cost sharing</td>
<td>Support with cost sharing of additional doses &amp; delivery costs</td>
<td>Gavi, PAHO</td>
</tr>
<tr>
<td>National regulatory approval / registration</td>
<td>Global harmonization mechanisms to speed up in-country processes</td>
<td>WHO</td>
</tr>
<tr>
<td>Indemnification &amp; liability agreements with manufacturers</td>
<td>Design of compensation mechanisms</td>
<td>Gavi, WHO, CEPI</td>
</tr>
<tr>
<td>Delivery of vaccines</td>
<td>Procurement &amp; delivery of Vx on behalf of participants</td>
<td>WHO, Gavi, UNICEF, PAHO</td>
</tr>
<tr>
<td></td>
<td>Support with in-country coordination</td>
<td></td>
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</tbody>
</table>
### Overview of regulatory timeline of early roll out candidates

**Legend (best-case scenario)**
- **Approved**
- **By End of 2020**
- **By End of Feb. 2021**
- **From March 2021 / No info**

<table>
<thead>
<tr>
<th>Vaccine candidates</th>
<th>FDA</th>
<th>MHRA</th>
<th>EMA</th>
<th>WHO EUL/PQ</th>
<th>Country reliance on PQ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASTRAZENECA</strong></td>
<td>Not applicable</td>
<td>21 Dec 2020 (emergency use)</td>
<td>Not applicable</td>
<td></td>
<td>Jan. 2021 onwards</td>
</tr>
<tr>
<td><strong>REST OF THE WORLD</strong></td>
<td>Pending</td>
<td>Not applicable</td>
<td>Jan. or Feb. 2021 (conditional approval)</td>
<td>To be determined (under active discussion)</td>
<td>Between March and June 2021 at latest</td>
</tr>
</tbody>
</table>

1. 1st lot authorization
2. Relying on EMA approval
3. If additional regulatory sites

**Presented by**: Soumya S.
Reminder – Recap of critical actions to ensure country readiness and delivery

Critical actions

Priority decision making on:

• Policies for use (in-country prioritization)
• Regulatory approvals (e.g. WHO reliance mechanism)
• Financing (ensuring fiscal space, consideration of WB and other loans)
• Indemnification & liability

Technical & operational issues

• Country readiness assessments (cold chain, health facility, HCW etc.)
• National Deployment and Vaccination Plan
• Key bottleneck analysis
BACK-UP
There are 4 regulatory pathways for country authorization

**Accelerated pathways**

- Reliance on WHO EUL/PQ direct reliance
- WHO roadmap process – facilitated by Regional champions & networks
- SRA direct reliance – on an exceptional basis

**National authorisation/registration**

- Participants that cannot rely on WHO or SRA might have to wait for allocation outcome before starting national authorization process
- National registration (if cannot rely on WHO PQ/EUL, SRA, WHO roadmap)

**Procurement by UNICEF / PAHO post-national authorization**

Our ask of you

Consider accelerated regulatory pathways to avoid delay in procurement after allocation

* SRA reliance to be considered on an exceptional basis, as it would not necessarily include an assessment of the programmatic suitability of vaccine candidates and data sharing could not be facilitated by WHO in that case
Indemnification and liability and compensation

Details

• All vaccines supplied through COVAX will undergo a rigorous regulatory process and will be approved for general use
• Given the speed and scale of deployment, manufacturers are unwilling to self-insure for product liability claims and are requiring all participants receiving vaccine doses to indemnify them against such claims
• **Lack of such an indemnification by a participant will limit access to vaccines**
• To decrease time and transaction costs in negotiating indemnity provisions between AMC participants and manufacturers, Gavi is negotiating with manufacturers to have a consistent approach on indemnification across manufactures
• In order to limit the number of claims brought under national courts and to provide fair compensation to injured vaccine recipient, if any, COVAX partners are looking to establish a **global compensation mechanism to cover unexpected serious adverse events (SAEs)** for AMC92 participants to access

Next Steps

• Legal review to determine if the indemnification requirement and/or accessing the compensation mechanism requires **implementing legislation**
• If implementing legislation is required, **participant to take all necessary steps to enact such legislation as soon as possible** before supply of vaccines under COVAX begins
Vaccine policy - Priority groups for COVID-19 vaccination

| Vaccine availability | Stage I: very limited  
(for 1-10% national population) | Stage II: limited  
(for 11-20% national population) | Stage III: moderate  
(for 21-50% national population) |
|----------------------|---------------------------------|---------------------------------|---------------------------------|
| *Ia:* health workers at high to very high risk of acquiring and transmitting infection | - Older adults (not covered in Stage Ib)  
- Individuals with co-morbidities or health status determined to be at significantly higher risk of severe disease or death  
- Socio-demographic groups at significantly higher risk of severe disease or death  
- Health workers engaged in immunization delivery  
- High priority teachers and school staff | - Remaining teachers and school staff  
- Other essential workers outside health and education  
- Pregnant women  
- Health workers at low to moderate risk of acquiring and transmitting infection  
- Personnel needed for vaccine production and other high-risk laboratory staff  
- Social/employment groups at elevated risk of acquiring and transmitting infection (unable to effectively physically distance) |
| *Ib:* older adults defined by country/region specific age-based risk |  |  |  |

Endorsed by SAGE, published on 19 October 2020