ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

October 30, 2020

For more information: www.cdc.gov/COVID19
Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings

- At the September 22\textsuperscript{nd} meeting, ACIP reviewed:
  - Overview of COVID-19 vaccine safety
  - Enhanced vaccine safety surveillance
  - Vaccine implementation
  - Disparities among COVID-19 epidemiology
  - Overview of vaccine equity and prioritization frameworks
  - Phase 1 allocation for COVID-19 vaccine: Work Group considerations
COVID-19 Work Group activities – October 2020

- COVID-19 Vaccine Work Group meets weekly

- Topics covered in October:
  - Review of available information on reinfection of COVID-19
  - Post-infection immunity
  - Discussions to finalize the Outcomes for GRADE
  - Modeling data for initial allocation of vaccine
  - Current epidemiology of COVID-19 in pregnant women
  - Review of ethical principles to inform initial allocation of vaccine
  - Clinical development program for two COVID-19 vaccines, including data from Phase I/II clinical trials and plans for Phase III clinical trials
  - Further discussions regarding COVID-19 vaccine allocation
Today’s agenda

Vaccine Development & Regulatory
- Update from VRBPAC meeting: Dr. Doran Fink (FDA)
- NVX-CoV2373 Vaccine Candidate: Dr. Filip Dubovsky (Novavax)
- Janssen’s SARS-CoV-2 Vaccine Program: Dr. Jerry Sadoff (Janssen)

Implementation
- Update on vaccine implementation planning: Dr. Janell Routh (CDC)
- Vaccinate with Confidence: Dr. Amanda Cohn (CDC)

Safety
- FDA safety surveillance systems: Dr. Steven Anderson (FDA)
- Post-authorization safety monitoring plans: Dr. Tom Shimabukuro (CDC)

Allocation and Epidemiology
- Modeling strategies for the initial allocation of COVID-19 vaccines: Dr. Matthew Biggerstaff (CDC)
- Updates to immunity and epidemiology to inform COVID-19 vaccine policy: Dr. Megan Wallace (CDC)
- Ethical principles for early vaccine allocation: Dr. Mary Chamberland (CDC)

Work Group Interpretation
- Work Group interpretation of data: Dr. Sara Oliver (CDC)
- Policy questions, Evidence to Recommendation Framework, and outcomes: Dr. Kathleen Dooling (CDC)
Vaccine Update

- Over 200 COVID-19 vaccines currently under development

- Within the United States:
  - Four vaccines in active Phase III clinical trials
  - Five vaccines in active Phase I/II clinical trials

Vaccine Update: Phase III clinical trials in the U.S.

- AZD1222 vaccine (AstraZeneca) announced removal of FDA hold 10/23, resuming Phase III trials

- Ad26.COV2.S vaccine (Janssen) announced lifting of safety pause 10/23, resuming Phase III trials

- BNT162b2 vaccine (Pfizer/BioNtech)
  - 42,133 participants enrolled as of 10/26/2020
  - 35,771 participants have received their second vaccination
  - 30% of U.S. participants enrolled have “diverse backgrounds”

- mRNA-1273 vaccine (Moderna): **Enrollment Complete**
  - 30,000 participants enrolled as of 10/22/2020
  - 25,654 participants have received their second vaccination

Vaccine Update: Phase III clinical trials in the U.S.

27% of participants living with comorbidities: including diabetes, cardiac disease, lung disease, obesity

22% healthcare personnel

Sources: https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf
## COVID-19 vaccines in human clinical trials – United States*

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Phase</th>
<th>Trial characteristics</th>
<th>Trial #</th>
<th>Recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273</td>
<td>Moderna TX, Inc.</td>
<td>mRNA</td>
<td>III</td>
<td>• 2 doses (0, 28d) • IM administration • 18-55, 56+ years</td>
<td>NCT04470427</td>
<td>Enrollment complete</td>
</tr>
<tr>
<td>mRNA-BNT162</td>
<td>Pfizer, Inc./BioNTech</td>
<td>mRNA</td>
<td>II/III</td>
<td>• 2 doses (0, 21d) • IM administration • 18-85 years</td>
<td>NCT04368728</td>
<td>✓</td>
</tr>
<tr>
<td>AZD1222</td>
<td>University of Oxford/AstraZeneca consortium**</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>• 2 doses (0, 28d) • IM administration • ≥18 years</td>
<td>NCT04516746</td>
<td>✓</td>
</tr>
<tr>
<td>Ad26COVS1</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>• 1 dose • IM administration • 18-55, 65+</td>
<td>NCT04436276</td>
<td>✓</td>
</tr>
<tr>
<td>--</td>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>• Single or 2 doses • IM administration • 18-49, 50+</td>
<td>NCT04537208</td>
<td>✓</td>
</tr>
<tr>
<td>NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>• 2 doses (0, 21d) • IM administration • 18-84</td>
<td>NCT04368988</td>
<td>Enrollment complete</td>
</tr>
<tr>
<td>V591</td>
<td>Merck</td>
<td>Viral Vector</td>
<td>I/II</td>
<td>• 2 doses (1, 57d) • IM administration • 18-55</td>
<td>NCT04498247</td>
<td>✓</td>
</tr>
</tbody>
</table>

*As of October 27, 2020
**Currently on hold in US
**COVID-19 vaccines in human clinical trials – United States**

As of October 27, 2020


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<th>Recruiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>AV-COVID-19</td>
<td>Aivita</td>
<td>AuDendritic cell</td>
<td>I/II</td>
<td>• 1 dose</td>
<td>NCT04386252</td>
<td>Not yet recruiting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 18+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VXA-CoV2-1</td>
<td>Vaxart</td>
<td>Viral vector (NR)</td>
<td>I</td>
<td>• 2 doses (1, 29d)</td>
<td>NCT04563702</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Oral tablet</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 18-54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INO-4800</td>
<td>Inovio Pharmaceuticals, Inc.</td>
<td>DNA plasmid</td>
<td>I</td>
<td>• 2 doses (0, 4w)</td>
<td>NCT04336410</td>
<td>Active, not recruiting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• SC administration/ electroporation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• ≥18 years</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Recruiting status as of October 27, 2020*
COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

### Inactivated Vaccines

3 inactivated vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIBP/Sinopharm BBIBP- CorV</td>
<td>Beijing Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Argentina</td>
<td>Phase III</td>
<td>NCT04560881</td>
</tr>
<tr>
<td>Sinovac CoronaVac</td>
<td>Sinovac/Instituto Butantan</td>
<td>Inactivated</td>
<td>Turkey, Brazil, Indonesia</td>
<td>Phase III</td>
<td>NCT04582344; NCT04456595; NCT04508075</td>
</tr>
<tr>
<td>WIBP vaccine</td>
<td>Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Morocco</td>
<td>Phase III</td>
<td>ChiCTR2000039000</td>
</tr>
<tr>
<td>WIBP/BIBP/Sinopharm vaccines</td>
<td>Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>UAE, Bahrain, Jordan, Egypt</td>
<td>Phase III</td>
<td>NCT04510207</td>
</tr>
</tbody>
</table>

### Protein Subunit Vaccines

10 protein subunit vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novavax NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein subunit</td>
<td>UK</td>
<td>Phase III</td>
<td>NCT04583995</td>
</tr>
</tbody>
</table>

*As of October 19, 2020

COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

Viral Vector Vaccines (non-replicating) 7 non-replicating viral vector vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cansino Ad5-nCoV</td>
<td>CanSino Biological Inc/Beijing Institute of Biotechnology</td>
<td>Non-replicating viral vector</td>
<td>Pakistan, Russia</td>
<td>Phase III</td>
<td>NCT04526990; NCT04540419</td>
</tr>
<tr>
<td>Gamaleya Gam-COVID-Vac</td>
<td>Gamaleya Research Institute</td>
<td>Non-replicating viral vector</td>
<td>Belarus, Russia</td>
<td>Phase III</td>
<td>NCT04530396; NCT04564716</td>
</tr>
<tr>
<td>Janssen Ad26.COV2.S</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Non-replicating viral vector</td>
<td>USA, Argentina, Brazil, others</td>
<td>Phase III</td>
<td>NCT04505722</td>
</tr>
<tr>
<td>Oxford ChAdOx1-S</td>
<td>University of Oxford/AstraZeneca</td>
<td>Non-replicating viral vector</td>
<td>UK, Brazil, India</td>
<td>Phase II/III</td>
<td>NCT04400838; NCT04536051; CTRI/2020/08/027170</td>
</tr>
</tbody>
</table>

7 non-replicating viral vector vaccines candidates are in Phase I/II

RNA Vaccines 7 RNA vaccines candidates are in Phase I/II

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech BNT162 (b1/b2)</td>
<td>BioNTech/Fosun Pharma/Pfizer</td>
<td>RNA</td>
<td>USA, Argentina, Brazil, others</td>
<td>Phase II/III</td>
<td>NCT04368728</td>
</tr>
</tbody>
</table>

*As of October 19, 2020
## Work group members

### ACIP members
- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

### Ex-officio/government members
- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

### CDC Co-leads
- Kathleen Dooling
- Sara Oliver

### Liaisons
- AAFP: Jonathan Temte
- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shecher (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

### Liaisons, cont’d
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

### Consultants
- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)
CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker
Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.