CureVac’s mRNA based Vaccine Candidate against SARS-CoV-2

Press Briefing Paul-Ehrlich-Institute
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Dr. Mariola Fotin-Mleczek, CTO
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Key Company Highlights

- **Founded** in 2000, currently 470 employees
- **Pioneer in developing mRNA therapies** with a proprietary and clinically validated platform technology addressing a broad range of diseases in prophylactic vaccines, oncology, and protein therapies
- Leveraging versatility of **non-modified mRNA** with longstanding RNAoptimizer™ platform: delivering low dose potent, differentiated, safe and efficacious compounds; Rabies protection in human with 1 millionth of a gram
- mRNA vaccine program against **SARS-CoV-2 (COVID-19)** with thorough preclinical testing. Initiation of Phase 1 study in June 2020
- Existing manufacturing capacity to deliver **hundreds of million of doses**
- Continued GMP manufacturing scale-up (GMP I-IV) and down-scaling mobile facilities to potentially supply **billions of doses**
- **Broad IP portfolio** covering platform, manufacturing and product candidates
- **Strategic partnerships** spanning with leading biopharmas, Bill & Melinda Gates Foundation and research institutes to maximize potential, including a partnership with CEPI for SARS-CoV-2 vaccine program
# Accelerating Efforts to Develop a SARS-CoV-2 Vaccine

## Covid-19 Program Overview

- Company has been rapidly advancing one mRNA vaccine candidate against SARS-CoV-2 out of several candidates
- The candidate encodes for full-length stabilized S (Spike)-protein and has been selected based on biological, biophysical and process development data
- Phase 1 trial planned with 168 subjects to show safety and immunogenicity of the vaccine
- Accelerated timeline to bring SARS-CoV-2 vaccine to the market
- Preparatory work and early clinical trials fully funded by CEPI
- CureVac is in close interaction with the Paul-Ehrlich Institute (PEI), EMA and the Belgian FAMHP
- Existing manufacturing capacity could provide hundreds of million of doses
- European commission committing a EUR 75 Mio. loan to create added capacity in GMP IV (billions of doses)

### Development Plan Overview

**Timeline:**

- **January 2020:** Design of multiple vaccine candidates
- **March 2020:** Lead candidate selected out of several candidates
- **March – June 2020:** GMP production of lead candidate
- **June 2020:** CTA approval
- **June 2020:** Start of Phase 1 clinical trial (First Patient In)
- **Autumn 2020:** First human Phase 1 clinical trial data (Safety and immunogenicity)

**Development plan supported by regulatory authorities**

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*Plan to make a vaccine available as soon as possible at approval – More than 100 mio. doses ready at launch*
CureVac’s SARS-CoV-2 mRNA Vaccine Candidate Induces Strong and Balanced Immune Response

CureVac’s SARS-CoV-2 mRNA vaccine candidate with high antibody titers leading to neutralizing antibodies against SARS-CoV-2 in mice.
CureVac’s SARS-CoV-2 mRNA Vaccine Candidate Induces Strong T Cell Response

CureVac’s SARS-CoV-2 mRNA vaccine induces multifunctional (IFN$\gamma^+$ and TNF$\alpha^+$) CD4 and CD8 T cell responses.
CureVac’s SARS-CoV-2 Project: 
Overview on the Design of the First-in-human Trial CVnCoV

- Partially blinded, placebo-controlled, dose-escalation study in healthy adults (18-60 years of age)
- Three dose groups of 2µg, 4µg, and 8µg with 48 vaccinees and 8 placebo recipients per group
- Two vaccinations administered by intra muscular injection on day 1 and day 29
- Sites in Tübingen, Hannover, Munich, and Ghent
- Participants will be followed for at least one year after the last vaccination
- Study will assess safety and reactogenicity as well as immunogenicity of the vaccine candidate

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<thead>
<tr>
<th>Dose-escalation study</th>
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<tr>
<td>2µg</td>
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<tr>
<td>N</td>
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<tr>
<td>Total N</td>
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N = 144 Vaccinees + 24 Placebo recipients 
Total = 168 Participants
Thank You For Your Attention!

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