CureVac: Second Interim Analysis of Pivotal Phase 2b/3 HERALD Study

June 17, 2021
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Study Introduction

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Interim Analysis Data

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Second-Generation Update

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Chief Financial Officer

Q&A Availability
The HERALD Study: Key Data from Second Interim Analysis

**PRIMARY OBJECTIVE**

47% Efficacy of CVnCoV in the prevention of COVID-19 cases of any severity

**PRIMARY ENDPOINT**

134 cases First episodes of virologically-confirmed cases of COVID-19 of any severity

13 COVID-19 Variants

- **~57%** Variants of Concern
- **~42%** Less explored variants
- **<1%** Wild type strain

124 sequenced, adjudicated cases

- Alpha (B.1.1.7) Original strain
- Delta (B.1.617.2)
- Gamma (P.1)
- C.37 (Peru)
- B.1.621 (Colombia)
- Other (+9 variants)

21% Lambda (C.37)

<57% Lambda (C.37)
The HERALD Study: Geographically Diverse and Multi-Variant

Latin America

~75% of study population

Europe

~25% of study population

~40,000 study participants

~35,000 ≤ age of 60

~5,000 > age of 60

10 Countries
The HERALD Study: Sequencing Efforts Define Basis for Efficacy Calculation

Day 1
First dose 12µg

Day 29
Second dose 12µg
15 days post second dose

Day 43
Case Collection

134 adjudicated cases

Europe: 44 cases
LATAM: 86 cases
119 cases ≤ age 60
15 cases > age 60

124 adjudicated sequenced cases

Europe: 44 cases
LATAM: 80 cases

LATAM: Latin America
COVID-19 Reality: Variants of Concern Spreading in Europe and Latin America

**SOUTH AMERICA**

- **Alpha strain** (B.1.1.7, 501Y.V1)
- **Beta strain** (B.1.351, 501Y.V2)
- **Gamma strain** (P.1, 501Y.V3)
- **Other incl. original strain**

**EUROPE**

- **Alpha strain** (B.1.1.7, 501Y.V1)
- **Beta strain** (B.1.351, 501Y.V2)
- **Gamma strain** (P.1, 501Y.V3)
- **Other incl. original strain**
- **Delta strain** (B.1.617.2)
- **Lambda strain** (C.37)

*As of June 17, source: www.nextstrain.org / South America- or Europe-focused sub-sampling*
High Variant Diversity Defines Basis for Efficacy in Second Interim Analysis

**LATIN AMERICA**

- **B.1.621 (Colombia)** ~11%
- **C.37 (Peru)** ~33%
- **Alpha** ~19%
- **Wild type** ~1%
- **Gamma** ~14%
- **Delta** ~1%
- **Other** ~22%
- **C.37 (Peru)** ~33%
- **Gamma** ~22%

**EUROPE**

- **Alpha** ~91%
- **Other** ~2%
- **Gamma** ~5%
- **Delta** ~2%
- **Other** ~2%

**TOTAL**

- **124 cases**
- **13 different COVID-19 variants**

- **Alpha** ~41%
- **Gamma** ~22%
- **Other** ~13%
- **Wild type** ~1%
- **B.1.621 (Colombia)** ~7%
- **C.37 (Peru)** ~5%
- **Delta** ~2%
- **Other** ~2%

80 adjudicated cases (65%)

44 adjudicated cases (35%)
High Variant Diversity in Overall Study Reflect New COVID-19 Reality

**Number of cases**

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EUROPE</strong></td>
<td>104 non-adjudicated cases</td>
</tr>
<tr>
<td>Belgium</td>
<td></td>
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<tr>
<td>Germany</td>
<td></td>
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<tr>
<td>Spain</td>
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</tr>
<tr>
<td>Netherlands</td>
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<tr>
<td><strong>LATIN AMERICA</strong></td>
<td>370 non-adjudicated cases</td>
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<tr>
<td>Panama</td>
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<tr>
<td>Mexico</td>
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<tr>
<td>Colombia</td>
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<tr>
<td>Argentina</td>
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<tr>
<td>Peru</td>
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**Virus Strains**

- B.1 (wild type)
- B.1.1 (wild type)
- B.1.1.1 (wild type)
- B.1.1.10 (wild type)
- B.1.1.7 (Alpha)
- B.1.351 (Beta)
- B.1.429 (Epsilon)
- B.1.617.2 (Delta)
- P.1 (Gamma)
- A.2.5
- B.1.1.348
- B.1.1.519 (Mexico)
- B.1.111
- B.1.160
- B.1.177
- B.1.1.177.43
- B.1.1.177.53
- B.1.1.177.73
- B.1.236
- B.1.280
- B.1.526
- B.1.621 (Colombia)
- B.1.623
- C.11
- C.36
- C.37 (Peru)
- N.5
- P.1.2
- P.2

**Non-adjudicated cases**

- 104 in Europe
- 370 in Latin America
- 29 overall
Preliminary Vaccine Efficacy Indicate Age and Strain Trends in Interim Analysis

INTERIM ANALYSIS EFFICACY

PRIMARY EFFICACY ENDPOINT

47%

Efficacy of CVnCoV in the prevention of COVID-19 cases of any severity across all strains

Efficacy BY AGE TRENDS

Efficacy BY STRAIN TRENDS
Reactogenicity Data on First 2,000 Vaccinated Trial Participants

**SYSTEMIC SYMPTOMS**

- **Fatigue**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Headache**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Myalgia**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Chills**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Arthralgia**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Fever**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Nausea**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Diarrhea**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

**LOCAL SYMPTOMS**

- **Pain**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Itching**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Swelling**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Redness**
  - Vaccination 1: 0%, 20%, 40%, 60%, 80%, 100%
  - Vaccination 2: 0%, 20%, 40%, 60%, 80%, 100%

- **Grade 1**
- **Grade 2**
- **Grade 3**

Percentage of Participants
The HERALD Study: Key Messages and Next Steps

Interim efficacy of first-generation vaccine candidate, CVnCoV, evaluated in most challenging variant-dominated environment

Interim efficacy of 47% against any severity of disease shows trend for age and strain related efficacy

Moving toward final analysis within 2-3 weeks on the basis of >200 cases to confirm age and strain related trends and also look at disease severity

Full commitment to proceed appropriate regulatory pathway for the most appropriate regulatory pathway.
Second-Generation Vaccines: New Backbone for Advanced Characteristics

- **Untranslated regions**
- **Poly-A tail**

- **Higher protein expression**
- **Balanced immune response**
- **Improved kinetics**

**Protein expression**

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<thead>
<tr>
<th></th>
<th>Gen 1</th>
<th>Gen 2</th>
<th>Gen 1</th>
<th>Gen 2</th>
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<tr>
<td>Cell surface</td>
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Joint development with GSK
Preclinical Non-Human Primate (NHP) Model*
Neutralizing antibodies, Pseudovirus assay

- CV2CoV, **faster onset** of neutralizing antibody production. 211 titer two weeks after first dose
- CV2CoV, **10-times higher** neutralizing antibody induction of CV2CoV compared to CVnCoV at peak level after 6 weeks
- Two-dose vaccination schedule of a **12µg dose** on day 0 and day 28

*Data generated in collaboration with Dan Barouch, Beth Israel Deaconess Medical Center, Harvard Medical School
Thank you for your attention