

CVnCoV – Positive Interim Phase 1 Data

November 10, 2020

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Key Highlights



Balanced immune response, with strong induction of binding and neutralizing antibodies and first indications of T cell activation



Quality of immune response comparable to recovered COVID-19 patients, closely mimicking immune response after natural COVID-19 infection



CVnCoV generally well tolerated across tested dose range of 2-12 μ g



Data support 12 μ g dose for pivotal Phase 2b/3 clinical trial



On track to initiate pivotal Phase 2b/3 before end of this year

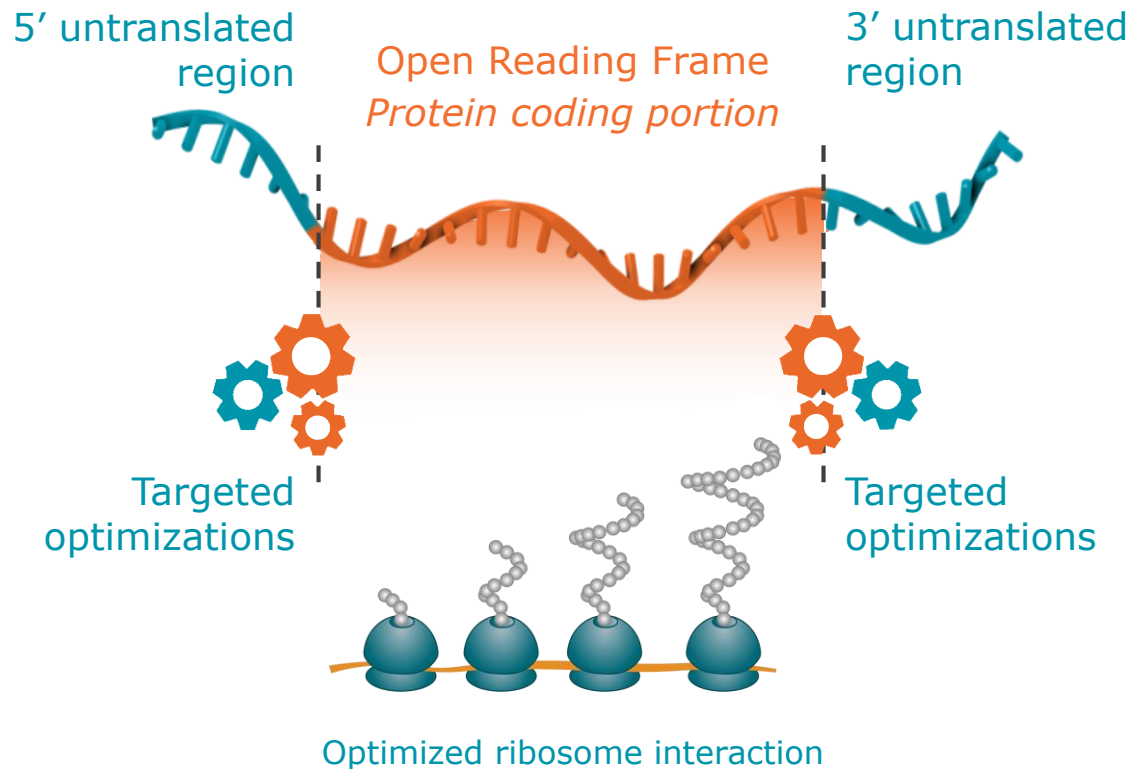


Progress and Path Toward Regulatory Approval

✓ Jan 2020	—●	Design of multiple vaccine candidates
✓ Mar 2020	—●	Lead candidate selection out of several candidates
✓ Jun 2020	—●	GMP production of lead candidate
✓ Jun 2020	—●	Start of Phase 1 dose escalation clinical trial
✓ Sep 2020	—●	Start of Phase 2a clinical trial in older adults
✓ Oct 2020	—●	Interim Phase 1 data and final dose selection
Q4 2020		Interim Phase 2a data
Q4 2020		Start pivotal Phase 2b/3
Q1 2021		Anticipated start of EMA submission

Technology Based on Unmodified mRNA

Extensively tailored untranslated regions allow for differentiated mode of action, mimicking natural immune responses through interferon type 1 induction



- Design of untranslated regions based on potent, tissue-specific regulatory elements
- Optimizations allow for increased translation efficiency and immunogenicity
- Maximizing ribosome interaction for increased protein expression enables **low dose activity**

CVnCoV Phase 1 Trial Design

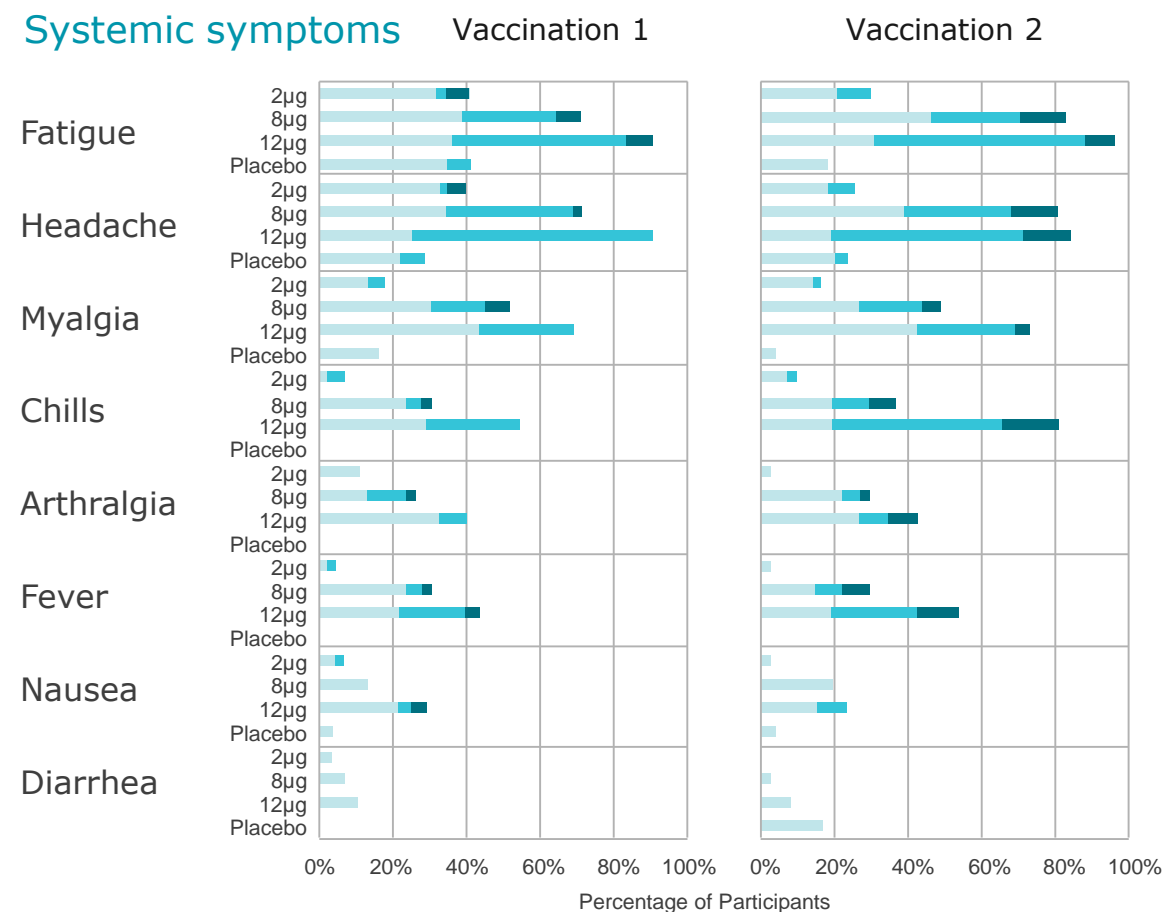
			Seronegative	Seropositive	Fully recruited
12µg	12µg	Sentinel group (11)	24	4	✓
8µg	8µg	Full cohort	46	6	✓
6µg	6µg	/	46	10	✓
4µg	4µg	/	46	10	✓
2µg	2µg	Full cohort	46	10	✓
Day 1 Prime vaccination	Day 29 Boost vaccination	Reported here: Day 36 & 43	Total: 220	Total: 41	

- Partially blinded, placebo-controlled, dose-escalation study in healthy adults (18-60 years)
- Clinical sites in Germany and Belgium
- Intra-muscular vaccinations on day 1 and 29
- Data and Safety Monitoring Board (DSMB) approval of tolerability and dose escalation

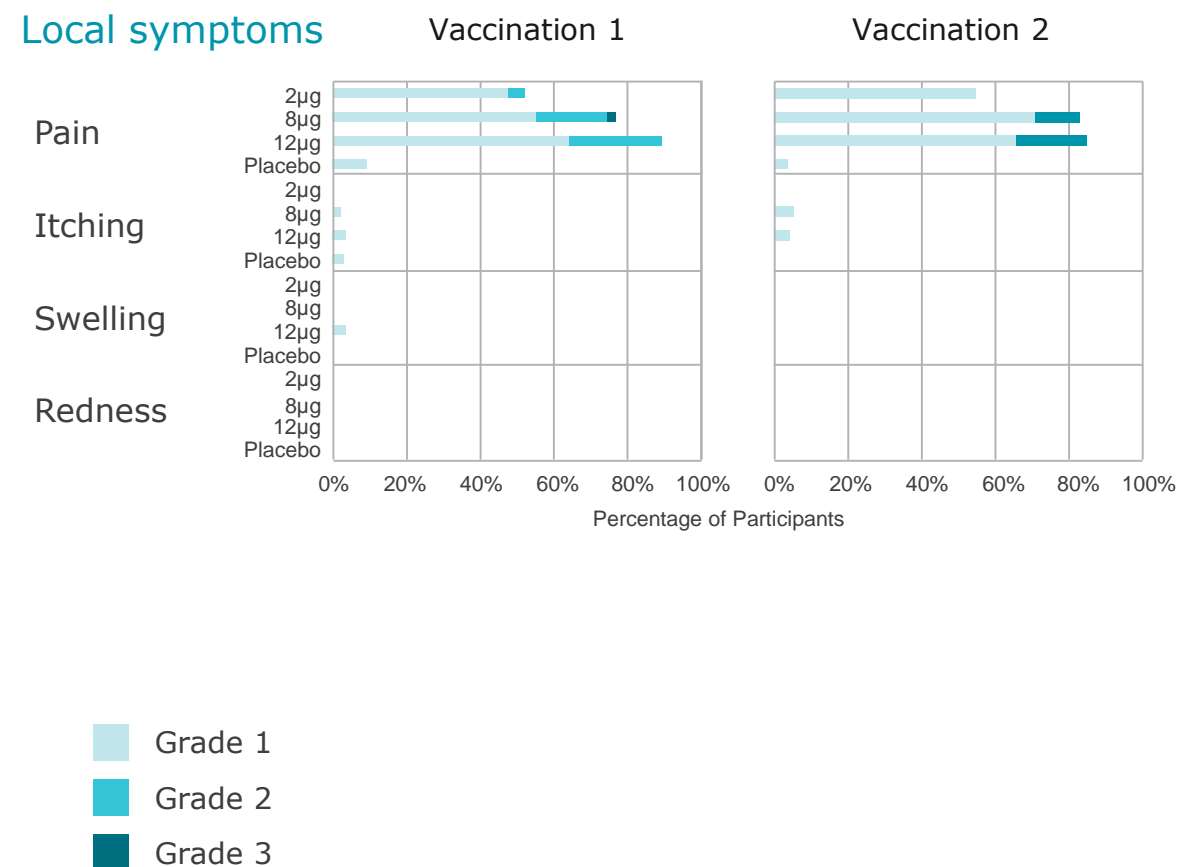
Reactogenicity Data

No serious adverse events or dose limitations were observed
All symptoms were transient and resolved rapidly within 24 to 48 hours

Systemic symptoms



Local symptoms



Analysis of SARS-CoV-2 Specific Antibody Responses

Binding antibodies:

- Measured by ELISA
- Spike protein (S1+S2)
- Receptor Binding Domaine (RBD)

Virus neutralizing antibodies:

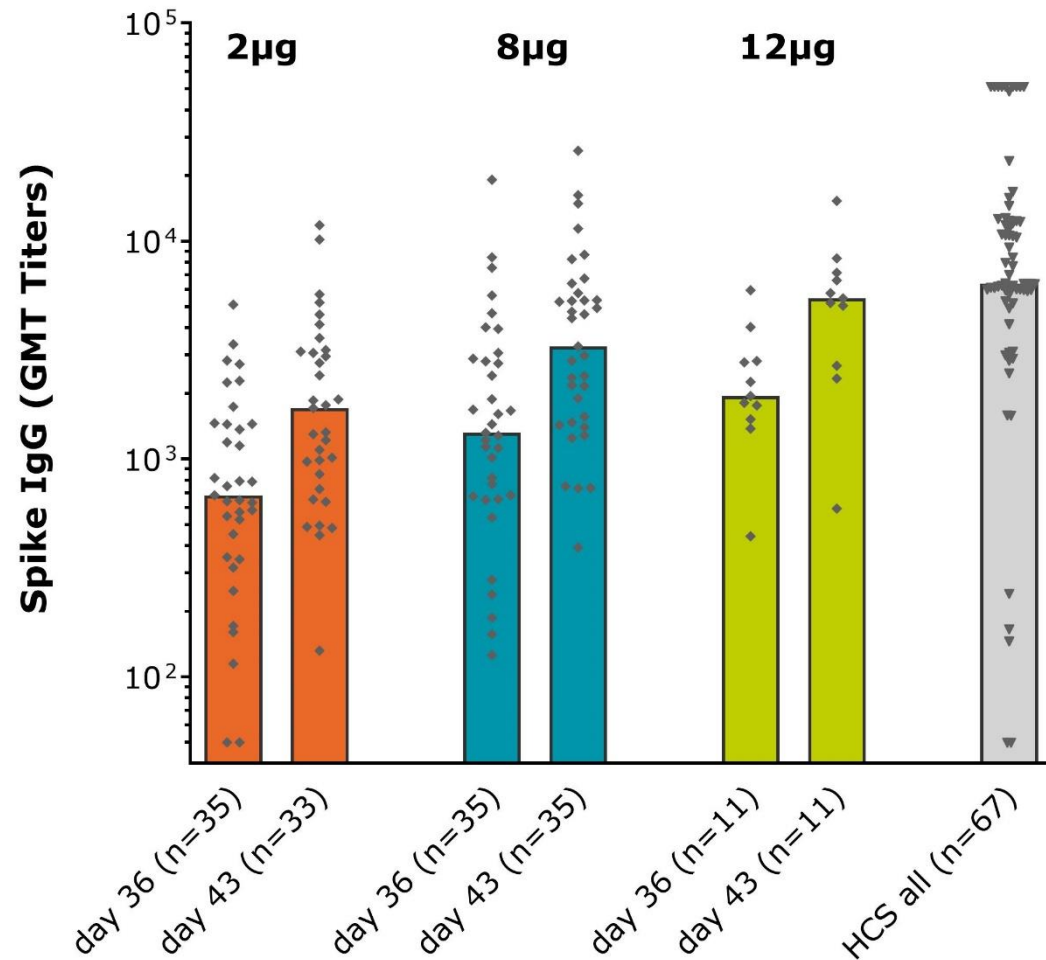
- Measured by micro-neutralization assay
- Live human SARS-CoV-2 virus with 25 TCID
- Positive titers by 50% of neutralization

Human Convalescent Sera (HCS) panel:

- Comparator with highest medical relevance
- 51 patients with multiple symptoms, 16 hospitalized
- Antibodies measured at the peak time

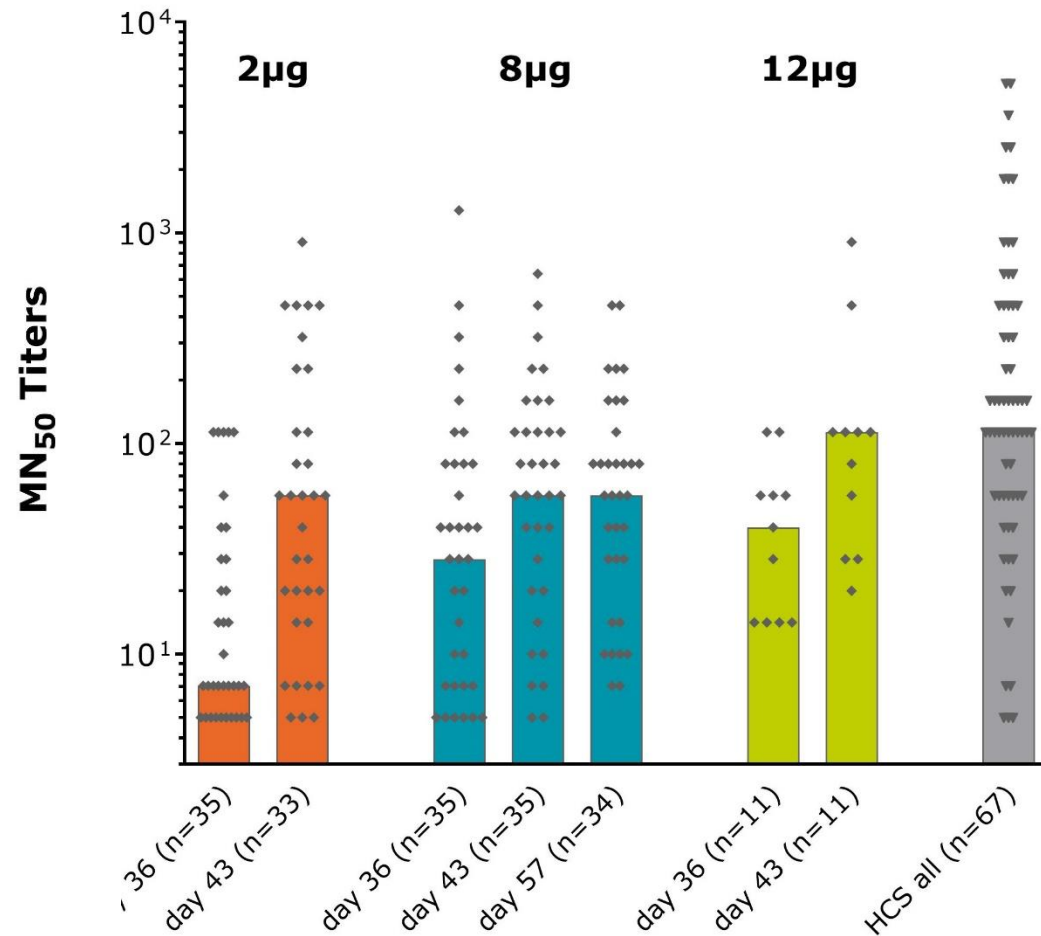


Spike Binding Antibodies: Show dose-dependent induction



- Dose-dependent induction of binding antibodies across tested dose range
- Immune response detected at lowest dose of 2µg
- Binding antibody titers reach highly medically relevant HCS level at 12µg

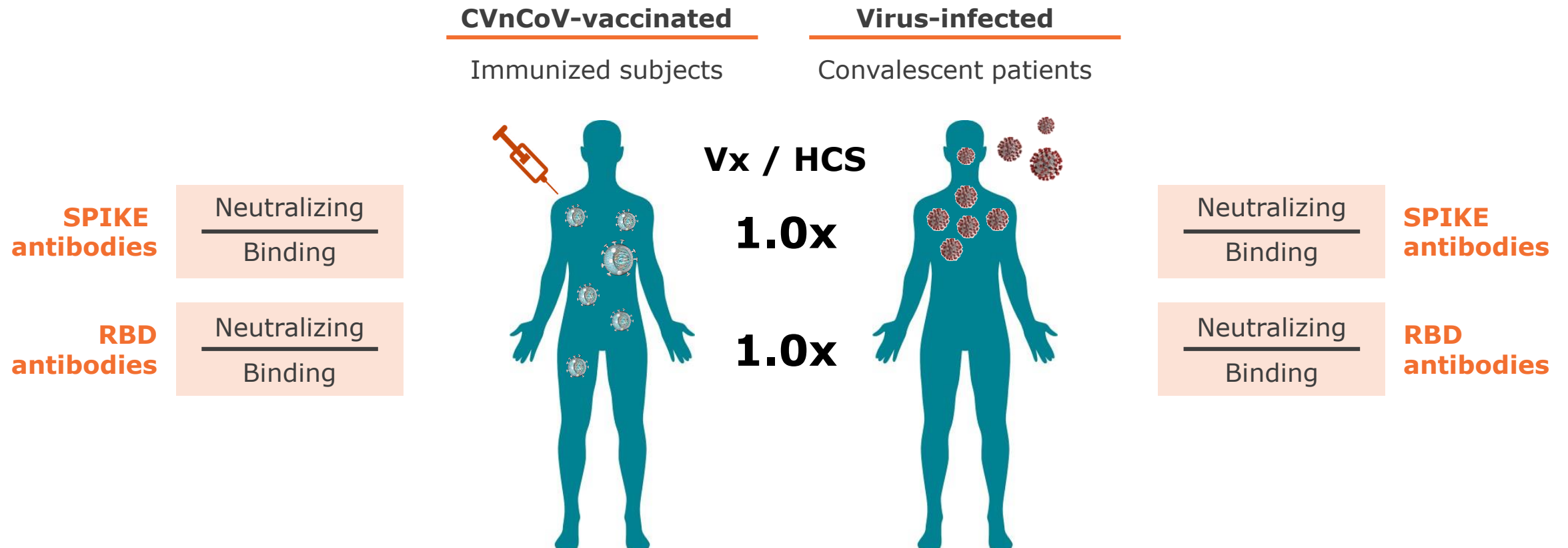
Neutralizing Antibodies: Reach highest relevant HCS level



- Titers remain stable after reaching peak level
- Immune response already at lowest dose of 2μg detected
- Neutralizing antibody titers reach highly medically relevant HCS level at 12μg

Proportion of Neutralizing vs. Binding Antibodies

Quality of immune response is reflected in antibody ratios, which are similar in CVnCoV-vaccinated subjects and convalescent patients

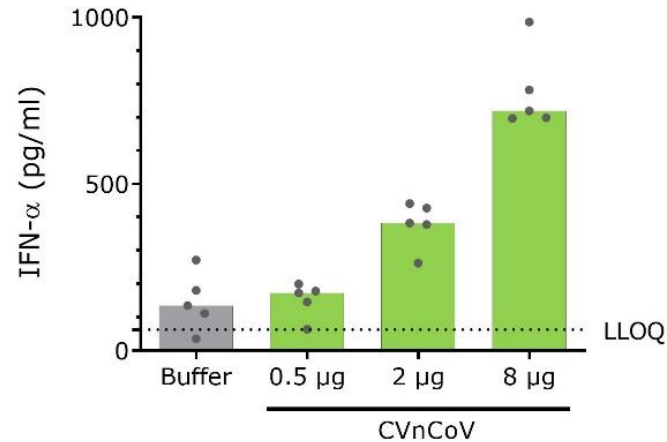


Unique Mechanism of Action Mediated by Interferon Type 1

In animal models...

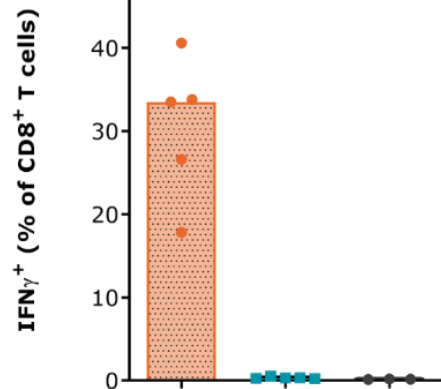
Rat model
Day 1 after 1 dose

**Dose dependent
induction of
IFN-α in rats**

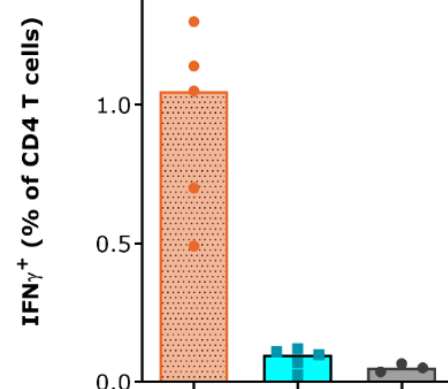


Mouse model
Day 15 after 2nd dose

**Induction of SARS-CoV-2
specific CD8⁺ T cells**

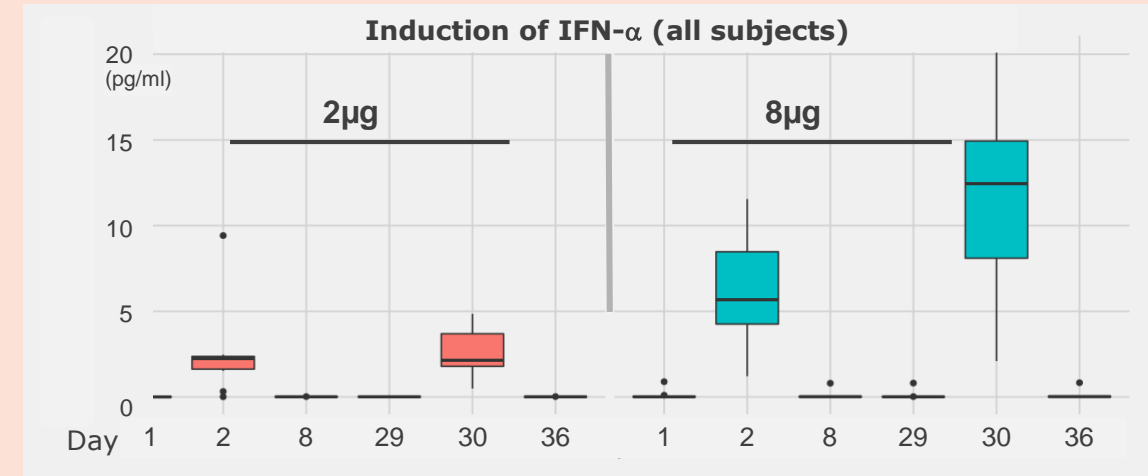


**Induction of SARS-CoV-2
specific CD4⁺ T cells**



CVnCoV Interim Phase 1 Data Presentation

...and in humans



Science

RESEARCH ARTICLES

Cite as: P. Bastard *et al.*, *Science*
10.1126/science.abd4585 (2020).

Auto-antibodies against type I IFNs in patients with life-threatening COVID-19

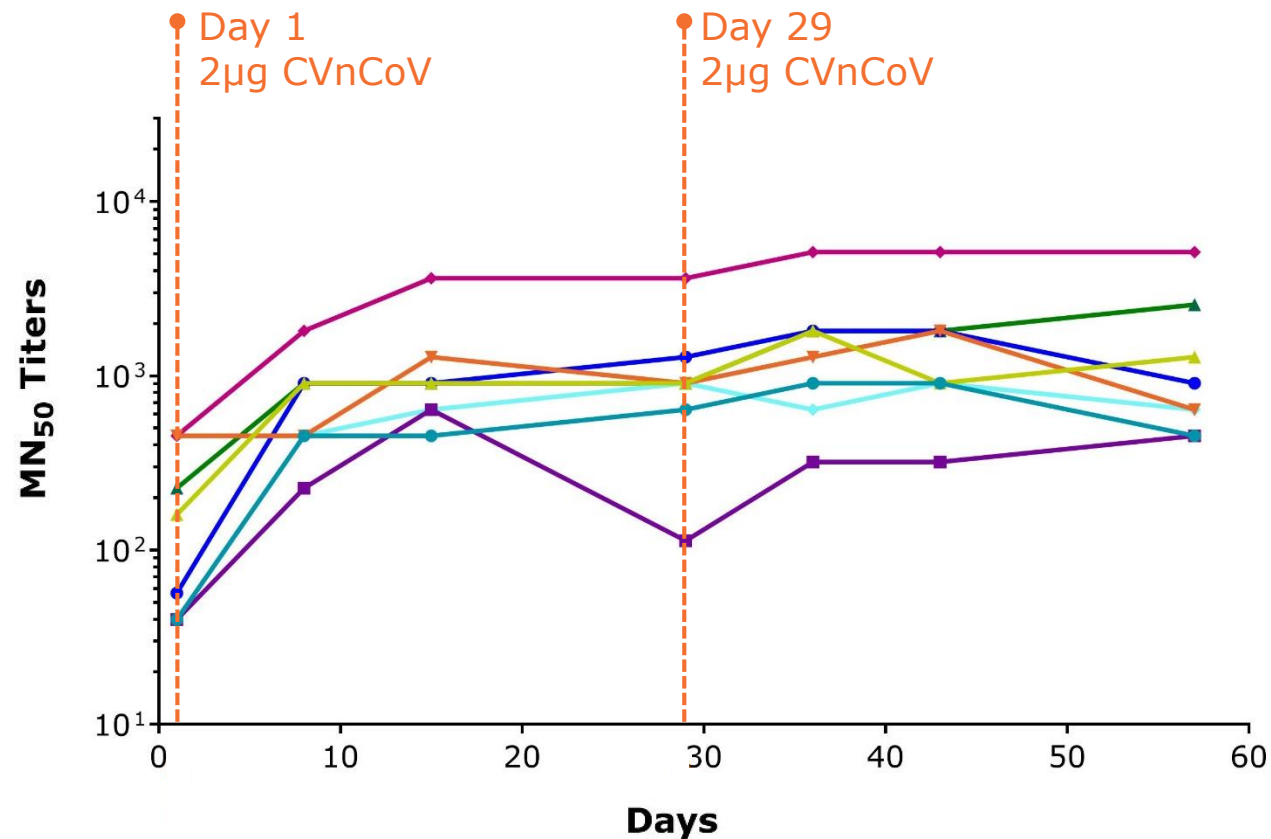
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Impaired type I interferon activity and exacerbated inflammatory responses in severe Covid-19 patients

Jérôme Hadjadj^{1,2,*}, Nader Yatim^{3,*}, Laura Barnabei¹, Aurélien Corneau⁴, Jeremy

Seropositive Subjects

Long-lasting booster effect of neutralizing SARS-CoV-2 antibodies induced with 2 μ g CVnCoV in seropositive subjects



- CVnCoV vaccine was well tolerated in seropositive subjects
- All seropositive subjects benefited from the vaccination
- Stable antibody titers imply induction of immune memory for long-term protection



Achieved goal to assess safety and identify optimal dose to advance clinical development



CVnCoV is well tolerable and demonstrated activity across all tested doses



On track for pivotal Phase 2b/3 and subsequent regulatory approval processes





**Thank you for your
attention**

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