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CUREVAC

the RNA people®

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

Data update August 26th, 2020

Pre-read for Aug 28th EU Member state experts review

- STRICTLY CONFIDENTIAL -

Key elements (1/2)

1 CureVac's mRNA platform

- Pioneer in developing mRNA vaccines and therapies; broad IP position: Proprietary mRNA optimization and protein design technology
- CureVac's rabies vaccine showed Virus Neutralizing Titers (VNTs) above WHO threshold at low doses for rabies and flu vaccine, enabling large scale production and supply
- External validation of platform: Strategic partnerships with leading biopharma (GSK Vaccines, announced July 20th 2020), CEPI; 640m$ private financing round closed on July 21st, 2020; IPO on NASDAQ Aug 14th , 2020

2 CVnCoV construct and preclinical data

- Clinical COVID-19 vaccine candidate selected based on biological properties (preclinical immunogenicity and safety) characterized in vitro and in vivo (mice and rats) and large scale manufacturability
- Robust immunogenicity and acceptable preclinical safety is consistent with data generated for other vaccines designed using CureVac's proprietary mRNA platform.
- CvnCoV induces VNTs and a strong and balanced immune response

3 Available CVnCoV Ph1 clinical data

- Phase 1 trial (First-in-human) in Belgium and Germany started in June 2020; ongoing with escalating dose levels
- Results from the ongoing Phase 1 in 18-60 year olds indicate acceptable reactogenicity profile at doses up to 8µg
- Encouraging immunogenicity data even at the lowest dose levels investigated; dose effect observed (based on VNTs and IgG SPIKE ELISA data)

Key elements (2/2)

4 Clinical development plan and project timelines

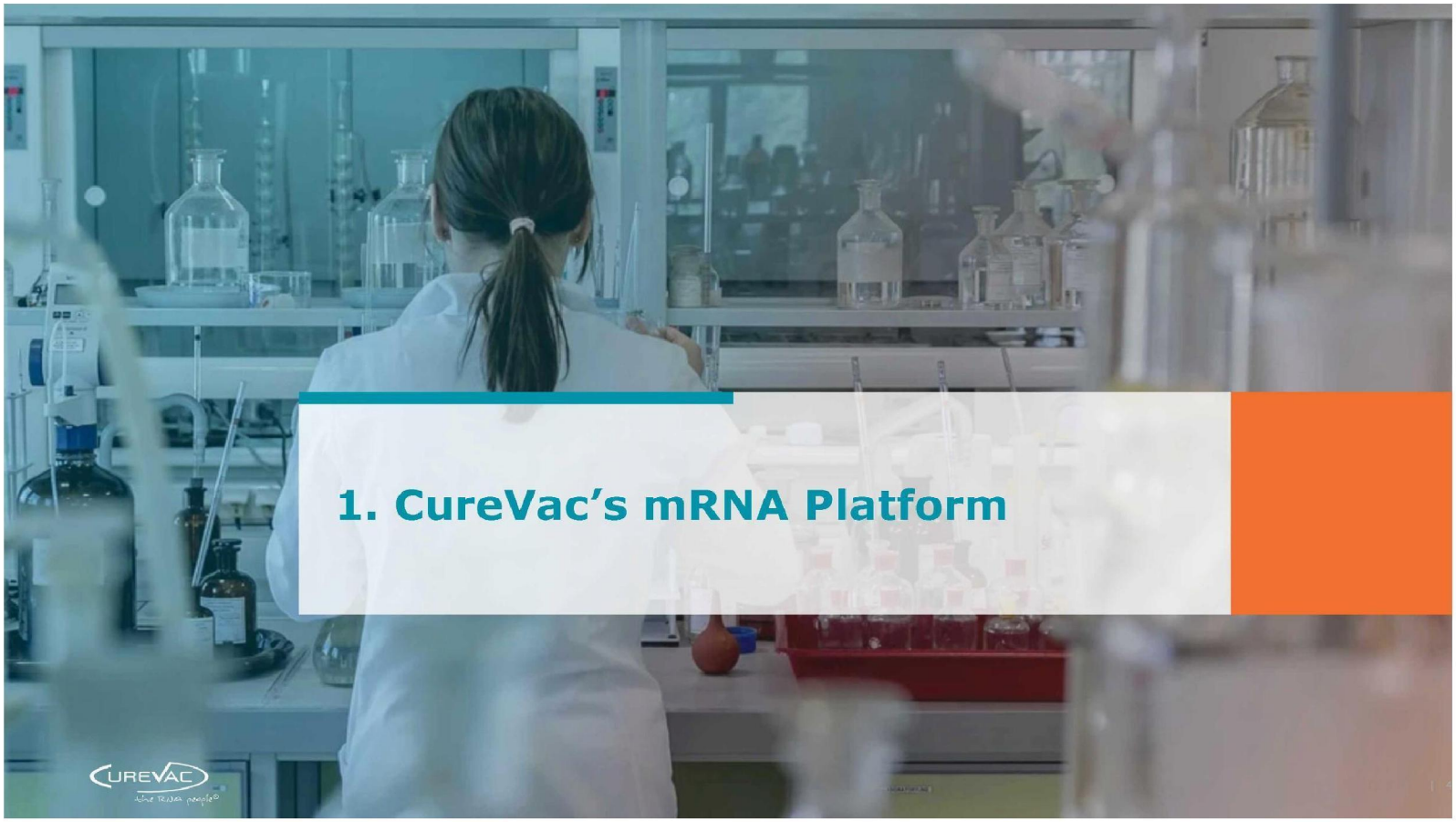
- Phase 2a study in over 60 age group starting early September
- Final dose selection for Phase 2b/3 planned for mid September
- Preparations ongoing to start pivotal Phase 2b/3 in early November
- Feedback pending from EMA (ETF) to align on clinical development plan and required data for approval
- CureVac will seek EMA conditional approval in Q1 2021 and full approval by Q3/Q4 2021

5 Manufacturing footprint, capacity and delivery plan

- CureVac is building a fully-integrated European vaccine manufacturing network
- Accelerating commercial GMP manufacturing capacity and ramp-up plans: establish 8 lines by multiplying GMP III process at European CMOs and acceleration of completion of larger scale CureVac GMP IV facility in Tübingen
- 225 million doses requested by EU to be delivered by end 1Q22 (15m by end 1Q21, 40m by end 2Q21, 50m by end 3Q21,60m by end 4Q21 and 60m by end of 1Q22; sufficient for 112.5m courses), and option for 180m additional doses in 2022

6 Target presentation and shelf-life

- Vaccination course is two injections, 28 days apart; standard 0.4 ml to 0.5ml intramuscular administration
- 6-10x multidose vials (formulated mRNA concentrate + diluent in boxes of 12-20) at conditional apprc improvement expected after full marketing authorization
- Target stability and shelf life: 6-12 months at 2-8°C for the formulated mRNA and 24 months at room temperature for diluent
- Post dilution ready to inject vaccine target stability: 24 h

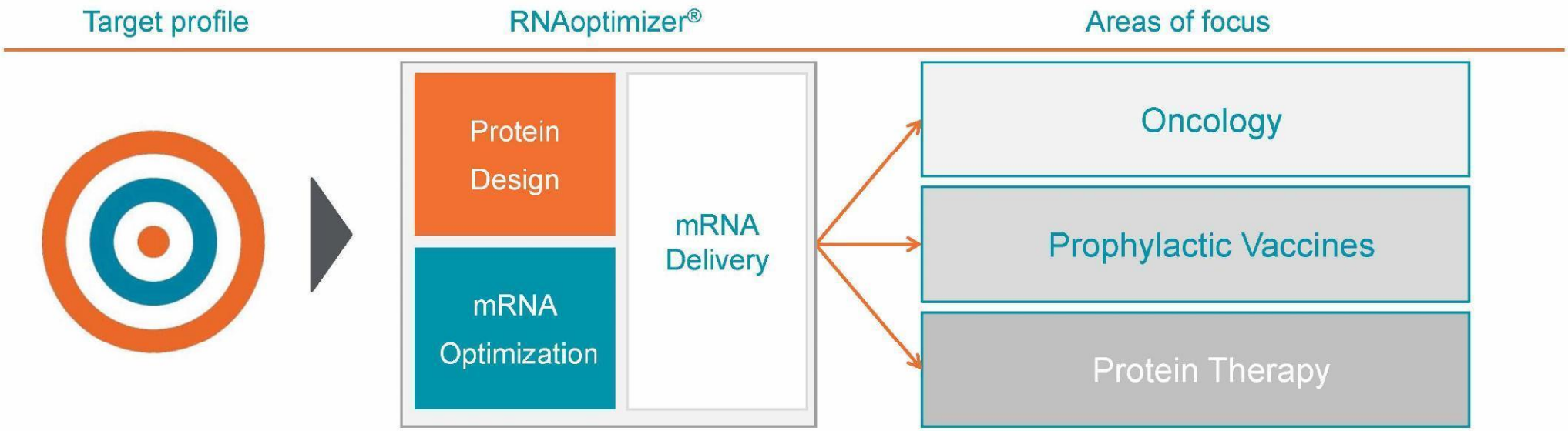

1. CureVac’s mRNA Platform

RNAoptimizer® Creates Unique, IP-protected Product Candidates

1 Identification of a target expression profile for each mRNA product candidate

2 RNAoptimizer® provides optimal mRNA solutions for each target indication

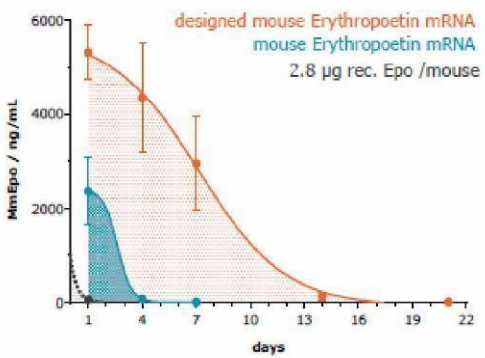
3 The optimization process allows us to pursue new and exclusive IP protection for each product candidate across our focus areas and proprietary technologies



Protein Design: Enables the Optimization of Specific Properties of the Encoded Protein

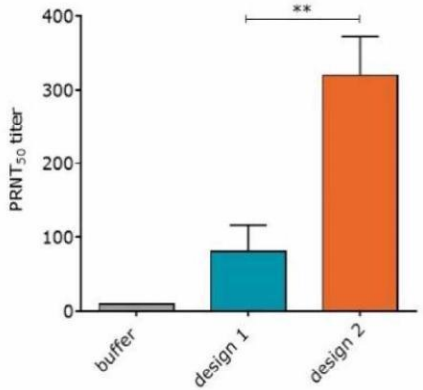
- Ability to modify amino acid sequence to optimize protein properties including half-life, stabilization of tertiary structure, oligomerization, secretion and immunogenicity
- Bespoke and multi-factorial to support distinct functions and requirements of the specific target protein

Extended half-life of secreted protein



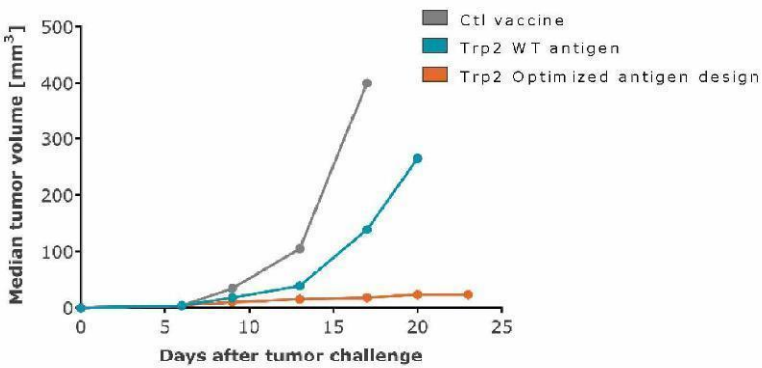
Relevant serum titers of functional Epo and different pharmacokinetic profiles

Oligomerization



Higher induction of neutralizing antibodies demonstrated via optimized mRNA

Modified immunogenicity



Tumor growth inhibited in murine melanoma model

mRNA Optimization: Optimizes Unmodified mRNA to Enhance Protein Expression and Stability

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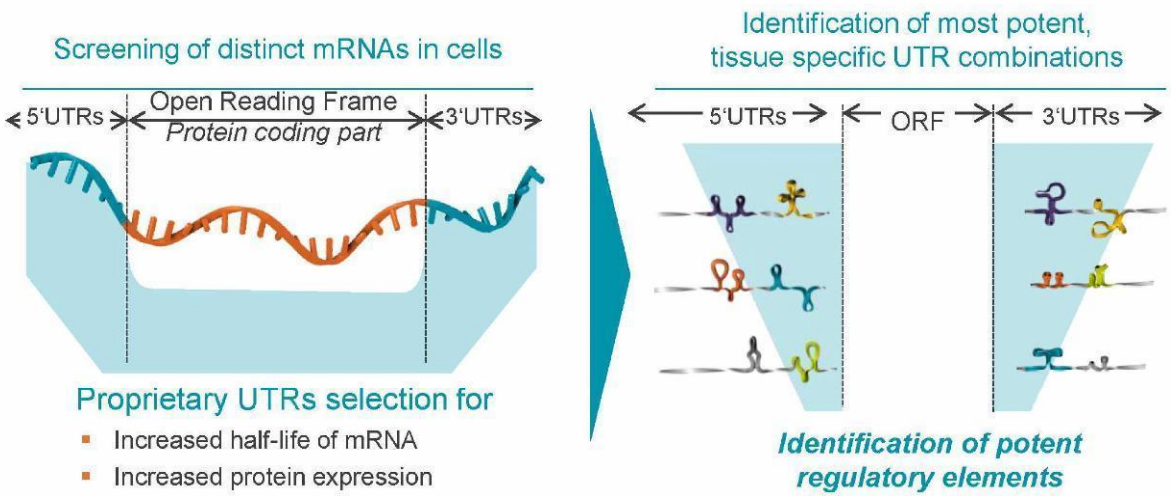
CureVac utilizes unmodified mRNA to extensively tailor mRNA UTRs

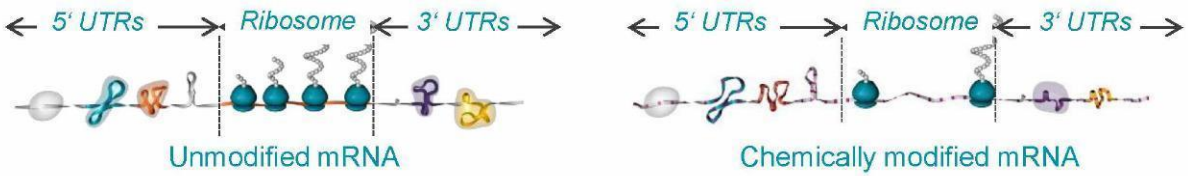


Proprietary UTRs selection for

- Increased half-life of mRNA
- Increased protein expression

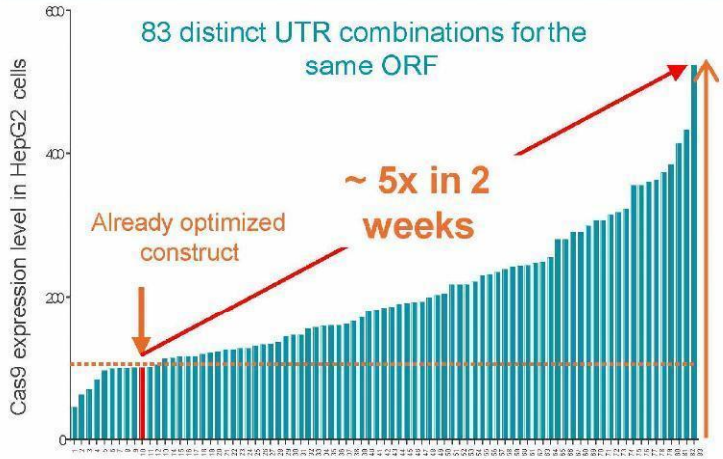
Identification of potent regulatory elements

CureVac's unmodified mRNA has a higher translation efficiency than chemically modified mRNA



- mRNA optimization process designed to generate the most efficacious mRNA by optimizing translation, stability and immunogenicity
- Ability to optimize six elements of mRNA including 5' cap, 5' UTR, ORF, 3' UTR, and 3' poly-A tail and 3' end

Optimized UTRs for higher expression



CureVac's Rabies Vaccine CV7202 Induces Protective Antibody Titers at dose Levels of 1µg and 2µg

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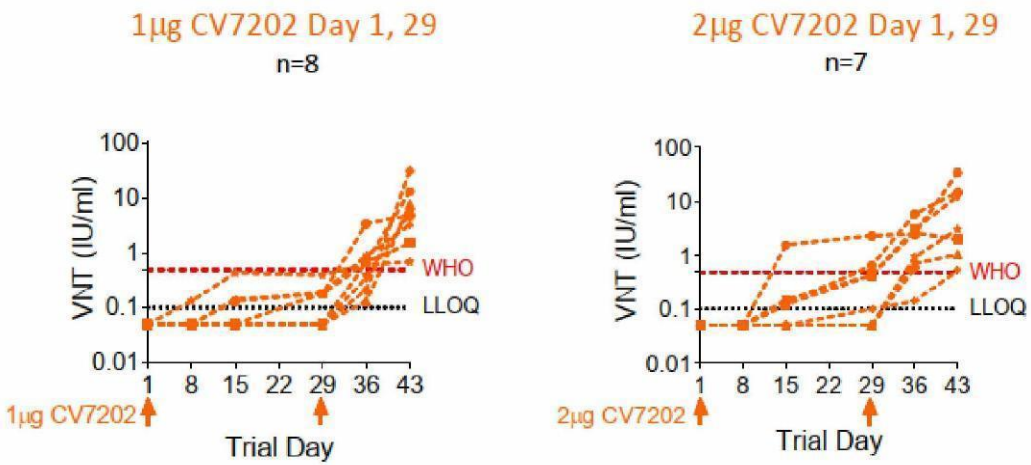
CV7202 –Rabies Vaccine –1µg dose x 2 (n=8); 2µg dose x 2 (n=7)



Preliminary data
Values <LLOQ are shown as half LLOQ

- Detectable VNTs as early as 8 days after 1 administration in some subjects
- After two IM doses of 1µg or 2µg, 28 days apart, all subjects with available data had VNTs above the ≥0.5IU/mL WHO recommended antibody level, 14 days after Dose 2 (Day 43)
- Vaccinations were well tolerated
- No vaccine related SAEs reported
- Durability of response: currently available follow-up at 6 month show stable antibody titers

Long Durability of Response Demonstrated Rabies and flu Vaccines

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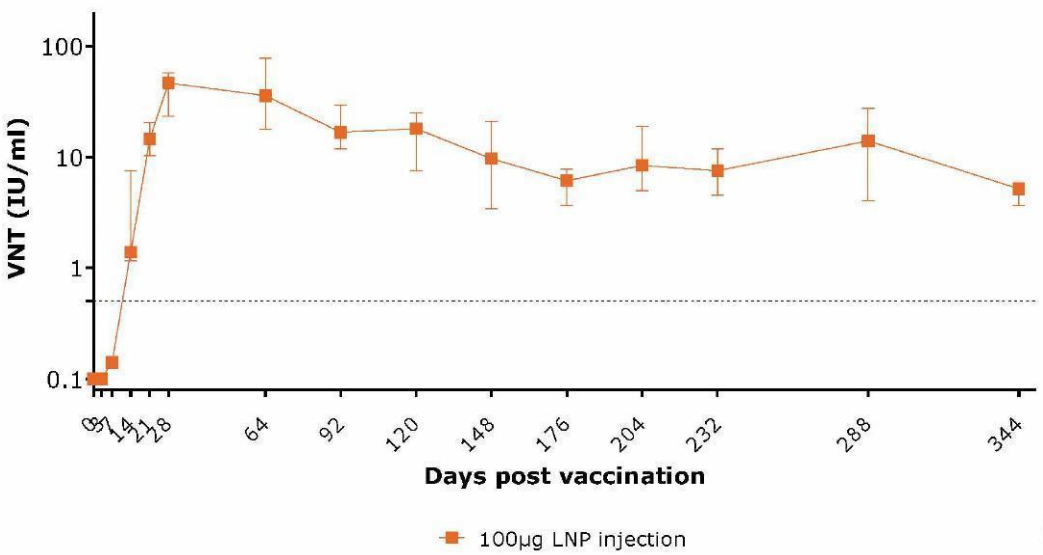
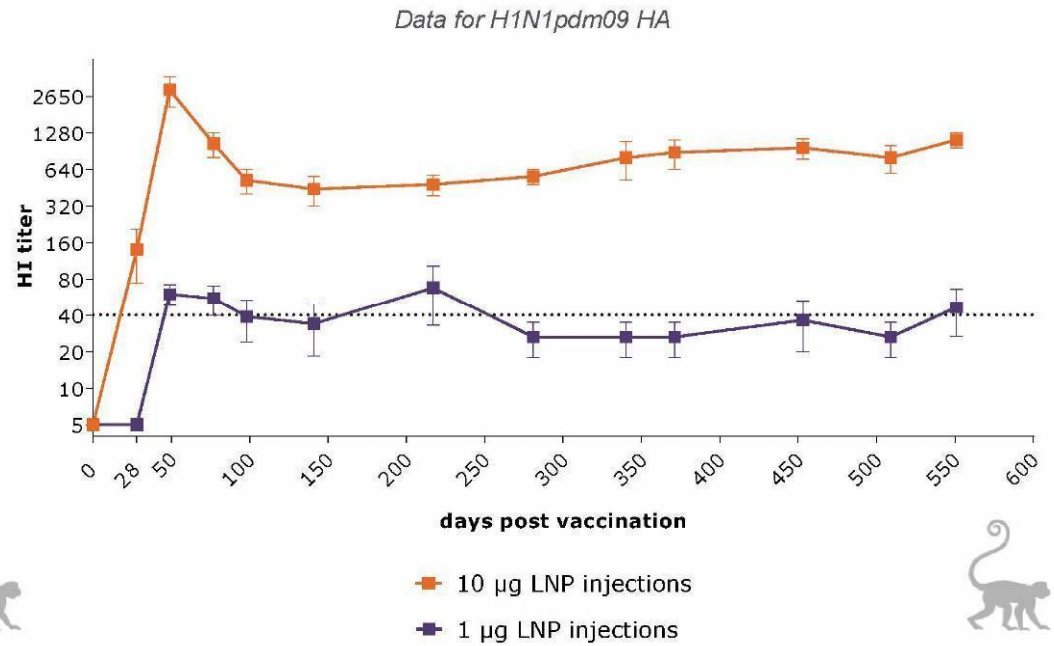
mRNA rabies vaccine induces high virus-neutralizing titers (VNT) after a single IM injection



mRNA flu vaccine demonstrated strong and durable immunogenicity in non-human primates (NHP)



2. CVnCoV Construct and Pre-Clinical Data

Fast-Track SARS-CoV-2 Vaccine Development

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Development Plan overview and 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 and start of Phase 1 clinical trial
- ✓ **August 2020:** CTA approval of Phase 2a clinical trial in older adults
- **September 2020:** Human Phase 1 clinical trial data (safety and immunogenicity) for final dose selection
- **October 2020:** CTA to be submitted for Phase 2b/3
- **Q1/2 2021:** Projected conditional approval of MAA - based on safety (n~3,500), immunogenicity and preliminary efficacy. Supply will start shortly after conditional approval based on lots manufactured at risk and will continue with commercial supply ramp-up
- **Q3/Q4 2021:** Projected full approval MAA submission

CVnCoV Induces a Strong and Balanced Immune Response

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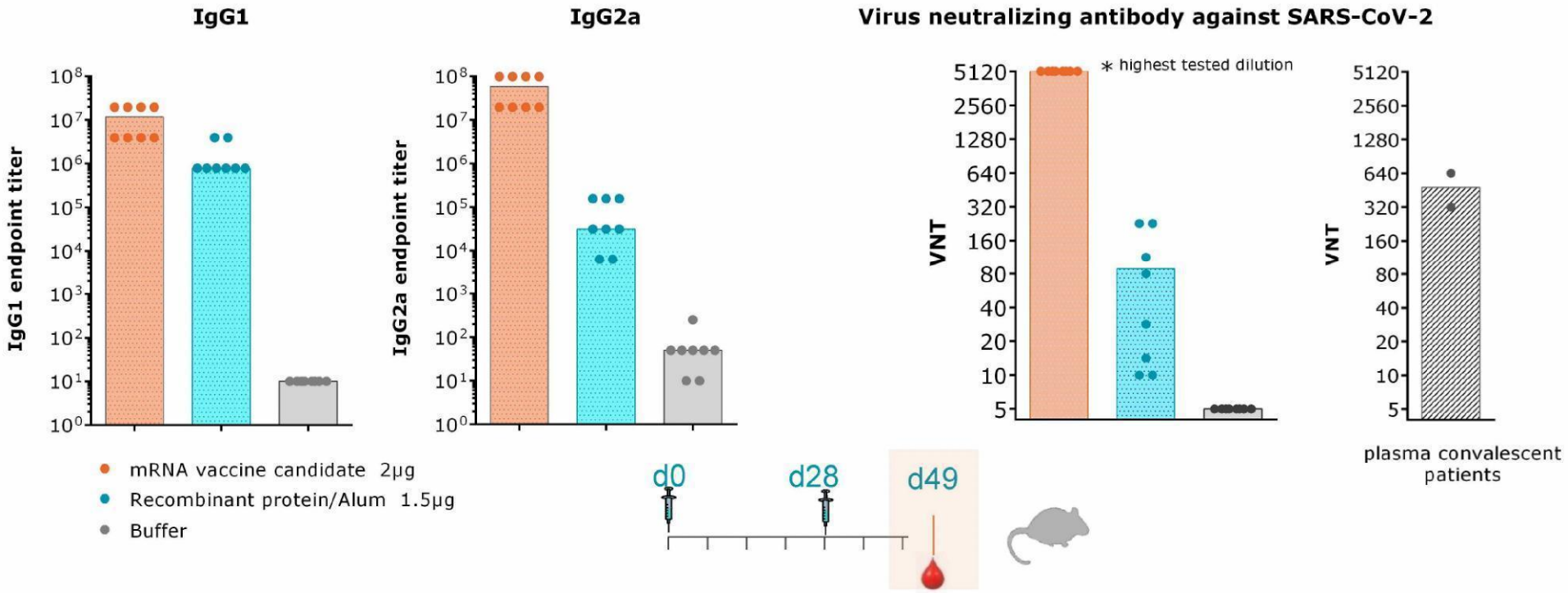
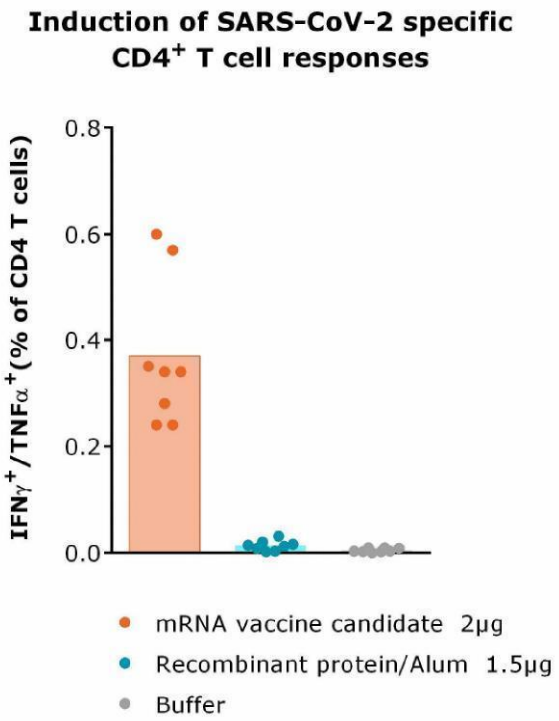
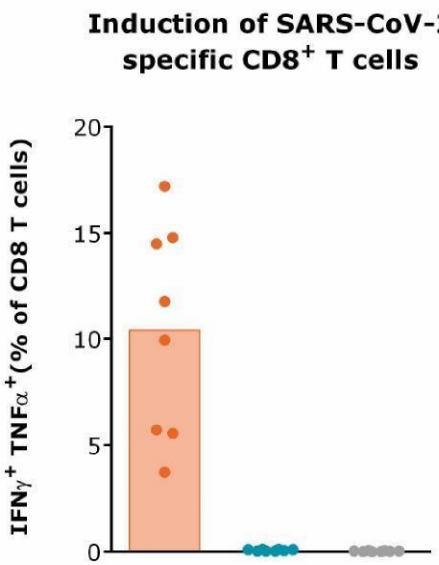
CureVac's SARS-CoV-2 mRNA vaccine candidate results in high antibody titers leading to neutralizing antibodies against SARS-CoV-2 in mice

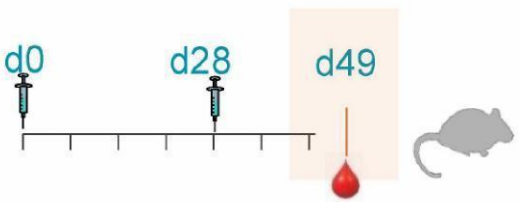


CVnCoV Induces a Strong T Cell Response

CureVac's SARS-CoV-2 mRNA vaccine induces multifunctional (IFN-γ^+ and TNF$^+$) CD4 and CD8 T cell responses in mice







Characterization of humoral and cellular responses: CVnCoV induces antibody responses with strong binding to the RBD

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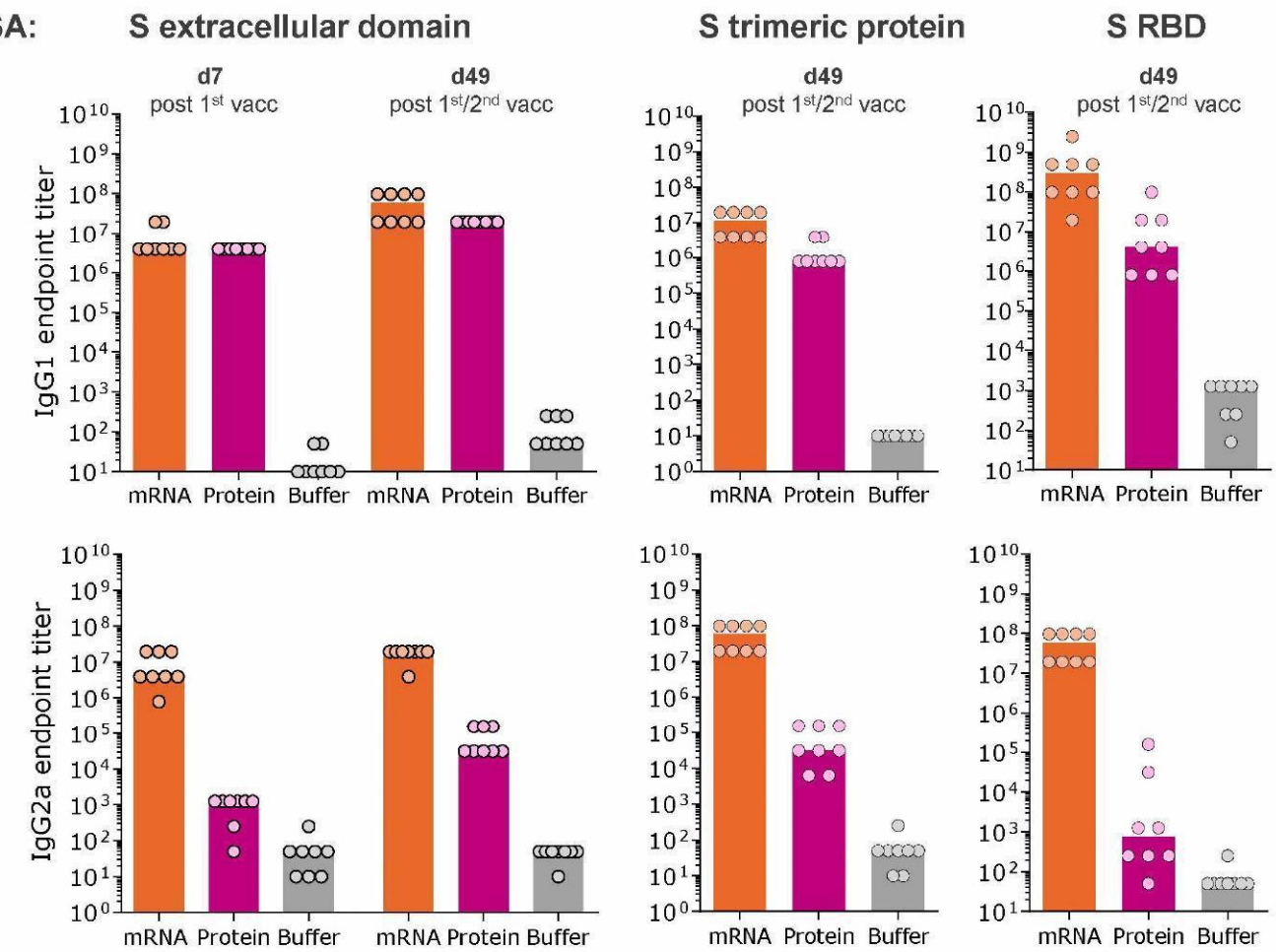
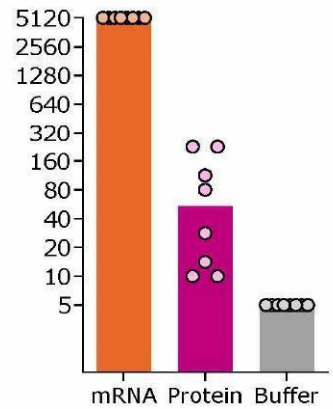
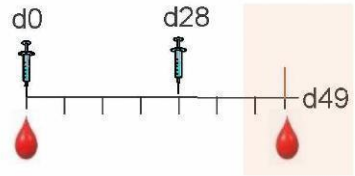
ELISA:



VNTs





Human positive control sera from reconvalescent patients: 1:320 to 1:640

- Encoded protein: SARS-CoV-S full length $K_{986}P$, $V_{987}P$
- Evaluation:
  - **ELISA:** coating with SARS-CoV-2 S extracellular domain, trimeric protein or RBD (receptor binding domain)
  - **VNTs:** Cytopathic effect (CPE) based microneutralization at VisMederi

Anti-SARS-CoV-2 IgG Antibody Titers in Rodents Correlate with Neutralizing Antibodies Above Inflection Point at ~10^4

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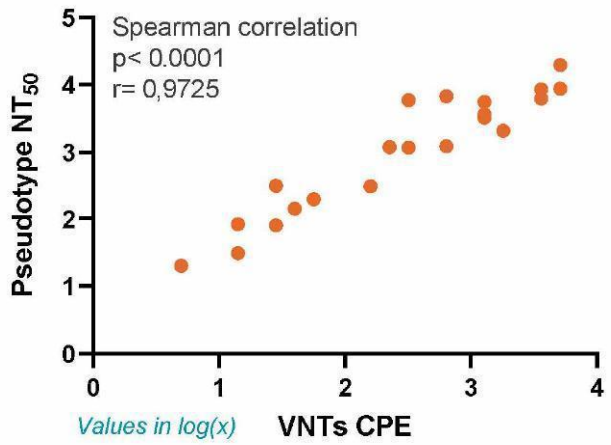
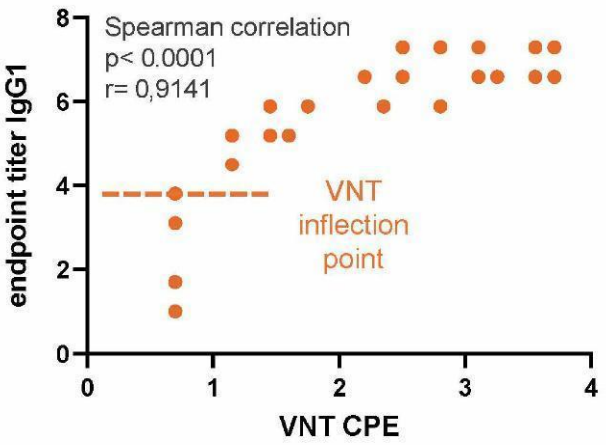
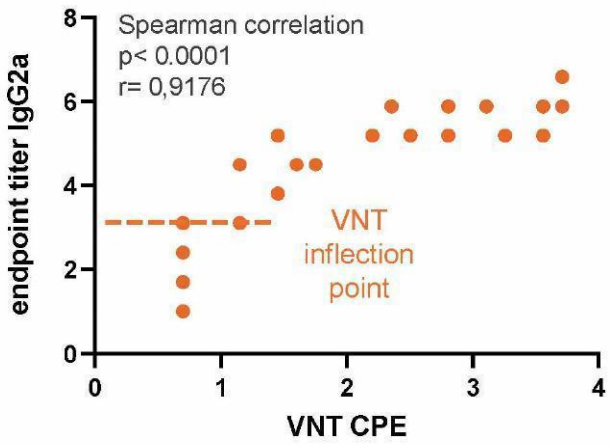
Correlation Analyses of Antibody Titers after dose 2

(data from rat immunogenicity study with CvnCoV)



- Standard VNT assay based on life virus (CPE) used for CVnCoV correlate with pseudo-type assay
- CureVac VNT assay shows lower values compared to pseudotype NT_{50}

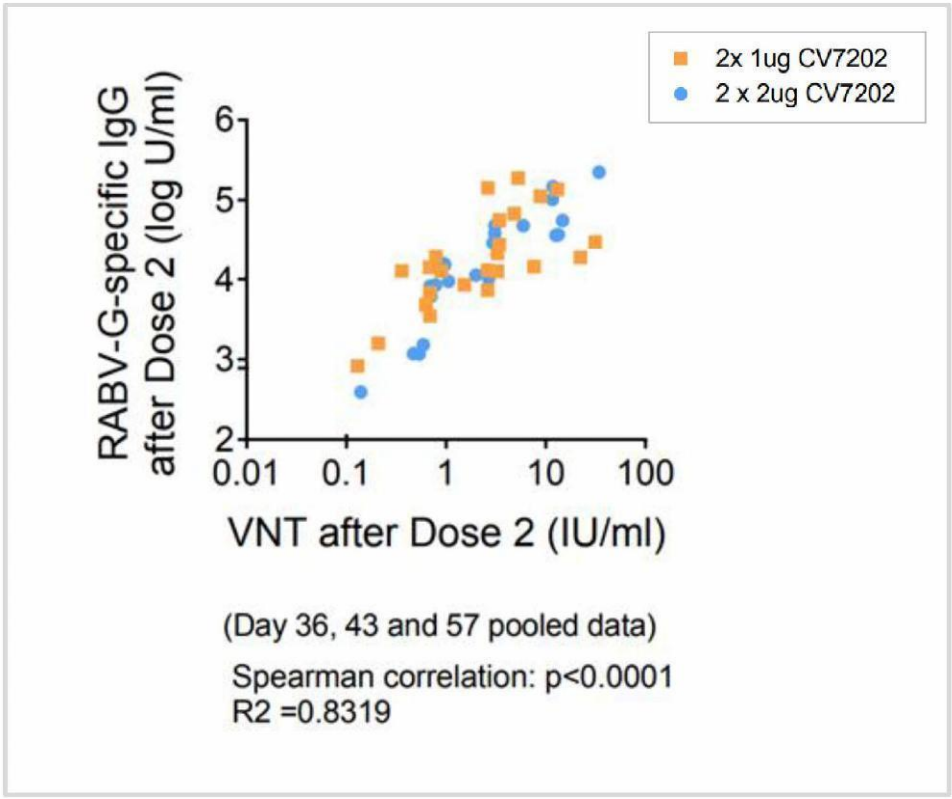




- Both IgG1 and IgG2a titers indicate significant VNT above a titer level of 10^4

Clinical data from CV7202 (Rabies Vaccine) Confirms Correlation Between IgG and VNTs in Humans

Values in log(x)



This correlation is expected be relevant for the development of CVnCoV


3. Available CVnCoV Clinical Data

Overview of Clinical Study Design of CureVac's First-in-Human CVnCoV trial

- Partially blinded, placebo-controlled, dose-escalation study in healthy adults (18-60 years of age)
- Several dose groups of 2µg, 4µg, 6µg, and 8µg with 48 vaccinees and 8 placebo recipients per group; 'sentinel group' vaccination with 12µg started after favorable DSMB review
- Two vaccinations administered by intra-muscular injection on day 1 and day 29
- Sites in Tübingen, Hannover, Munich and Gent
- Participants will be followed for at least one year after the last vaccination
- Study assesses safety and reactogenicity as well as immunogenicity of CVnCoV

		2µg	4µg	6µg	8µg	Total
N	Seronegatives	46	46	46	46	184
N	Seropositives	10	9	5	2	26
Total N	CVnCoV + placebo	56	55	51	48	210

Note: as study is blinded number of subjects receiving placebo is unknown and max. 8 per dose level

Ongoing Phase 1 Results Indicate Acceptable Reactogenicity Profile at Doses up to 8µg

Available data set as of Aug 26th, 2020

Systemic and Local Solicited Events by Dose Level and Dosing Occasion (as % of subjects at each time point)

	Systemic Solicited Events				Local Solicited Events			
	2µg	4µg	6µg	8µg	2µg	4µg	6µg	8µg
1st Dose								
Mild	41%	46%	37%	31%	41%	66%	49%	54%
Moderate	7,1%	24%	33%	35%	3,6%	1,8%	7,8%	17%
Severe	3,6%	9,1%	5,9%	15%	0%	1,8%	2,0%	2,1%
N	56	55	51	48	56	55	51	48
2nd Dose								
Mild	29%	59%	28%	40%	44%	62%	50%	67%
Moderate	7,4%	20%	25%	27%	0,0%	4,4%	6,3%	0%
Severe	1,9%	8,9%	16%	20%	0,0%	0,0%	0,0%	0%
N	54	45	31	15	54	45	31	15

- Grade 1 to Grade 3 reactions appear to increase with dose
- Most Grade 3 events resolved to lower Grades after one day (others remained at Grade 3 for 2 days)
- Lower reactogenicity in 41-60 year old adults (yoa) vs 18-40 yoa (data not shown)

No Apparent Increase of Symptoms after Dose 2 vs. Dose 1

Ongoing Phase 1 Results Reactogenicity Data Per Symptoms and Dose

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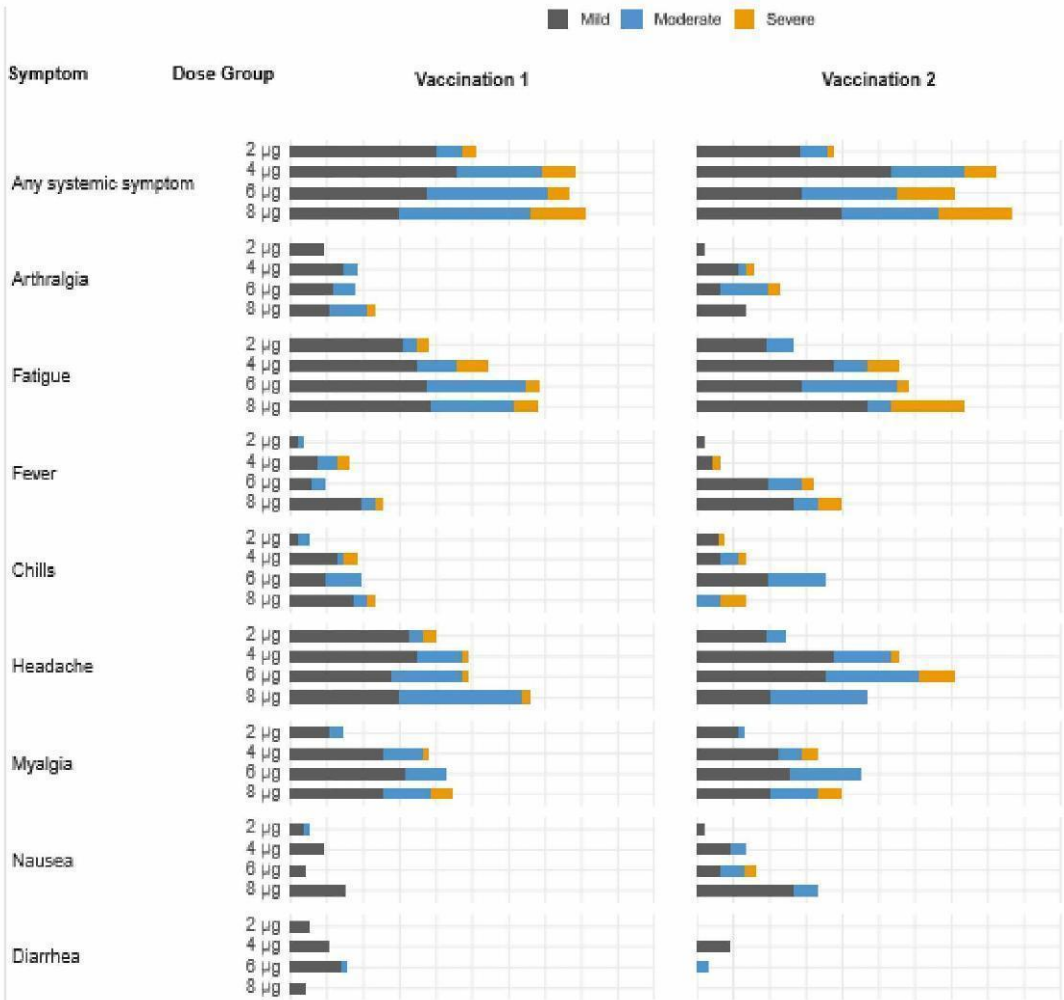
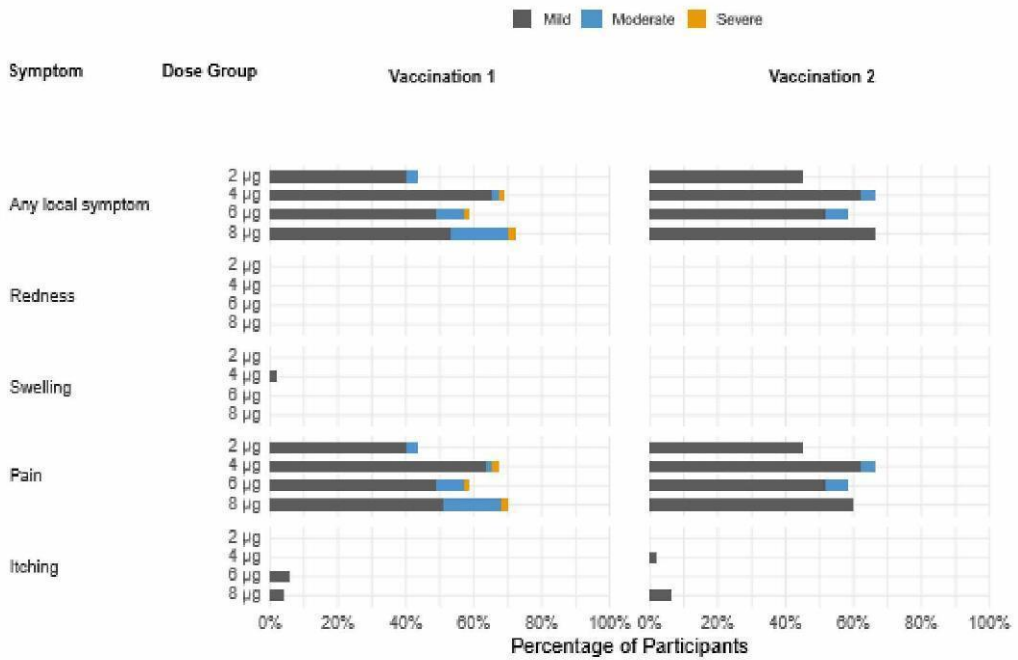
Available data set as of Aug 26th, 2020





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Increase in IgG Titers with Dose and Time at Low Dose Levels

IgG SPIKE ELISA: Sentinel and Observer Blind Groups – *Preliminary Data*

Available data set as of Aug 26th, 2020

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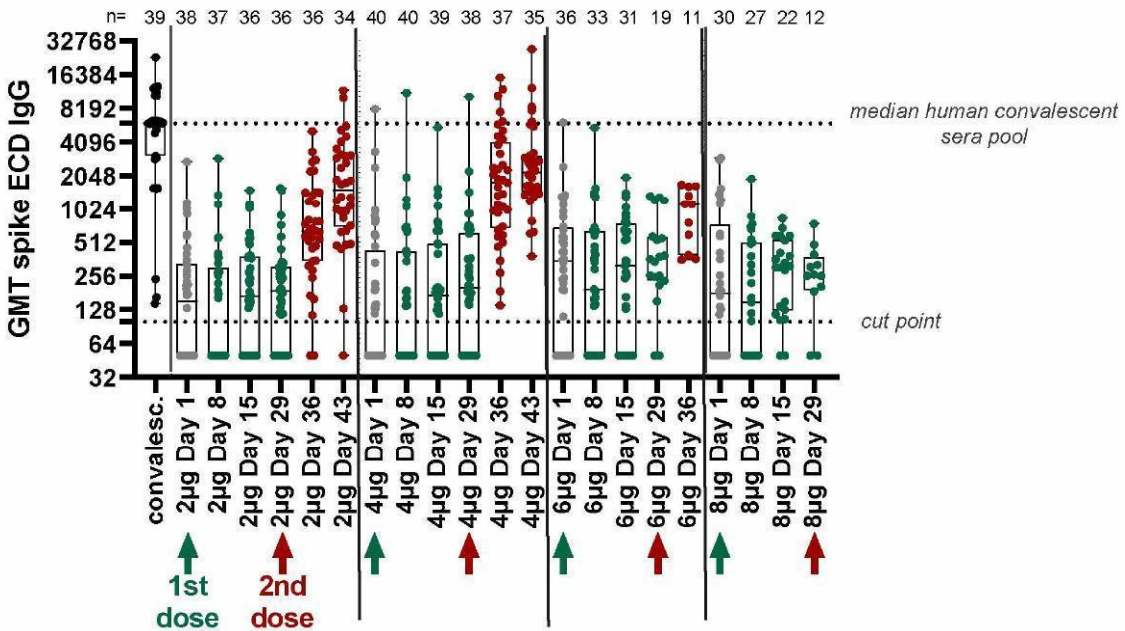


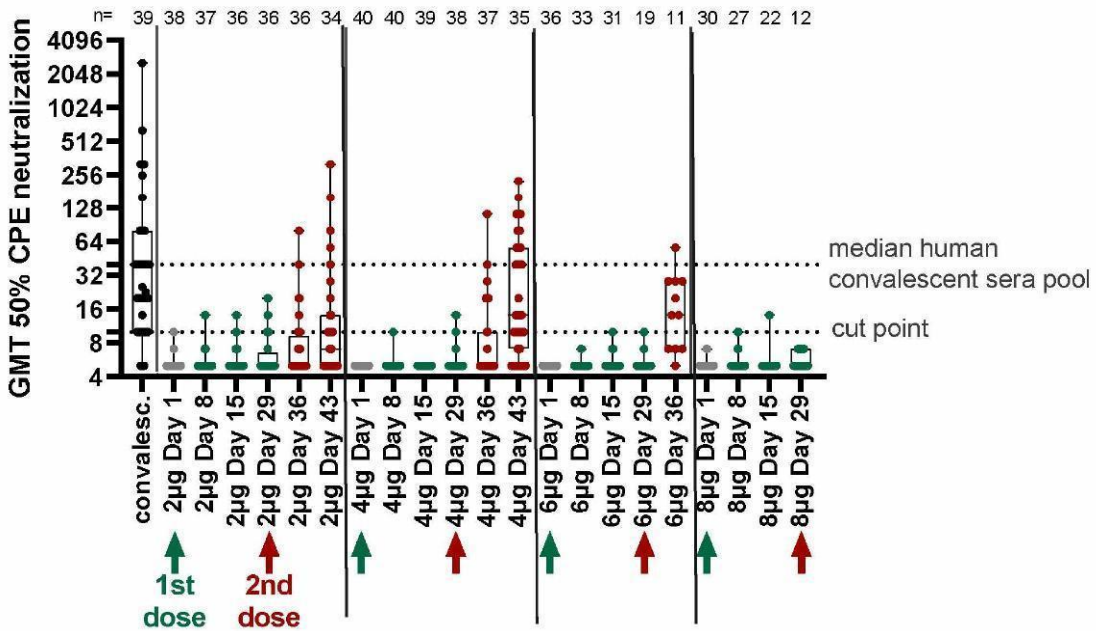
Box: 50% middle values with median
Bars: min to max
Cut points (=100): lower possible reciprocal dilution over cut-off (=LOD+matrix effect)
Values below cut point shown as =0.5*cut point
Validated assay precision range: 223.9-27455.6

	1st dose		2nd dose	
Seroconversion 2 µg				
fold increase over baseline	Day 15	Day 29	Day 36	Day 43
≥2	8 of 36 (22%)	8 of 36 (22%)	28 of 36 (78%)	31 of 34 (91%)
≥4	1 of 36 (3%)	3 of 36 (8%)	18 of 36 (50%)	26 of 34 (76%)
≥8	0 of 36 (0%)	0 of 36 (0%)	13 of 36 (36%)	21 of 34 (62%)
Seroconversion 4 µg				
fold increase over baseline	Day 15	Day 29	Day 36	Day 43
≥2	10 of 39 (26%)	13 of 38 (34%)	33 of 37 (89%)	31 of 35 (89%)
≥4	2 of 39 (5%)	6 of 38 (16%)	25 of 37 (68%)	27 of 35 (77%)
≥8	0 of 39 (0%)	0 of 38 (0%)	24 of 37 (65%)	24 of 35 (69%)
Seroconversion 6 µg				
fold increase over baseline	Day 15	Day 29	Day 36	Day 43
≥2	6 of 31 (19%)	10 of 19 (53%)	9 of 11 (82%)	na
≥4	2 of 31 (6%)	6 of 19 (32%)	8 of 11 (73%)	na
≥8	1 of 31 (3%)	1 of 19 (5%)	5 of 11 (45%)	na
Seroconversion 8 µg				
fold increase over baseline	Day 15	Day 29	Day 36	Day 43
≥2	10 of 22 (45%)	7 of 12 (58%)	na	na
≥4	4 of 22 (18%)	5 of 12 (42%)	na	na
≥8	1 of 22 (5%)	1 of 12 (8%)	na	na

Note: placebo subjects have been excluded from analysis
Data for 6 and 8 mcg is preliminary as only low numbers available at this time, but indicates encouraging seroconversion already after 1st dose

Increase in VNT with Dose and Time at Low Dose Levels

Virus Neutralizing Titers (VNT): Sentinel and Observer Blind Groups – *Preliminary Data*



	1st dose		2nd dose	
Seroconversion 2 µg				
Titer	**Day 15**	**Day 29**	**Day 36**	**Day 43**
≥ cut point	2 of 36 (6%)	8 of 36 (22%)	9 of 36 (25%)	15 of 34 (44%)
≥ median HCS	0 of 36 (0%)	0 of 36 (0%)	2 of 36 (6%)	5 of 34 (15%)
Seroconversion 4 µg				
Titer	**Day 15**	**Day 29**	**Day 36**	**Day 43**
≥ cut point	0 of 39 (0%)	3 of 38 (8%)	10 of 37 (27%)	25 of 35 (71%)
≥ median HCS	0 of 39 (0%)	0 of 38 (0%)	2 of 37 (5%)	14 of 35 (40%)
Seroconversion 6 µg				
Titer	**Day 15**	**Day 29**	**Day 36**	**Day 43**
≥ cut point	1 of 31 (3%)	1 of 19 (5%)	7 of 11 (64%)	na
≥ median HCS	0 of 31 (0%)	0 of 19 (0%)	1 of 11 (9%)	na
Seroconversion 8 µg				
Titer	**Day 15**	**Day 29**	**Day 36**	**Day 43**
≥ cut point	1 of 22 (5%)	0 of 12 (0%)	na	na
≥ median HCS	0 of 22 (0%)	0 of 12 (0%)	na	na

Box: 50% middle values with median
Bars: min to max
Cut point (=10): lowest reciprocal dilution
Values below cut point are shown as 0.5*cut point
Validated assay precision range: 10-538.2

Note: placebo subjects have been excluded from analysis
Data for 6 and 8 mcg is preliminary as only low numbers available at this time, but 6 mcg indicates encouraging VNT 1 week after 2nd dose

Virus Neutralizing Titers (VNT) Show Time Effect Even at the Lower Doses (2, 4 and 6 µg)

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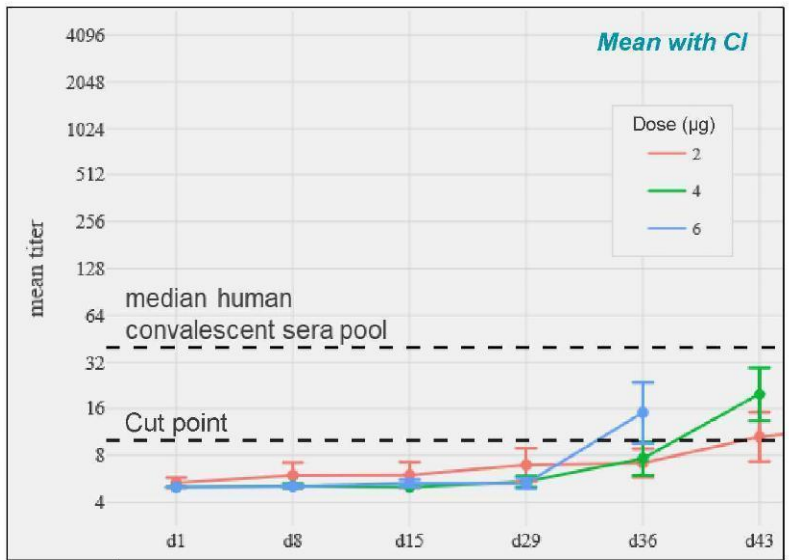
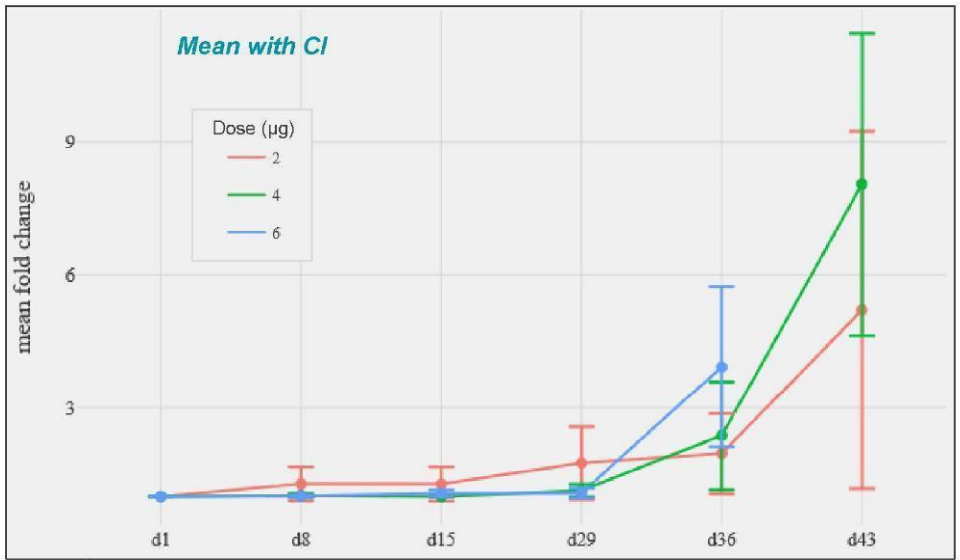
Preliminary Data

Available data set as of Aug 26th, 2020

Summarized µg groups of GMTs & fold changes to baseline



n	Day 1	Day 8	Day 15	Day 29	Day 36	Day 43
2 µg	39	38	36	36	36	34
4 µg	40	40	39	38	37	35
6 µg	36	33	31	19	11	na



n	Day 1	Day 8	Day 15	Day 29	Day 36	Day 43
2 µg	39	38	36	36	36	34
4 µg	40	40	39	38	37	35
6 µg	36	33	31	19	11	na

Note: placebo treated subjects have been excluded from analysis
Data for 8 mcg not presented as available sample size and time points (i.e. no post 2nd dose data) too early
Values below cut point are shown as = 0.5 cut point

8 µg data post 2nd dose available by mid September

4. Clinical Development Plan and Project Timelines

Clinical Development Plan (CDP) to be finalized after consultation with EMA

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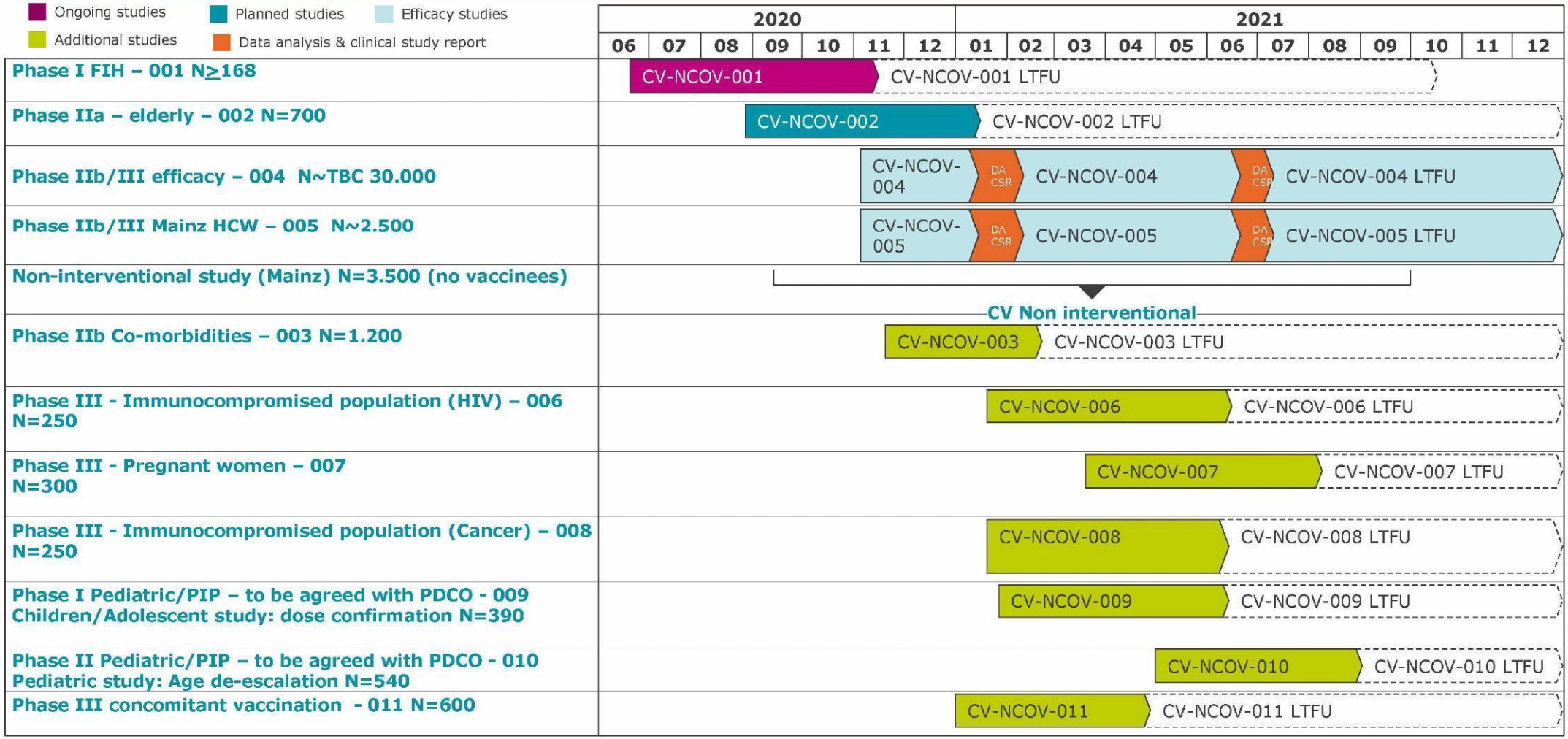

Abbreviations: CSR: Clinical study report; DA: Data analysis; FIH: First in human; FU: Follow-up; L2L: Lot to Lot LTFU: Long-term follow-up; PIP: Paediatric Investigational Plan; PDCO: Paediatric Committee; TBC: To be Confirmed

Dose-Confirmation Study (CV-NCOV-002) Including Older Adults to Commence

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- **Study:** Phase 2a dose-confirmation study including older adults >60 years of age.
  - Partially observer-blind, controlled, multicenter clinical
  - 18-60 YOA also included
  - Initial phase followed by expansion phase
- **Study goal:** To evaluate the safety, reactogenicity and immunogenicity of CVnCoV in [older] adults

Initial Phase

- **Participants will be enrolled sequentially at different dose levels [double dose 4µg, 6µg, 8µg]**
- Primary vaccination schedule D1, D29
- Half of the participants will receive a booster dose at M6
- "Double-dose" at D1 in one open-label group

Each dose level (in groups enrolling participants aged >60) will be initiated with Sentinel participants

Expansion Phase

- Two cohorts, 200 participants will receive vaccine, and 20 participants will receive control
- Cohort 1: 18-60 years of age: will be initiated once the selected dose has been determined for this age group
- Cohort 2: >60 years of age: will be initiated once the selected dose has been determined for this age group

Competent authorities & Ethics approval received, clinical sites initiated

CV-NCOV-002 Trial: Initial Phase Trial Groups

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Cohort	Age (years)	Group	Vaccination Schedule			Blinding
			Primary Doses		Booster Dose	
			Day 1	Day 29	Day 180	
CVnCoV 6 µg	18-60	Group 1 (n=90)	CVnCoV 6 µg	CVnCoV 6 µg	CVnCoV 6 µg (n=45)	Primary doses: Observer-blind Booster dose: Open-label
CVnCoV 6 µg	>60	Group 2 (n=60)	CVnCoV 6 µg	CVnCoV 6 µg	CVnCoV 6 µg (n=30)	Primary doses: Observer-blind Booster dose: Open-label
CVnCoV 8 µg	>60	Group 3 (n=60)	CVnCoV 8 µg	CVnCoV 8 µg	CVnCoV 8 µg (n=30)	Primary doses: Observer-blind Booster dose: Open-label
CVnCoV 8 µg (4 µg double dose)	>60	Group 4 (n=20)	Left deltoid area: CVnCoV 4 µg Right deltoid area: CVnCoV 4 µg	CVnCoV 4 µg	-	Open-label
Active control	18-60	Group 5 (n=9)	Hepatitis A vaccine	Hepatitis A vaccine	-	Observer-blind
	>60	Group 6 (n=12)	Pneumococcal vaccine	Pneumococcal vaccine	-	Observer-blind

CV-NCOV-002 Trial: Expansion Phase Trial Groups

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Cohort	Age (years)	Group	Vaccination Schedule			Blinding
			Primary Doses		Booster Dose	
			Day 1	Day 29	Day 180	
Expansion	18-60	n=200	CVnCoV dose level TBD	CVnCoV dose level TBD	-	Observer-blind
		n=20	Hepatitis A vaccine	Hepatitis A vaccine	-	
	>60	n=200	CVnCoV dose level TBD	CVnCoV dose level TBD	-	Observer-blind
		n=20	Pneumococcal vaccine	Pneumococcal vaccine	-	

CureVac will Seek EMA Conditional Approval followed by Full Registration

Conditional Approval

- Basis for conditional approval will be data from studies 001, 002, 004 (Phase 2b part) and 005
- CureVac will conduct rolling submission to support conditional approval
- Robust preclinical and CMC data package will be provided in the initial submission
- Clinical data from all ongoing studies will be submitted (to achieve conditional approval requirements pending EMA scientific advice)
- **Complete submission in 1Q 21**

Full Registration

- When sufficient clinical and manufacturing data are available, CureVac will seek full approval
- Full registration submission will be based on data from 001, 002, 004 (Phase 2b/3) and 005 studies
- Case driven efficacy
- Submission package will include additional safety data from 003 study and preliminary durability of response from 001 and 002 studies
- Post-approval commitments anticipated
- **Complete submission by end of 3Q 21**

EMA Scientific Advice has been requested and is anticipated by 10 September

Study CV-NCOV-004: Phase 2b/3 Efficacy Study

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Phase 2b

Objective:
Safety, Reactogenicity and Immunogenicity

Subjects:
≥18 years of age, N=4,000

Randomized 1:1

Groups

2 doses of CvnCoV
Administered 28 days apart (stratified by age group and country)

2 doses of Twinrix Control Vaccine*
Administered 28 days apart (stratified by age group and country)

Outcomes

- Safety: solicited local and systemic reactions, and unsolicited adverse events
- Immunogenicity: ELISA antibodies and virus neutralizing antibodies post-dose 1 and 2 (subset of subjects)
- COVID-19 case ascertainment for efficacy**
- Assessment of SARS-CoV-2 infection rates between groups

DSMB review of safety data from Phase 2b

Phase 3

Objective:
Efficacy and Safety

Subjects:
≥18 years of age, N≥26,000***

Randomized 1:1

Groups

2 doses of CvnCoV
Administered 28 days apart (stratified by age group and country)

2 doses of Twinrix Control Vaccine *
Administered 28 days apart (stratified by age group and country)

Outcomes

- Safety: collection of medically-attended adverse events, adverse events of special interest (AESIs), and serious adverse events (SAEs) through one year post-dose 2
- COVID-19 case ascertainment for efficacy**

***Sample size may be adjusted based on change in expected COVID-19 incidence rate and/or actual drop-out rate during the conduct of the study.

*Under discussion

**Cases of COVID-19 from Phase 2b and Phase 3 will be pooled for the primary analysis of efficacy.

Key Project Milestones in 2020

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#	Milestone	Planned Date
1	Start of study in older adults (study 002)	Early September
2	Final dose selection for phase 2b/3	Mid September
3	Hamster challenge incl. disease enhancement results	End Sept
4	Non-Human Primate challenge study results	Mid October
5	Safety and immuno data post second dose in 140 older adults	End October
6	Start of clinical efficacy study	Early November
7	Initial safety and immuno data in special populations	End December
8	Safety data in ~3,500 subjects post second dose and immuno in a subset	December/January

5. Manufacturing Footprint, Capacity Increase and Delivery Plan for EU APA

CureVac is Building a Fully-Integrated European Vaccine Manufacturing Network

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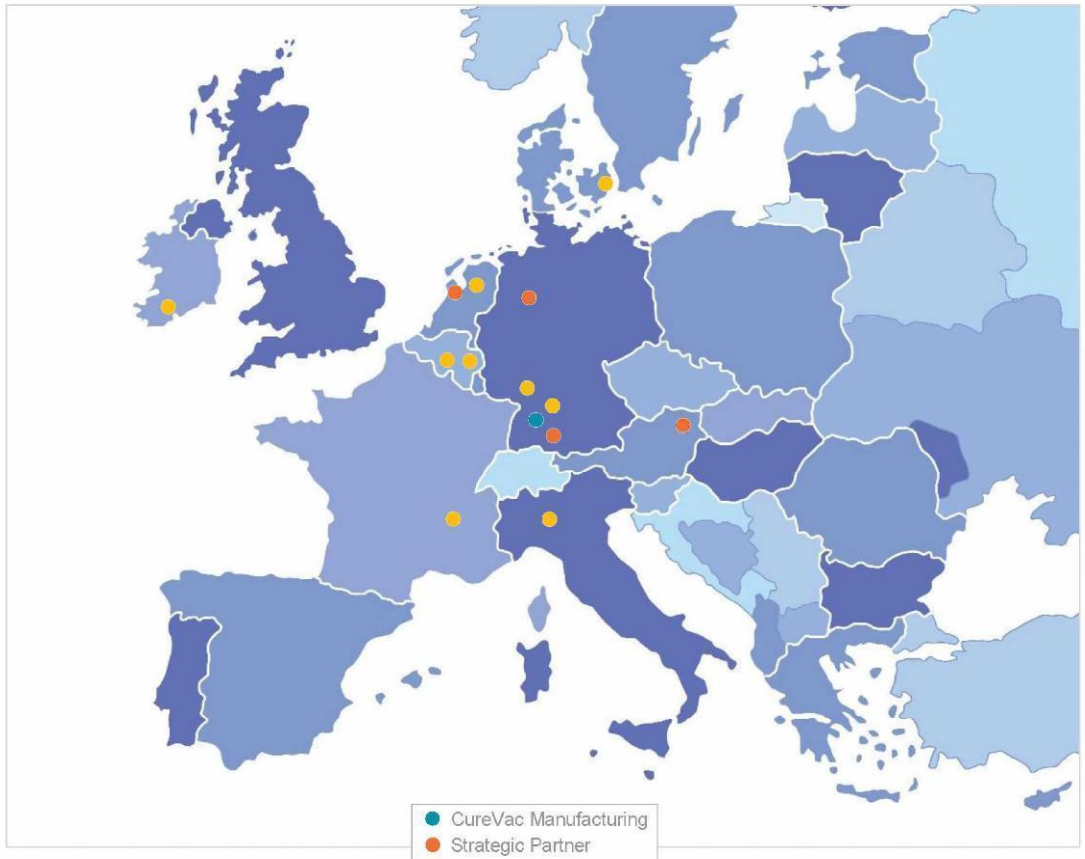
Strictly confidential – several partnerships in final negotiation stages



pDNA Production
- CureVac — Tübingen, DE
- PlasmidFactory — Bielefeld, DE

Drug Substance
- CureVac — Tübingen, DE
- WACKER — Amsterdam, NL
- Eurogentec — Liège, BE
- AGC Biologics — Søborg, DK
- CELONIC — Heidelberg, DE
- Rentschler Biopharma — Laupheim, DE

LNP Formulation
- CureVac — Tübingen, DE
- CELONIC — Heidelberg, DE
- POLYMUN SCIENTIFIC — Klosterneuburg, AT
- abbvie — Ireland

Fill & Finish
- ThermoFisher SCIENTIFIC — Monza, IT
- VETTER — Ravensburg, DE
- POLYMUN SCIENTIFIC — Klosterneuburg, AT
- abbvie — Ireland

Diluent
- ThermoFisher SCIENTIFIC — Monza, IT
- Catalent — Italy
- FAREVA — France
- BePharBel — Courcelles, BE

Process represents fully scaled production capability

CureVac is scaling-out its target manufacturing capacity from 1 to 8+ GMPIII lines with accelerated ramp up plans

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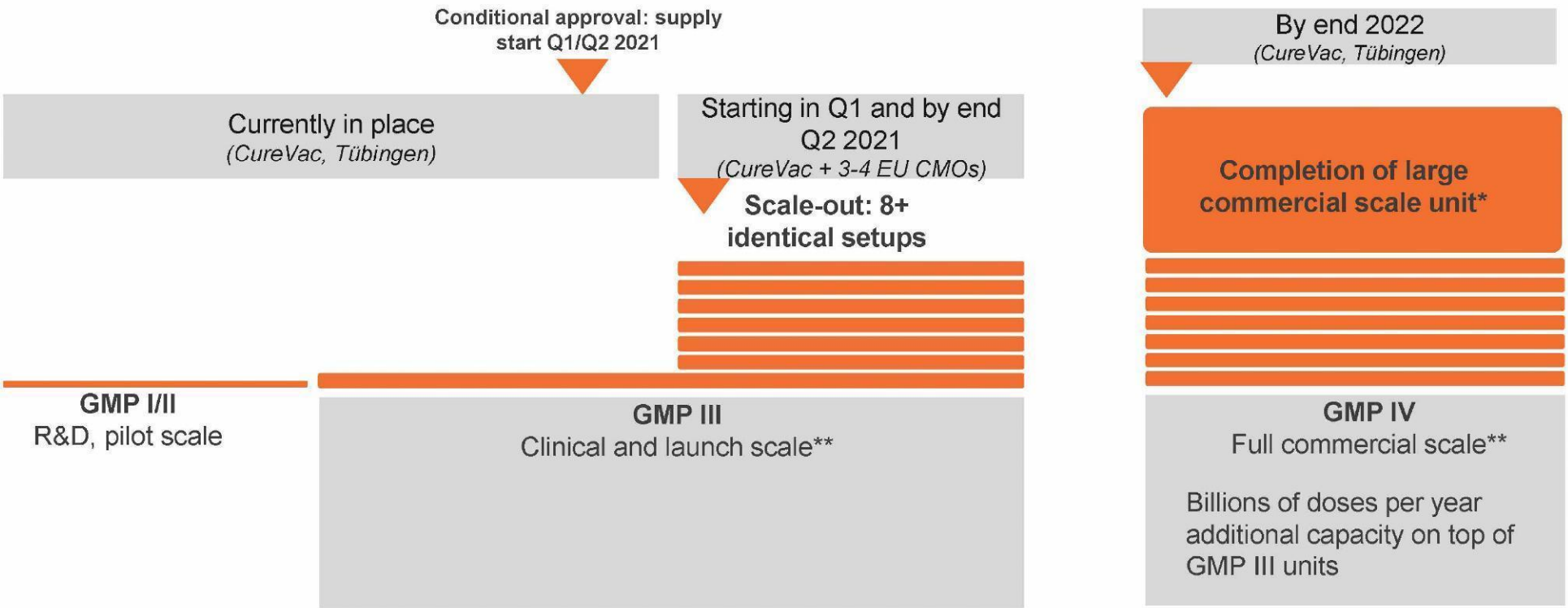

* Facilitated through a 75m€ EIB loan

** Capacity calculations based on a mid-range 4µg dose per injection

Phasing of Deliveries for EU APA: Majority of CureVac's Capacity Allocated to Europe

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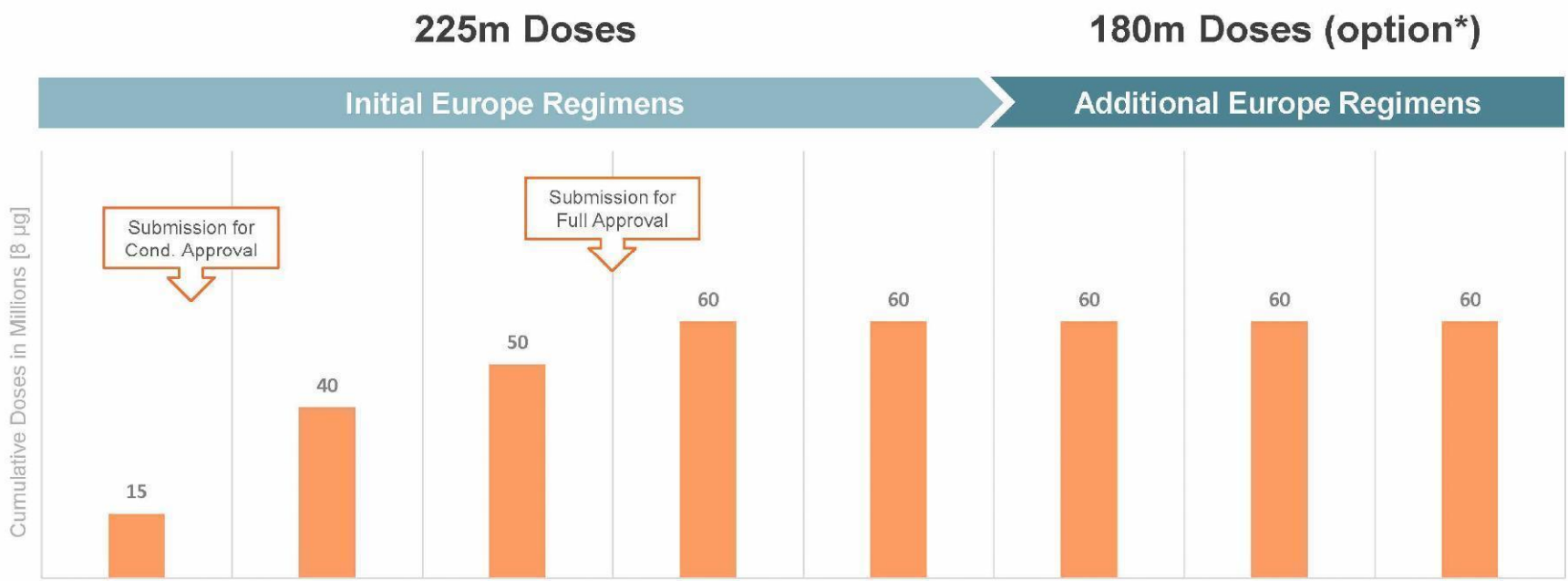

	1Q 21	2Q 21	3Q 21	4Q 21	1Q 22	2Q 22	3Q 22	4Q 22
Tendered Doses	15	40	50	60	60	60	60	60
% of Manf. Capacity	90%	75-85%	45-55%	40-50%	40-50%	40-50%	40-50%	40-50%

**Option to be confirmed by a firm order within 30 days after conditional marketing authorization by EMA (expected from end Q1 2021)*

6. Vaccine Presentation and Shelf-Life

CVnCoV Presentations Upon Approval

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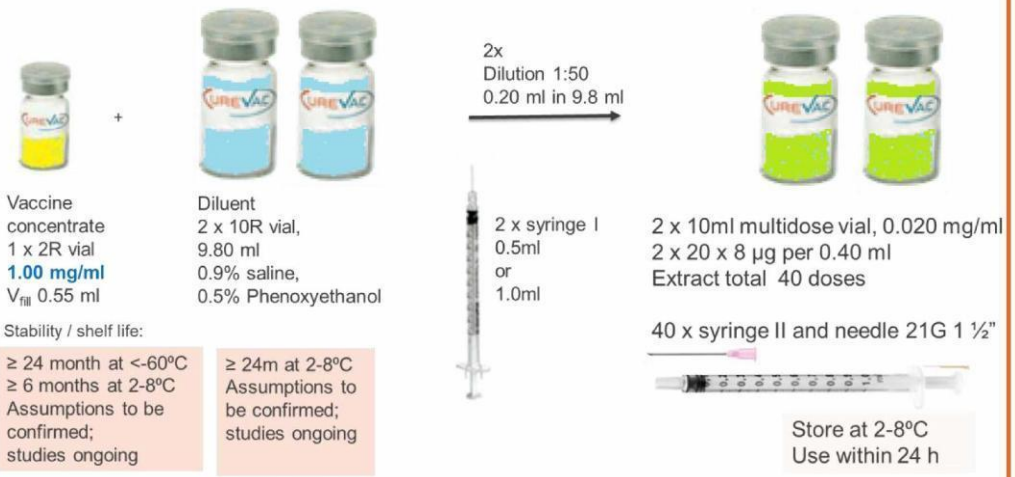
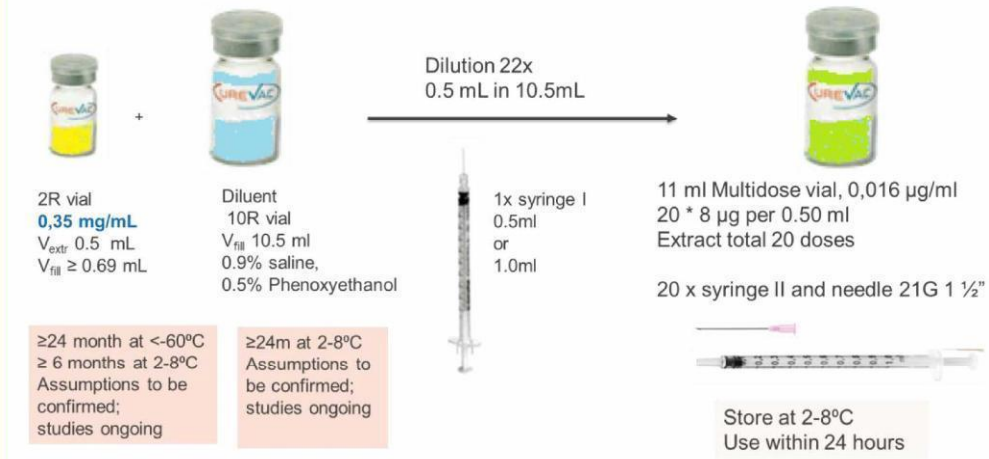
Presentation for conditional approval (Q1/Q2 2021)
Illustrating a 8µg dose



Launch presentation for full approval (Q4 2021)
Illustrating an 8µg dose



- The injected volume for one dose is expected to be 0.4 ml (conditional approval) and 0.5ml (full approval)
- Concentrated mRNA vials and diluent vials will be packed separately

Note: Current Phase 1 storage is at -80°C; stability studies for commercial product are ongoing to support shelf-life at 2-8°C.
1 month stability at 5°C available; 6 months available by November 2020

Target 2 to 8 °C Stability is a Distinctive Feature of CVnCoV

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	Formulation	Logistics	Fill & Finish	Packaging/ Labelling	Logistics	Storage	Distribution	Hospital	Patient
Current (Ph1)	RT	5°C	RT	RT	-80°C	-80°C	-80°C	-80°C	RT
Target	**RT**	**5°C**	**RT**	**RT**	**5°C**	**5°C**	**5°C**	**5°C**	**RT**

Target stability

- Storage: 5°C for the concentrated vaccine vial, and room temperature (25°C) for the diluent
- Shelf life: 6-12 months for the vaccines vial and 24 months for the diluent vial

Ongoing data collection to support target stability profile

- Ongoing ICH stability up to 12 months for 1mg/ml GMP material. So far, 1 month stability at 5°C is encouraging; 3 moth data by early-September and 6 months by mid-November 2020
- ICH stability on the target concentration to start in September, after clinical dose selection

Perspective on feasibility of achieving target profile

- Development experience with rabies vaccine: ICH stability data supports 6 months at 5°C for a 1mg/ml concentration, and indicative stability data of more diluted solutions show equivalent stability after 6 months
- A longer stability for CVnCoV is expected since integrity of current starting material is higher than rabies vaccine
- In general, LNP formulation itself is stable for up to 5 freeze thaw cycles

Stability Data for Diluted Vials Supports Target Profile of 22h+2h in Syringe at 5°C or 25°C

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In-use stability for GMP-Drug Product samples diluted 1:100 in 0.9% saline (without preservative – currently generating similar data with 0.5% phenoxyethanol, the recently selected preservative)

1.In use stability study at storage temperature 5°C

Storage temperature			5°C ± 3°C							
Analysis			Pull point							
Parameter	Analytical Method	Acceptance Criteria	0h	0h+2h RT	4h	4h+2hRT	12h	12h+2h	22h	22h+2h RT
Appearance	Visual inspection	White solution	Conform	conform	conform	conform	conform	conform	conform	conform
API Integrity HPLC	PA-003205 Bestimmung der RNA-Integrität mittels HPLC-UV	≥70%	82%	78%	80%	76%	78%	74%	75%	75%

2. In use stability study at storage temperature 25°C

Storage temperature			25°C ± 2°C, 60% RH ± 5%							
Analysis			Pull point							
Parameter	Analytical Method	Acceptance Criteria	0h	0h+2h RT	4h	4h+2hRT	12h	12h+2h	22h	22h+2h RT
Appearance	Visual inspection	White solution	conform	conform	conform	conform	conform	conform	conform	conform
API Integrity HPLC	PA-003205 Bestimmung der RNA-Integrität mittels HPLC-UV	≥70%	82%	78%	80%	76%	72%	71%	75%	72%

Process represents fully scaled production capability

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CUREVAC

the RNA people®

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