

COVID-19 Vaccine Development Update

July 9, 2020

Zydus has employed a multi pronged approach to combat the pandemic of Covid-19



Multi pronged approach to fight the pandemic of COVID-19



Diagnostic Products

- Launched Covid-KAVACH ELISA tests under the technology transfer from ICMR
- This test was found to have high sensitivity and specificity & also has the advantage of testing 90 samples together in a single run of 2.5 hours



Wellness Products

- We have preponed the launch of our sanitizer range under the Nycil brand which was originally planned for 2021
- We did this in a record time and it has provided a great impetus to overall Zydus Wellness portfolio



Prophylactic Vaccines

- Our DNA Vaccine ZyCoV-D has undergone extensive pre-clinical studies and found to be safe, well tolerated and immunogenic.
- Now, we plan to initiate the clinical trials for this DNA vaccine and fast track its registration



Therapeutic Products

- Contributed via vast supplies of HCQ and now Dexamethasone
- Biological approach via long acting PEG-Interferon α -2b in India & Mexico. USFDA IND planned in Aug' 20
- Aim to launch Remdesivir (via licensing from Gilead) & Favipiravir



NCEs

- Received approval from COFERIS, Mexico to study Desidustat in the management of COVID-19
- We will conduct a Phase 2b, for Desidustat in the Management of mild, moderate and severe COVID-19 patients



Leveraging our capabilities in vaccine development and manufacturing, we fast-tracked the development of ZyCoV-D vaccine program

20+ years

...of experience. started journey in 1998*

Growth Driver

...major growth driver for India geography*

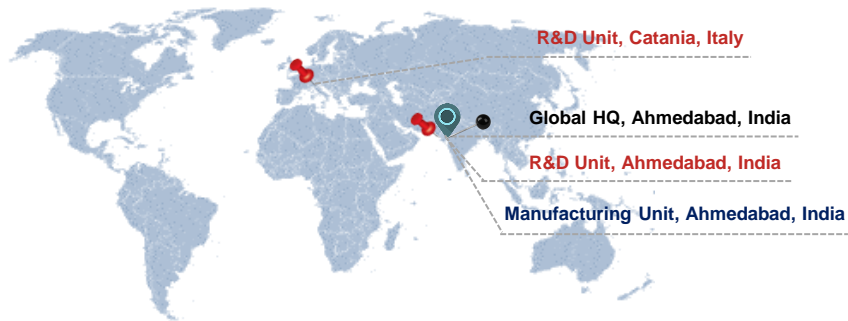
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Manufacturing (5) and R&D (2) Facilities*

300+

...dedicated scientists and Workforce*

Current Strengths & Capabilities



Vaccine Technology Centre (VTC)
Ahmedabad, Gujarat, India



Etna Biotech
Catania, Italy

Mfg. & Supply:

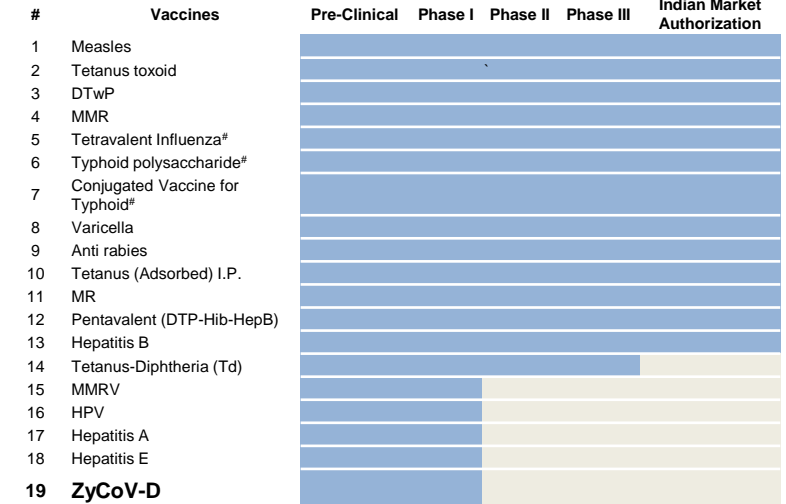
- Dedicated manufacturing capabilities catering to differentiated portfolio*
- Vaccine innovation comes from two R&D centers focused on developing newer vaccines*
- Capacity to produce several Millions of doses. Aiming to build lean and agile supply chain

Portfolio: Focus on innovative and differentiated vaccines catering to unmet needs

Portfolio



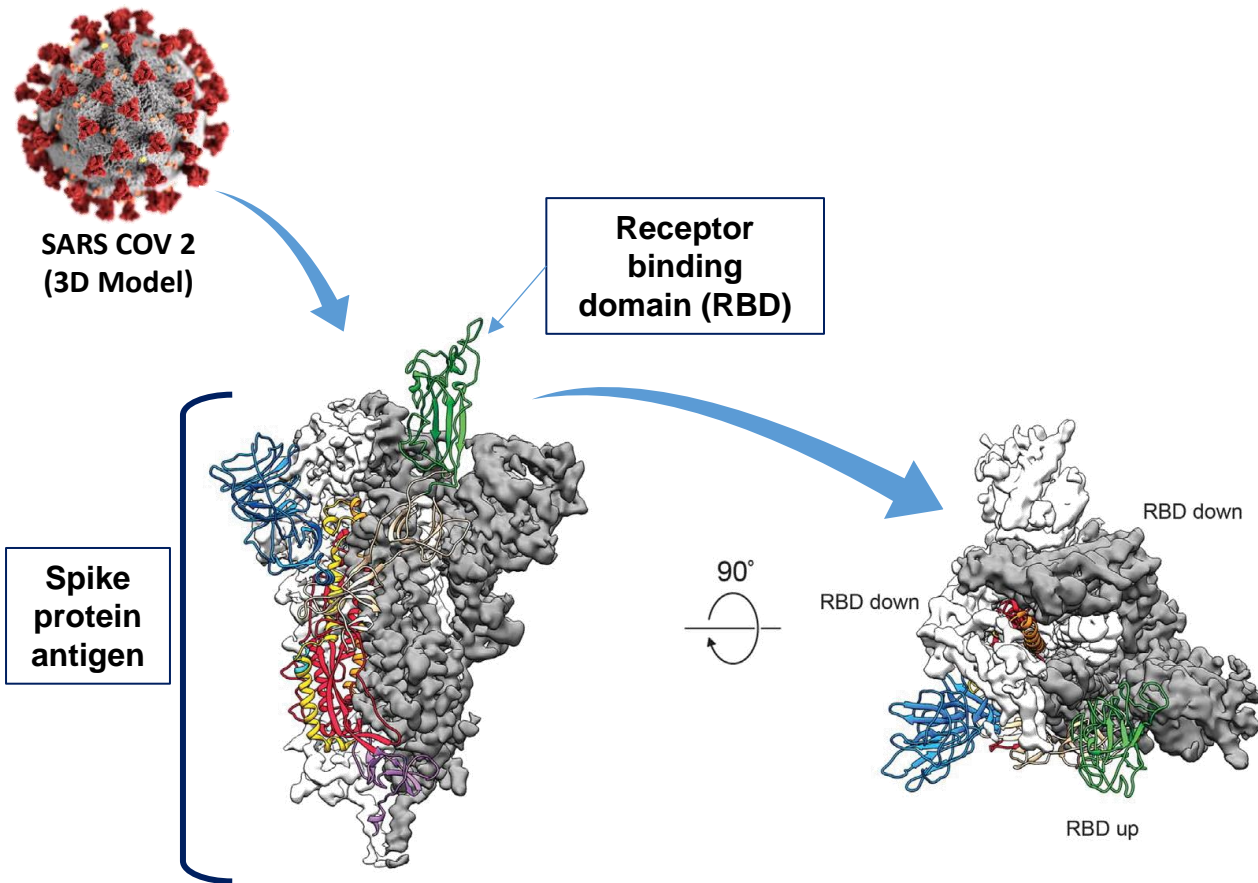
Zydus Vaccine Pipeline: Commercialized / Market Authorization Received*



- **R&D:** Robust Product Pipeline coming out of dedicated R&D facilities in India & Europe. 2nd company in the world to develop Typhoid conjugate vaccines*
- Capabilities to conduct research from “Concept to First-in-man trials” under one roof across vaccines types

- Live Attenuated
- Sub-unit
- DNA Vaccines
- Inactivated
- Inactivate Toxins

ZyCoV-D Vaccine : A Novel Approach for COVID-19 Vaccine Development with favourable vaccine characteristics



Benefits of DNA vaccine platform



Safety:

- DNA Vaccines are non-infectious
- Carries no potential toxicity from viral vectors
- Minimum to no risk of vaccine enhanced diseases



Efficacy and Boosting:

- Stimulate both the humoral and cellular arms of the adaptive immune system
- DNA Vaccines pose minimal risk of anti-vector immunity and are efficacious

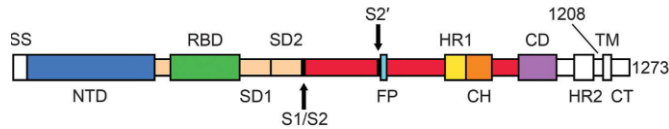


Rapid and Scalable Manufacturing:

- Ease of manufacturing related to minimal biosafety requirements (BSL-1)
- Rapid development from concept to human in 6 months
- Improved vaccine stability and lower cold chain requirements

Source: Daniel Wrapp et al. Science 2020;367:1260-1263

ZyCoV-D vaccine has successfully completed preclinical development and has received permission to initiate human clinical trials



DNA vaccine construct finalization



Preclinical evaluation in mice, rats, guinea pigs and rabbits



Strong cellular and antibody response with no safety and toxicity concerns

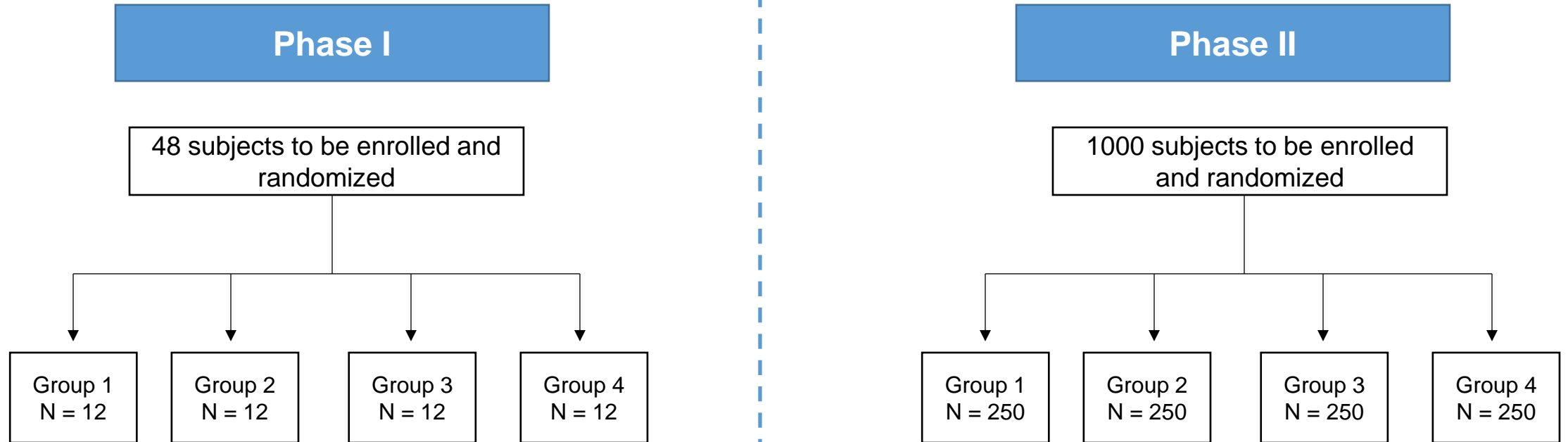


- ✓ GMP Batch manufacturing done
- ✓ Clinical trial permission received from DCGI

Strong preclinical evidence paving the path for human clinical trials

- In animal studies the vaccine was found to elicit a **strong immune response in multiple animal species like mice, rats, guinea pigs and rabbits.**
- The **antibodies** produced by the vaccine were able to **completely neutralize the wild type virus in virus neutralization assay** indicating the protective potential of the vaccine candidate.
- **No safety concerns** were observed for the vaccine candidate in **repeat dose toxicology studies** by both intramuscular and intradermal routes of administration.
- In rabbits, **up to three times the intended human dose was found to be safe**, well tolerated and immunogenic.
- Zydus has **already manufactured clinical GMP batches** of the vaccine candidate and plans to initiate the clinical trials in July 2020 across **multiple sites in India in over 1000 subjects.**

Phase I/II Study Design of ZyCoV-D



The Phase I/ II randomized, placebo-controlled, will evaluate the safety, tolerability, and immunogenicity of escalating dose levels of ZyCoV-D

Key takeaways and next steps for ZyCoV-D

- ✓ DNA based vaccine
- ✓ Safety and Immunogenicity established in animal models
- ✓ Fast-track clinical development program being executed
- ✓ Large scale manufacturing planned to deliver millions of doses in 2020-21
- ✓ To cater huge demand of vaccine for frontline healthcare workers as well as general population in India and globally, we shall utilize,
 - Our internal capacities and
 - Leverage external partnerships to expand manufacturing capacities

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