Zydus' vaccine for COVID-19 (ZyCoV-D) successfully completes preclinical development and receives permission to initiate human clinical trials

- *The vaccine is found to be immunogenic in multiple animal species.*
- *Antibodies produced in animal studies are able to completely neutralize the wild type virus*
- *Preclinical toxicity studies find the vaccine to be well tolerated, safe and immunogenic*
- *The Company plans to start the human clinical trials in July 2020.*

Ahmedabad, India, 03 July, 2020

Zydus an innovation-driven, global pharmaceutical company, announced that it's plasmid DNA vaccine candidate for COVID-19 (ZyCoV-D) developed indigenously at its Vaccine Technology Centre in Ahmedabad, India has successfully completed the preclinical phase and has now received permission from the Drug Controller General of India - Central Drugs Standard Control Organisation (CDSCO) to initiate Phase I/II human clinical trials in India.

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.

With ZyCoV-D, the Company has successfully established the DNA vaccine platform in the country using non-replicating and non-integrating plasmid carrying the gene of interest making it very safe. Further, no vector response and with absence of any infectious agent, the platform provides ease of manufacturing the vaccine with minimal biosafety requirements (BSL-1). The platform is also known to show much improved vaccine stability and lower cold chain requirements making it easy for transportation to remotest regions of the country. Furthermore, the platform can be rapidly used to modify the vaccine in couple of weeks in case the virus mutates to ensure that the vaccine still elicits protection.

Company intends to now rapidly ramp up the production capacities of ZyCoV-D at multiple sites and facilities to cater to Indian and global demand.

Zydus' Vaccine research programme

Vaccine Technology Centre of Zydus Cadila has wide range of capabilities in developing and manufacturing viral, toxoid, polysaccharide, conjugate and other subunit vaccines for unmet needs. In fact, Zydus was the first company in India to develop and indigenously manufacture the vaccine to combat Swine Flu during the pandemic in 2010. In past, it has also indigenously developed numerous vaccines successfully including tetravalent seasonal influenza vaccine (first company in India to indigenously develop and commercialize), Inactivated Rabies vaccine (WHO Prequalified), Varicella vaccine (first Indian company to indigenously develop and receive market authorization), Measles containing vaccines (MR, MMR, Measles), Typhoid conjugate vaccine, pentavalent vaccine (DPT-HepB-Hib) etc to name a few. The company also has a strong pipeline of vaccines like Measles-Mumps-

Rubella-Varicella (MMRV), Human papillomavirus vaccine, Hepatitis A, Hepatitis E vaccines which are at various stages of development.