

August 14, 2024

The Manager, Listing Department The National Stock Exchange of India Ltd. Exchange Plaza, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051

NSE Symbol: PANACEABIO

BSE Limited Corporate Relationship Department, Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001

BSE Scrip Code: 531349

Re.: Press Release - Initiation of Phase III Clinical Trial of DengiAll by ICMR and Panacea Biotec

Dear Sir/Madam,

As India celebrates the 78th Independence Day, Panacea Biotec and Indian Council of Medical Research are proud to share that with the approval of the Drugs Controller General of India (DCGI), we have started the Phase III clinical trial of our tetravalent dengue candidate vaccine, DengiALL in India. The clinical trial will be conducted at 19 sites with 10,335 participants across India.

The development of DengiALL was initiated at Panacea Biotec in 2006 with the licensing and transfer of novel attenuated tetravalent strains of dengue virus between Panacea Biotec and National Institutes of Health, USA. Panacea Biotec has undertaken Phase I/II clinical trials in the Indian population with 3 years of safety follow-up completed in 2020. Subsequently, Panacea Biotec and ICMR entered into an MOU in March 2022 for Phase III clinical trials in India.

A copy of the Press Release titled "Initiation of Phase III Clinical Trial of DengiAll by ICMR and Panacea Biotec" being issued to the media, etc. in this regard is enclosed for your kind reference and record please.

Kindly acknowledge the receipt.

Thanking you,

Sincerely yours,

for Panacea Biotec Ltd.

Vinod Goel Group CFO and Head Legal & Company Secretary

Encl. As Above.





Press Release

Initiation of Phase III Clinical Trial of DengiAll by ICMR and Panacea Biotec

August 14, 2024, New Delhi: As India celebrates the 78th Independence Day, Panacea Biotec Limited and Indian Council of Medical Research are proud to share that with the approval of the Drugs Controller General of India (DCGI), we have started the Phase III clinical trial of our tetravalent dengue candidate vaccine, DengiALL in India. The clinical trial will be conducted at 19 sites with 10,335 participants across India.

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On the occasion, **Dr. Rajesh Jain, Chairman and Managing Director**, at Panacea Biotec, said "DengiALL vaccine development has a long way since it was initiated in 2006 in collaboration with the National Institute of Health USA. We are excited to announce that our dengue vaccine candidate has successfully entered the penultimate Phase 3 clinical trials in India in collaboration with the Indian Council of Medical Research. This milestone brings us one step closer to providing a safe and effective solution for preventing dengue fever, a disease that poses a significant public health challenge. We are committed to ensuring that this vaccine meets the highest standards of safety and efficacy, and we are optimistic about its potential to make a meaningful impact on the lives of millions."

About DengiALL®

DengiALL® is a tetravalent recombinant live attenuated tetravalent candidate vaccine that targets all the 4 serotypes of Dengue that are prevalent across the world.

Attenuated strains are designed to mimic natural infection closely to stimulate the immune system to recognize and fight the virus if the person is later exposed to wild-type dengue strains. The challenge with dengue is that there are four distinct serotypes (DEN-1, DEN-2, DEN-3, and DEN-4), and infection with one serotype can sometimes exacerbate the severity of subsequent infections with another serotype. Therefore, the attenuated strains are carefully engineered to balance safety with the ability to induce robust and protective immunity across all four serotypes.

One of the key concerns in dengue vaccine development is the phenomenon of antibody-dependent enhancement (ADE), where antibodies from a previous dengue

infection or vaccination can enhance the severity of a subsequent infection. By attenuating the virus carefully, NIH's approach aims to minimize the risk of ADE while still providing effective immunity against all four dengue serotypes.

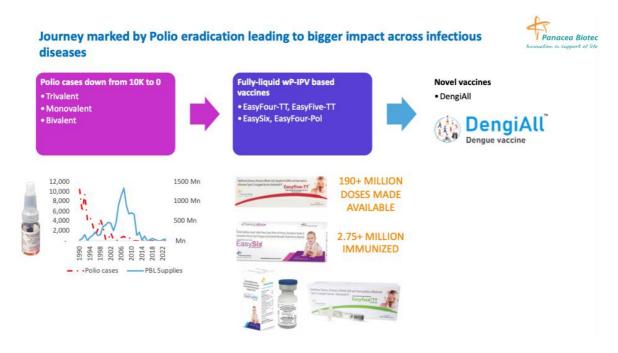
About Panacea Biotec

Panacea Biotec Limited is a leading pharmaceutical and biotechnology company with established research, manufacturing and marketing capabilities.

Panacea Biotec has played a vital role in Polio eradication in India by delivering over 10 billion doses of oral polio vaccines. Anticipating stagnancy in Polio cases in early 2000's, Panacea Biotec developed and launched the world's first monovalent and bivalent oral polio vaccines that finally helped India to reach 0 cases in 2011. Our journey has been marked by Polio eradication leading to bigger impact across infectious diseases.

Panacea Biotec has pioneered in the development of innovative fully liquid combination vaccines that can be stored at 2-8 degree Celsius temperature. We have also launched world's first fully liquid wP-IPV based hexavalent vaccine EasySix™ (DTwP-HepB-Hib-IPV) in India in March 2017. We have also made available over 200 million doses of fully liquid combination vaccines across the world.

The other key vaccines in portfolio are Easyfive -TT (DTwP-HepB-Hib), EasyFour -TT (DTwP-Hib), IPV based tetravalent vaccine - EasyFour -Pol (DTwP-IPV) and Bivalent oral polio vaccine (type-1 and type-3). Panacea Biotec's new vaccines in pipeline are Pneumococcal Conjugate Vaccine - NucoVac-11 and Recombinant Tetravalent Dengue Candidate Vaccine - DengiALL and Td (tetanus and diphtheria – reduced).



Panacea Biotec remains focused on merging cutting-edge science and technology with an unwavering commitment towards unmet medical needs while ensuring

affordability. It has research collaborations with leading national and international research organizations and corporations. Panacea Biotec group has around 2,000 employees.

For more information, visit: www.panaceabiotec.com Follow our news page for the latest updates. Follow us via @PanaceaBiotec and LinkedIn.

For more information:

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