

Media Release

CPL Biologicals launches Cadiflu-S, World's first virus like particle (VLP) vaccine for seasonal influenza

Highlights

- *Cadiflu-S is India's first indigenously developed vaccine for seasonal influenza*
- *First Virus Free seasonal influenza vaccine in India: a major breakthrough*
- *Vaccine with least chances of allergies since the vaccine does not contain egg proteins, antibiotics or preservatives*

Ahmedabad, Nov 17, 2016: CPL Biologicals Pvt. Ltd, a joint-venture biotechnology company of Cadila Pharmaceuticals Ltd, India and Novavax Inc., USA, has become the first company in India to indigenously develop 'Cadiflu-S', a vaccine for Seasonal Influenza. Responding to the Government of India's initiative of 'Make in India' campaign, the Ahmedabad based company launched 'Cadiflu-S', which is also the first Virus Like Particles (VLP) technology based Influenza vaccine in the world.

The company has set up the vaccine facility at Dholka near Ahmedabad in Gujarat, India, with an initial investment of Rs. 100 crore. The plant has the capability of producing up to 25 million doses of vaccine every year.

'Cadiflu-S' does not contain any viruses, and is a major technological breakthrough since it completely eliminates the possibility of any infection to the vaccinated person from the vaccine. The viruses present in other available vaccines can, at times, replicate in human body thereby causing disease by the vaccine itself. Moreover, the VLP based vaccine does not contain any egg proteins, antibiotics or preservatives, and thus provides huge relief to people who are prone to allergies.

The indigenous production of 'Cadiflu-S' for seasonal influenza will provide a major boost to the government's initiative of preventing any probability of pandemic flu-like situation. The seasonal vaccine which is supposed to be administered every year due to changing strains of the virus, protects even healthy individuals, both children and adults, from the influenza which at times could lead to other highly infectious and chronic illnesses. The seasonal influenza virus

affects the lungs and other areas of the respiratory tract. People with chronic conditions of Cardiac Ailments, Diabetes Mellitus, Metabolic Diseases, Renal Failure and Asthma run a high risk of developing complications.

‘Cadiflu-S’ is developed by incorporating the gene sequences of multiple immunogenic proteins (HA, NA and M1 antigens) of Influenza virus to produce a complex envelope Virus Like Particle vaccine. Each dose of the recombinant baculovirus-based vaccine, Cadiflu-S (0.5 ml) contains three strains of flu viruses namely, A/California/7/2009 (H1N1)-like virus, A/HongKong/4801/2014 (H3N2)-like virus, B/Brisbane/60/2008-like virus. World Health Organisation (WHO) in Feb 2016 recommended composition of influenza virus vaccines for use in the 2016-2017 northern hemisphere influenza season. The current market for Seasonal Influenza vaccine in India is estimated at 2 – 2.5 million dosages per year and is rapidly growing.

Commenting on the launch, **Dr. Rajiv Modi**, *Chairman and Managing Director*, Cadila Pharmaceuticals Ltd. said, “Building on the success of ‘Cadiflu-S’, we will be launching a series of vaccines, including many first-of-its kind in the world, using Novel technology platforms like VLPs and Nanoparticles. The VLP technology provides us a huge edge as it takes only 12-14 weeks to develop the new strain specific vaccine, as against 24 to 32 weeks for the development of a conventional vaccine. If there is a necessity tomorrow, we can launch other types of pandemic flu vaccines, like H7N9 vaccines at a much faster pace compared to conventional vaccines.”

Dr. James F. Young, *Chairman*, Novavax Inc, said, “We have successfully completed Phase III trials at 10 centers across India to evaluate the Immunogenicity and Safety of this Seasonal Influenza Virus-Like Particle (VLP) Vaccine. ‘Cadiflu-S’ has received Drugs Controller General of India’s (DCGI) approval for launching the vaccine in India. We have also developed a strong pipeline that include Rabies 3 dose vaccine, Pancreatic Cancer vaccine, Rabies single dose vaccine, Hepatitis E vaccine, Varicella zoster virus vaccine and Human Papilloma vaccine.”

CPL Biologicals has obtained all the necessary approvals from the concerned regulatory authorities for commercialisation of ‘Cadiflu-S’ vaccine. Apart from the Indian markets, the company will also be looking to cater to the Middle East and South East Asian markets in coming years.

About CPL Biologicals Pvt. Ltd - www.cplbio.com

Based in Ahmedabad, India, CPL Biologicals Pvt. Ltd. is an independent joint-venture biotechnology company established in 2009 by Novavax Inc., USA and Cadila Pharmaceuticals Limited, one of India's largest privately held pharmaceutical companies. The company develops prophylactic vaccines based on Novavax Inc's Virus Like Particles (VLPs), recombinant nanoparticles and adjuvant technologies, which are groundbreaking innovations that improve global health through safe and effective vaccines. CPL Biologicals conducts end-to-end research, development and manufacturing based on these technologies in India.

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