

Sun Pharma, ICGEB to develop novel dengue vaccine

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International Centre for Genetic Engineering and Biotechnology (ICGEB) and Sun Pharma has announced their new collaboration for development of a dengue vaccine, targeted against all the four serotypes of Dengue virus that cause disease in humans.

ICGEB has developed a tailored recombinant virus-like-particle (VLP) based tetravalent dengue vaccine, containing host-receptor binding domain of envelope protein of all the four DENV serotypes. ICGEB has conducted pre-clinical studies over the past seven years and developed the existing Know-How and Patents for this dengue vaccine candidate.

This is the second collaboration between Sun Pharma and ICGEB focusing on dengue. The first one announced in May 2016 was related to the development of a botanical drug for treatment of Dengue. The current collaboration is focussed on developing a novel, safe & effective vaccine for the prevention of dengue.

Initial findings of ICGEB's Dengue vaccine indicate that the candidate induces serotypespecific non-cross-reactive and strongly neutralizing antibodies without disease enhancing concerns.

These features of the candidate vaccine differentiate this vaccine development programme from other vaccine programs that are developed or in development globally. This vaccine development will focus on suitability for all target population whether previously affected or non-affected, including paediatric and adults and traveller population.

Commenting on the new collaboration signed with ICGEB, Mr Kirti Ganorkar, Executive VP & Head, Global Business Development, Sun Pharma, said, "Our new collaboration with ICGEB for developing an affordable dengue vaccine is part of our broader commitment for developing new and improved vaccines and drugs against flaviviruses that are of significant

health importance to India and rest of the world. Our decision to partner with ICGEB on dengue vaccine program followed extensive due diligence and expert consultations on existing dengue vaccine programs globally."

According to Dr Salunke, Director - International Centre for Genetic Engineering and Biotechnology (ICGEB), "Despite recent approval of a dengue vaccine and several candidates being at advance stage of clinical trials, the development of a safe, affordable and efficacious dengue vaccine still faces major challenges. I am pleased that the Dengue Vaccine Development program led by Dr. Navin Khanna at ICGEB is now proceeding to clinical development phase with Sun Pharma. The initial support from DBT and subsequent funding from Wellcome Trust has enabled ICGEB to bring this vaccine candidate at the stage it is today. We acknowledge the continued support of DBT and Wellcome Trust for these efforts at ICGEB. Our pre-clinical data is very encouraging and this could be an ideal dengue vaccine candidate for all target populations."

According to the agreement signed today, Sun Pharma will fund & support further development of the vaccine candidate and existing ICGEB Know-How and Patents. ICGEB will grant Sun Pharma exclusive rights and licenses for development and commercialisation of this vaccine globally.

ICGEB will receive pre-defined royalty & milestone payments. A joint development committee, comprising members of both the organisations, will be established to provide oversight to the dengue vaccine development program. According to the agreement signed, ICGEB shall disclose and make available to Sun Pharma all such existing ICGEB Know-How as well as effective completion of technology transfer by ICGEB to Sun Pharma within stipulated timeframe. Since, ICGEB is not related to promoter/promoter group/ group companies of Sun Pharma, this transaction does not fall under related party transaction.

Sun Pharma will set-up a Dengue Vaccine Advisory group to provide technical and regulatory support to the vaccine development programme. It will also be exclusively responsible for all Regulatory filings for the product globally including, without limitation, CDSCO-India, WHO, USFDA, EMA, MHRA etc. The company will explore commercialisation opportunities to provide this vaccine to patients across India, Emerging Markets, Western Europe, Japan and USA at affordable costs post Regulatory approvals in these markets. The immediate priority of this partnership is to complete the Toxicology studies for further development of the program.

Sun Pharma invests over \$300 million annually on research and development in pharmaceuticals and biologics. The Company will use its in-house expertise as well as expertise of its Associate company, ARTES Biotechnology GmbH, in development of dengue vaccine. ARTES will add their experience and proprietary know-how in production of VLP based vaccines from yeast production cell lines. Hep-B and HPV vaccines developed by ARTES are licensed to several companies worldwide and a Malaria vaccine program is sponsored by PATH (Malaria Vaccine Initiative).