



FOR IMMEDIATE RELEASE

Sun Pharma & ICGEB announce new exclusive collaboration to develop novel dengue vaccine for India & Global markets

- *Novel Dengue Vaccine development to focus on its suitability for all population including affected and non-affected paediatric, adults and travellers*
- *Partnership follows extensive & expert due-diligence of global dengue vaccine programs*
- *Sun Pharma to explore global commercialisation opportunities for the vaccine across India, Emerging Markets, Western Europe, Japan and USA*

NEW DELHI, OCTOBER 19, 2016: International Centre for Genetic Engineering and Biotechnology (ICGEB) and Sun Pharma (*Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies*) today 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 serotype-specific 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.

COMPETITIVE EDGE OF SUN PHARMA – ICGEB’S NOVEL DENGUE VACCINE

The novel dengue vaccine being developed through this partnership is expected to provide a competitive edge in three critical parameters:

1. **SAFETY:** The vaccine is made in yeast, a GRAS (generally regarded as safe) organism and it is non-replicating. It also circumvents interference and associated safety concerns of live attenuated virus. Thus, it lowers the risk of adverse effects of disease enhancement.
2. **EFFICACY:** The vaccine predominantly induces serotype-specific virus neutralizing antibodies. Thus, has low or no pathogenic potential.
3. **AFFORDABILITY:** The unique ‘four-in-one’ vaccine design obviates the need for developing four monovalent vaccines; a single vaccine needs to be produced; uses the high expression potential of the yeast expression system; may have shorter immunization schedule.

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 US\$ 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). Taken together, the Company has past experience in development of Hep-B and Typhoid vaccines, as well as complex vaccines, such as HPV and Malaria.

DENGUE DISEASE OVERVIEW

Dengue is a neglected mosquito-borne viral disease that is rapidly spreading globally. Dengue incidence has increased by more than 30-fold in the past 50 years. Currently, half of the global population lives under dengue threat; and an estimated 390 million infections occur worldwide every year with approx. 100 million cases of clinical disease and over 25,000 deaths. All four dengue virus serotypes are now endemic in India. Dengue infections result in massive economic losses, strained health services, morbidity and mortality, especially among children. Mosquito control efforts have been unsuccessful in reducing viral transmission.

Currently, there are no available antivirals, which presents a public health challenge in India and other parts of the world, including developed nations. There is no specific treatment other than supportive clinical care, which is extremely difficult in developing countries with poor resources. The development of vaccine against dengue poses challenge because immune responses to the four dengue virus serotypes cross react and instead of cross-protection, enhance the disease. The Sun Pharma - ICGEB dengue vaccine candidate is expected to provide a competitive edge over others in all three critical parameters of Safety, Efficacy & Affordability that define an ideal dengue vaccine.

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About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 47 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes



US\$ 2.1 billion. In India, the company enjoys leadership across 12 different classes of doctors with 32 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 8% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live

About International Centre for Genetic Engineering and Biotechnology

The ICGEB is an international, non-profit research organization. Established as a special project of UNIDO, it became fully autonomous in 1994 and now counts over 60 Member States. The International Centre for Genetic Engineering and Biotechnology provides a scientific and educational environment of the highest standard and conducts innovative research in life sciences for the benefit of developing countries. It strengthens the research capability of its Members through training and funding programmes and advisory services and represents a comprehensive approach to promoting biotechnology internationally. The Centre is dedicated to advanced research and training in molecular biology and biotechnology and holds out the prospect of advancing knowledge and applying the latest techniques in the fields of biomedicine, crop improvement, environmental protection/remediation, biopharmaceuticals and biopesticide production. With Components in Trieste, Italy, New Delhi, India and Cape Town, South Africa, the Centre forms an interactive network with Affiliated Centres in ICGEB Member States. ICGEB is part of the United Nations System. For further information please visit www.icgeb.org

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