



MEDIA RELEASE

## Telangana Chief Minister lays foundation for Shantha Biotechnics's 460 crore insulin manufacturing facility in Hyderabad

*- A world-class state-of-the-art facility will be built at Muppireddipalli to manufacture Sanofi's Insuman<sup>®</sup>, a human insulin for diabetes patients*

**Hyderabad, India – January 29<sup>th</sup>, 2015** – Shantha, a Sanofi Company, announced today the laying of the foundation stone in Hyderabad, by Telangana's Honourable Chief Minister, K. Chandrasekhar Rao, for a new production facility to manufacture Insuman<sup>®</sup> a leading Human Insulin product from Sanofi's range of diabetes treatments. Sanofi will make an investment of INR 460 crores in this insulin facility. Located in Muppireddipalli (Telangana), the facility will be equipped with the latest technology to produce Insuman<sup>®</sup>. This will be Sanofi's second plant aside from the Company's existing Insuman<sup>®</sup> manufacturing plant in Frankfurt. The construction of the 13,400 square-meter building will begin immediately, with the site fully operational by 2019.

The **Honourable Chief Minister, Shri K Chandrasekhar Rao** welcomed the commitment towards health, technology transfer and job creation by Shantha in Telangana State. Also, present on this special occasion, was Dr. Varaprasad Reddy, the founder and Chairman of Shantha Biotechnics.

Speaking on the occasion, **Honourable Chief Minister, Shri K Chandrasekhar Rao** said, "I am delighted that Sanofi has decided to manufacture Insuman<sup>®</sup> insulin in Telangana state, so that it helps the 65 million diabetics in India have better access to affordable insulin. We are shortly going to launch a new Industrial policy that will fast track projects and make Telangana one of the most favoured destinations, for investments, in the world."

Describing the significance of this project, **Dr. Harish Iyer, CEO, Shantha Biotechnics** said, "Laying the foundation stone for the Insuman<sup>®</sup> insulin manufacturing site is an important milestone in our journey, at Shantha, to improve public health in India. For the first time, we will be able to manufacture insulin – in cartridges here. The new high technology facility will benefit from our existing biotechnology production expertise. This state-of-the-art facility will have the capability to ramp up manufacturing volumes to 60 million Insuman<sup>®</sup> cartridges per year, within two to three years of commercial manufacturing."

While Sanofi's Frankfurt facility will continue to manufacture the human insulin, Insuman<sup>®</sup>, Shantha Biotechnics' INR 460 crore facility will contribute towards addressing the local demand for Insuman<sup>®</sup>.

**Dr. Shailesh Ayyangar, Managing Director - India and Vice President - South Asia, Sanofi** said "By setting up a manufacturing site at Shantha Biotechnics for our diabetes product - Insuman<sup>®</sup>, Sanofi is a front runner in its endeavor of addressing the growing epidemic of diabetes in India. Furthermore, the technology transfer and a successful collaborative effort within the Sanofi Group, underline our commitment to investing and 'making in India'. We look forward to the successful

completion of the Insuman<sup>®</sup> site construction, so that many more diabetic patients in India can have easier access to better disease management and quality of life.”

Type 2 Diabetes is a prominent Non Communicable Disease (NCD). Globally, diabetes afflicts close to 382 million people with India alone accounting for over 65 million cases\*. The number of people with diabetes in India is expected to rise to 109 million by 2035\*. Out of the estimated 42 million patients on insulin in India, ~ 3.3 million patients are prescribed Regular Human Insulin (RHI) for diabetes management and control\*. The local production of Insuman<sup>®</sup> will thus enable patients in India get access to the best available therapeutic options in diabetes.

Post completion, the facility will operate with High Performance Work Systems, which drive production efficiencies and save energy. The facility is expected to meet local and international demand.

### **About Insuman<sup>®</sup>**

Insuman<sup>®</sup> (human insulin) is used in people with diabetes (type 1 and type 2) who need treatment with insulin. It is produced from rDNA technology in Sanofi laboratories ensuring quality and purity. Insuman<sup>®</sup> is licensed in 90 countries for use. Since its first introduction 17 years ago, more than 5 million patient-years with Insuman<sup>®</sup> have been accumulated. In clinical studies with Insuman<sup>®</sup>, more than 1,500 patients have been included.

Sanofi India launched Insuman<sup>®</sup> cartridges in 2011, with an innovation of 3 metallic bullets in cartridges – this is unique to only Insuman<sup>®</sup> cartridges. With the 3 metallic bullets, patient has to tap or roll only three times (versus ~15-20 times) so that they can have a proper mixing and homogenous suspension which will help them to achieve a predictable response and glycemic control.

### **About Shantha**

Shantha, which was acquired by Sanofi Pasteur Holding in 2009, is a biotechnology pioneer from the emerging countries, founded by Dr. K I Varaprasad Reddy in 1993 in Hyderabad, India. Shantha is a fully integrated biotechnology company involved in R&D, manufacturing and marketing.

Shantha's mission is to develop, produce and market human healthcare products that are affordable and meet the highest International standards. Shantha's products complement Sanofi Pasteur's portfolio. Four of its licensed vaccines are WHO-prequalified: Shan5<sup>™</sup> pediatric vaccine, Shanchol<sup>™</sup> cholera vaccine, Shanvac-B<sup>®</sup> hepatitis B vaccine, and ShanTT<sup>™</sup> tetanus vaccine. Sanofi Pasteur and Shantha are also developing a new pediatric combination vaccine based on Shan5 that will incorporate Sanofi Pasteur's Inactivated Polio Vaccine (IPV) in order to secure polio eradication.

### **About Sanofi**

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

In India, Sanofi is present since 1956.

### **Forward Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2013. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.*

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\*International Diabetes Federation. IDF Diabetes Atlas, 6th edn. Brussels, Belgium: International Diabetes Federation, 2013. <http://www.idf.org/diabetesatlas>

# Prevalence, diagnosis, treatment rate from IDF Atlas and translating to insulin patients’ data from IMS sales

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