Panacea Biotec

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WHO Pre-Qualification (PQ) of Pentavalent Vaccine Easyfive-TT (DTwP-HepB-Hib) of Panacea Biotec

New Delhi, 19th September 2013: Panacea Biotec, one of the leading research based Health Management companies of India, today informed that **World Health Organization (WHO) has completed the evaluation process of pre-qualification (PQ) of its Pentavalent vaccine EasyfiveTT (DTP-HepB-Hib) and WHO has, vide its communication dated 17th September 2013, informed that they are initiating the arrangements for PQ. WHO has also informed the UNICEF (the procurement agency for Global markets) of the positive outcome of the evaluation process and will be issuing the letter to UNICEF informing the PQ of EasyfiveTT mono (1 dose) and multi-dose (10 dose) presentations and the details of PQ will be published on WHO webpage soon.** The Company has successfully completed the audit of its Lalru and Baddi facilities, conducted by WHO team from 28th Feb till 1st March, 2013.

The Company is now preparing itself to supply EasyfiveTT vaccine (pentavalent vaccine that protects against five diseases – Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus influenzae type b (Hib) of early childhood) to UNICEF and other international agencies involved in procurement of vaccines at Global as well as National levels in various countries.

Considering the above facts, Dr. Rajesh Jain, Joint Managing Director said, "It was a great experience to have worked with every individual involved in Vaccines operations at both Lalru and Baddi sites in re-building our new Quality Management System (QMS). The whole effort was focused right from getting the organisation ready for change to designing systems to prevent problems. Paying attention to even small issues like house-keeping rules, meeting discipline were as important as re-designing every single

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work flow design. We had focused on getting our thinking process right and move from paper quality to robust QA system ensuring patient safety as our key goal. Today, the Company internally has subject matter experts and the champions on every aspect of Quality Management System. The new QMS brought in sufficient attention to science and decision making process while taking quality decisions keeping patient safety in mind. In the end it was a collective and collaborative effort for change and has to continue with even greater enthusiasm to the next level in the coming years. I would like to take this opportunity to thank all our Customers, Partners, Suppliers, Bankers, Investors and Employees for their faith and continued support during this challenging period."

Panacea Biotec developed and introduced the world's first fully liquid pentavalent vaccine in the year 2005 and achieved WHO pre-qualification in July 2008. Since then until June 2011, the Company had supplied over 45 million doses for usage in around 31 GAVI/non-GAVI countries worldwide.

Fully Liquid Pentavalent Vaccine continues to be a high priority vaccine for WHO, UNICEF and GAVI. UNICEF continues to increase procurement of pentavalent year on year and has purchased pentavalent vaccine 168.5 mn doses worth US$ 418 mn spending 40.5% of funds spent on all vaccines purchased in 2011 as compared to 97.5 mn doses worth US$ 292 mn purchased in the year 2010. As per the GAVI forecasts, the overall demand for pentavalent vaccine is expected to increase to over 234 mn doses by 2016 and thereafter to 256 mn doses by 2019 for all the 73 GAVI eligible countries.

About Panacea Biotec

Panacea Biotec is one of India's leading research-based health management companies with established research, manufacturing and marketing capabilities. Panacea Biotec occupies the position of 2nd largest vaccine producer in India and has been ranked amongst leading biotechnology companies (*ABLE Survey 2013*) & is amongst top 50 pharmaceutical companies in India (*ORG-IMS-MAT-March 2013*). The company has collaborations and tie-ups with leading national and international research organizations and corporations. The product portfolio of the Company includes innovative prescription products in niche therapeutic areas such as diabetes management, renal-disease management, Organ Transplantation, Oncology, anti-osteoporosis, gastro-intestinal and pain management products and vaccines. The company's state of the art manufacturing facilities for vaccines and pharmaceutical formulations comply with several International regulatory bodies like USFDA, BfArM Germany, ANVISA Brazil and WHO-cGMP standards. Panacea Biotec has four dedicated state-of-the-art research and development centers and six manufacturing facilities.

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