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Aiming indigenous affordable biologics for all

10 April 2014 | News | By Rahul Koul Koul

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Tergene Biotech was founded by Dr Mosuvan Kuppusamy, a biotechnologist well known in the vaccine industry with three decades of experience in research and manufacturing of biologics. Having been associated earlier with the various prominent companies, Dr Kupusamy wanted to follow his heart and finally decided to start his own venture. The company started its research and development (R&D) activities in the year 2010 by acquiring lab space in Biotechnology Incubation Centre, Hyderabad.

The initial recognition came when its in-house R&D centre was recognised by the Department of Scientific and Industrial Research (DSIR) in 2011. The main research focus was in developing affordable vaccines against infectious diseases based on the polysaccharide-carrier protein conjugate platform. Besides vaccines against infectious diseases, Tergene is working on the development of therapeutic vaccines against antibiotic resistance, cancer and allergy.

Tergene is developing bio-conjugate platform technologies for novel vaccines and antibody drug conjugates. It has developed the multivalent Pneumococcal Conjugate Vaccine (PCV- 15) employing an innovative micro reactor based conjugation chemistry. Initial funding support for the PCV-15 project was received from BIRAC and the company successfully established the proof of concept, eventual scale-up and validation of the process. In recognition of this achievement, Tergene was awarded with Biotechnology Industry Research Assistance Council (BIRAC) Innovators Award-2013 in the Healthcare sector.The award is in recognition of the company's significant contribution to innovative research towards the "Development of an Indigenous India specific 15 valent Pneumococcal Conjugate Vaccine".

The company deeply acknowledges the Biotechnology Industry Partnership Program (BIPP) from BIRAC for the financial support and hand holding in the successful completion of the innovative technology platform. This award boosts up the company's morale and encourages in pursuing the next stage of clinical validation and early commercialization of the vaccine. The PCV-15 vaccine is awaiting preclinical and clinical evaluation.

Another significant achievement of the company is the development of a cost effective production technology for CRM-197,

the safest carrier protein and a key ingredient in the development of PCV-15. It also finds application in other therapeutic vaccines against cancer and allergy.

Tergene offers its partners a full range of services from bioprocess development to manufacturing to approval of the finished product. A basket of vaccines against bacterial pneumonia is under various stages of development. Vaccines currently under advanced stage of development include a multivalent pneumococcal vaccine and Meningococcal vaccine. Tergene also had the options to develop a Haemophilius influenzae B conjugate vaccine and acellular pertussis vaccine directed to prevent the main causative bacterial agents of pneumonia, but is presently focused on the pneumococcal polysaccharide conjugate vaccine.

The company is setting up a manufacturing facility (as per Good Manufacturing Practices norms) near Chennai, Tamil Nadu. The state-of-the-art facility will be operational by the end of 2014 and will be used to manufacture vaccines, biopharmaceuticals and probiotics. This will give Tergene a manufacturing facility matching the specifications of the US Food and Drug Administration. The suite will have up to 1000 L of fermentation capacity besides state of the art down stream equipments and purifications systems. The suite will have the necessary support areas such as formulation and fill-finish facility for liquid and lyophilized vials. All bio waste generated in the process will be thermally inactivated prior to treatment.

According to Dr M Kuppusamy, "The present ecosystem is good enough for ignition and proof of concept stages but the real challenge for start ups is in mobilising funds for Pre-clinical and Clinical evaluations. Uncertainty and delay in regulatory approvals for preclinical and clinical evaluation is of great concern for us."

Mentioning that collaboration is crucial during initial phase, Dr Kuppusamy added,"A public private partnership is a real opportunity for start-ups promoted by scientists with technology as the prime investment. Hence, we appreciate the timely help from the department of biotechnology (DBT)."

On being asked about the product among the basket that looks most appealing, Dr Kuppusamy elaborated,"The CRM-197 is a critical game-changer in the development of affordable conjugate vaccines. The company has already started supply of GLP grade CRM-197 to research institutions at competitive price. The company is in the process of building a GMP compliant manufacturing facility for CRM-197 with an annual capacity of 10 kg."