

# Pfenex Inc., Through Its Reagent Proteins Division, Announces Capacity Expansion for cGMP CRM197 Production

San Diego, CA January 16, 2013 – Pfenex Inc.'s Reagent Proteins division announced today that its CRM197 manufacturing partner, Serum Institute of India Ltd., has commenced the construction of a new large scale cGMP CRM197 production facility. This new facility, targeted for completion in 2014, will be the largest dedicated CRM197 production facility in the world with annual capacity to produce in excess of 50 kilograms of cGMP grade CRM197. The additional capacity will enable Reagent Proteins to meet the increasing global demand for CRM197 and to continue to support conjugate vaccine products currently being developed by its partners. Serum Institute utilizes Pfenex Expression Technology™ as the production platform, enabling high titers of this high quality conjugate vaccine carrier protein. The Pfenex CRM197 currently being manufactured at Serum Institute is also being used by Serum Institute as the carrier protein for its own internal pneumococcal polysaccharide conjugate vaccine programs.

Reagent Proteins offers pre-clinical and cGMP grade CRM197 carrier protein to the vaccine industry enabling novel conjugate vaccine development efforts. In addition, Reagent Proteins provides partners access to a Type 2 Biologics Master File in support of regulatory submissions for their conjugate vaccines. Currently, Pfenex CRM197 is a component in preclinical and clinical stage human vaccine products in development in both North America and Europe.

“CRM197 is increasingly being used by the global vaccine development community, and this new facility allows us to not only meet the growing needs of our current partners, but also allows us to support new research and development efforts” said Dr. Bertrand Liang, CEO of Pfenex Inc. “By leveraging our long standing relationship with Serum Institute of India, we are able to further provide our partners with access to high quality vaccine components produced using the powerful Pfenex Expression Technology™, all the way from early stage research through the clinic and into commercialization.”

“By utilizing the powerful Pfenex Expression Technology™, we are easily able to expand our production capabilities, and together with Reagent Proteins we will have world's largest installed dedicated capacity for the production of cGMP CRM197,” said Dr. Umesh Shaligram of Serum Institute. “This expansion is imperative to meeting both our own internal needs as well as helping our partner, Reagent Proteins, meet the rising worldwide demand for CRM197 and provide the vaccine development community with a rapid and scalable path into the clinic and through to commercialization.”

## **About Reagent Proteins**

Reagent Proteins is a leading supplier of reagent, pre-clinical and cGMP grade proteins to the biopharmaceutical and vaccine development community. With over 5,000 catalog products, Reagent Proteins ensure that scientists have ready access to a comprehensive offering of high quality proteins to enable their development efforts to proceed efficiently. For more information please visit [www.reagentproteins.com](http://www.reagentproteins.com)

## **About Pfenex Inc.**

Pfenex Inc. is a protein production company leveraging the unique and powerful Pfenex Expression Technology™ platform based on the microorganism, *Pseudomonas fluorescens*, for the production of research proteins, reagent proteins, biosimilars and innovator biopharmaceuticals. For more information please visit [www.pfenex.com](http://www.pfenex.com)

## **About Serum Institute of India Ltd.**

Serum Institute of India Ltd. is the world's largest producer of Measles and DTP group of vaccines. It is estimated that two out of every three children immunized in the world are vaccinated by a vaccine manufactured by Serum Institute. Serum Institute of India was founded in 1966 with the aim of manufacturing life-saving immuno-biologicals, which were in shortage in the country and imported at high prices. Thereafter, several life-saving biologicals were manufactured at prices affordable to the common man and in abundance, with the result that the country was made self-sufficient for DTP (Diphtheria, Tetanus and Pertussis) group of vaccines, MMR (Measles, Mumps and Rubella) group of vaccines and then later on Hepatitis B, HiB, Meningococcal A and combination vaccines.

## **About CRM197**

CRM197 is a non-toxic mutant of diphtheria toxin having a single amino acid substitution of glutamic acid for glycine. CRM197 is a well defined protein and functions as a carrier for polysaccharides and haptens making them immunogenic. It is utilized as a carrier protein in a number of approved conjugate vaccines for diseases such as meningitis and pneumococcal bacterial infections. Pfenex CRM197 is a recombinant form expressed in *Pseudomonas fluorescens* using the Pfenex Expression Technology™ platform. Pfenex CRM197 has been shown to have equivalent structural, functional and biological activity to CRM197 produced using existing native expression host technology.

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