



**-FOR IMMEDIATE RELEASE-**

**PFENEX INC., THROUGH ITS *REAGENT* PROTEINS BUSINESS DIVISION, ANNOUNCES SUBMISSION OF BIOLOGICS MASTER FILE FOR RECOMBINANT CRM197 TO US FDA**

***Biologics Master File will support cGMP grade CRM197 carrier protein use by Reagent Proteins partners in conjugate vaccine clinical development programs.***

**San Diego, CA May 17, 2011** – Pfenex Inc.’s *Reagent* Proteins division announced today that it has submitted a Biologics Master File (BMF) to the United States Food and Drug Administration for its cGMP grade CRM197 carrier protein to support the development of conjugate vaccine products by its partners.

*Reagent* Proteins is supplying cGMP grade CRM197 carrier protein to multiple partners in support of their novel conjugate vaccine development efforts. As part of the product offering partners are granted access to the BMF in support of regulatory submissions for their conjugate vaccines. The BMF was developed in partnership with Pfenex’s cGMP manufacturing partner, Serum Institute of India Ltd.

Serum Institute is a global leader in vaccine development and production whose vaccines have been used in over 140 countries around the world. It is estimated that two out of every three children immunized in the world is vaccinated by a vaccine manufactured by Serum Institute. 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 program.

“This filing with the US FDA marks another important milestone for our *Reagent* Proteins business unit,” said Dr. Bertrand Liang, CEO of Pfenex Inc, “The ability to provide our partners with access to high quality vaccine components produced using the powerful *Pfenex* Expression Technology™ as well as supporting their regulatory agency filings through providing access to Biologics Master Files, demonstrates our unique value proposition. By leveraging our long standing relationship with Serum Institute of India, we are able to provide our customers with a rapid and scalable path into the clinic and through to commercialization”

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#### **About *Reagent* Proteins**

***Reagent* Proteins** is a leading supplier of reagent, pre-clinical and cGMP grade proteins to the biopharmaceutical and vaccine development community. We 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 is vaccinated by a vaccine manufactured by Serum Institute. Serum Institute of India was founded in 1966 with the aim of manufacturing life-saving immunobiologicals, 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.

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