



Serum Institute of India Private Limited has achieved World Health Organization (WHO) prequalification for PNEUMOSIL® , containing CRM197 produced in Pfenex Expression Technology

SAN DIEGO, January 8, 2020 - Pfenex Inc. (NYSE American: PFNX) today announced that Serum Institute of India Private Limited (Serum Institute) achieved World Health Organization (WHO) prequalification for Pneumosil, a 10-valent pneumococcal conjugate vaccine. Pneumosil contains the recombinant carrier protein CRM197 produced by Serum Institute under a license to the Pfenex Expression Technology®.

Under the agreement with Serum Institute, Pfenex is eligible to receive annual fees, milestone payments, and a tiered low single digit royalty based on net sales for all products developed by Serum Institute that use the CRM197 carrier protein produced via the Pfenex Expression Technology.

“Our partnership with Serum Institute continues to be successful. We are thrilled to have played a part in their mission to help ensure that children of low- and middle-income countries have access to lifesaving vaccines at a sustainable price,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex.

“I am extremely pleased to see the WHO PQ of Pneumosil. This could help pave the way for saving lives by using a highly cost-effective Pneumococcal vaccine. For this vaccine, we have used Pfenex Expression Technology for the manufacturing of recombinant CRM197 (rCRM197) co-developed with Pfenex. I am also pleased to note that our next product in the pipeline which utilizes rCRM197 is also in late stage clinical development,” said Adar Poonawalla, Chief Executive Officer of Serum Institute of India.

Pneumosil covers over 71% invasive pneumococcal disease (IPD) causing serotypes, and targets the Indian Universal Immunization Programme and Asian, African and other countries under the Gavi Advanced Market Commitment (AMC).

A second product being developed by Serum Institute which also utilizes CRM197 as one of its carrier proteins and is subject to the Pfenex Expression Technology license is a thermostable Pentavalent Meningococcal Conjugate Vaccine (A, C, Y, W-135, X). This product is currently in a Phase 3 clinical study and is also targeted for developing countries.

About CRM197

Pfenex CRM197 is a non-toxic mutant of diphtheria toxin having a single amino acid substitution of glutamic acid to glycine at position 52. 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 several approved conjugate vaccines for diseases such as *Streptococcus pneumoniae*, *Haemophilus influenzae b* and *Neisseria meningitidis*. Pfenex CRM197 is a recombinant, soluble form produced by the Pfenex Expression Technology® platform. CRM197 is currently being used by vaccine development focused pharmaceutical partners, including Merck and the Serum Institute of India Private Ltd., (SIPL). In 2018, Merck announced that it had initiated multiple Phase 3 clinical studies of PCV-15 (V114), an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. SIPL who is developing a 10-valent pneumococcal conjugate vaccine, Pneumosil recently achieved World Health Organization Prequalification (PQ).

About Pfenex Inc.

Pfenex is a development and licensing biotechnology company focused on leveraging its Pfenex Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented Pfenex Expression Technology platform, Pfenex has created an advanced pipeline of potential therapeutic equivalents, and vaccines. Pfenex's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide injection). PF708 has been approved in the U.S. for the treatment of osteoporosis in certain patients at high risk for fracture, and marketing authorization applications are pending in other jurisdictions. In addition, Pfenex is developing hematology/oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology. Pfenex also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines.

Cautionary Note Regarding Forward-Looking Statement –

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Pfenex's future expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding Pfenex's expectation with respect to its agreement with Serum Institute, including its potential to receive annual fees, milestone payments and future royalties; and Pfenex's expectations with respect to the potential benefits of Pneumosil. Pfenex's expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Actual results may differ materially from those indicated by these forward-looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, the ability to successfully demonstrate the efficacy and safety of product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates or may require additional clinical trials or modifications to ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; Pfenex's ability to manage operating expenses; Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives; Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products; unexpected expenditures; and litigation and other proceedings regarding intellectual property rights. Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Quarterly Report on Form 10-Q for the period ended September 30, 2019 filed with the Securities and Exchange Commission and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

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