



## Pfenex Licensee Successfully Completes a Phase 3 Study and Enters Registration for Pneumosil®

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*Serum Institute of India first Licensee to complete a Phase 3 clinical trial with CRM197 produced in Pfenex Expression Technology®*

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**SAN DIEGO, March 6, 2019** —Pfenex Inc. (NYSE American: PFNX) today announced that Serum Institute of India Private Limited (SIPL), has completed a pivotal Phase 3 study for Pneumosil® a 10-valent pneumococcal conjugate vaccine, in which Serum Institute indicates all primary and secondary objectives were met. Pneumosil contains the recombinant carrier protein CRM197 produced by Serum Institute under a license to the Pfenex Expression Technology®. Following review of the Complete Study Report and product dossier by the Drug Controller General of India (DCGI), Serum Institute has received an export license for Pneumosil.

Serum Institute has already initiated the process of World Health Organization (WHO) prequalification for Pneumosil. The prequalification process could take up to 12 months to complete.

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 of India that use the CRM197 carrier protein produced via the Pfenex Expression Technology.

“Our partnership with Serum Institute continues to be extremely successful. We are thrilled to have played a part in their mission to ensure that under-privileged children of the world are protected through vaccination from birth onwards,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex. “This is the first of several vaccines under development with amongst others Serum Institute and Merck that has concluded its clinical program. We look forward to continuing to be a partner in bringing these important products to the market”.

The commercial market for Pneumosil will include India and certain countries in the developing world, covering over 71% invasive pneumococcal disease (IPD) causing serotypes, and targeting the Indian UIP and Asian, African and other low- and middle-income countries under the Gavi Advanced Market Commitment (AMC).

A second product being developed by Serum Institute that is subject to the Pfenex Expression Technology license is a thermostable Pentavalent Meningococcal Conjugate Vaccine (A, C, Y, W-135, X), which also utilizes CRM197 as one of its carrier proteins. This product will shortly enter into Phase 3 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 completed a Phase 3 program in which all primary and secondary objectives were met and has received an export license for Pneumosil.

### **About Pfenex Inc.**

We are a clinical-stage development and licensing biotechnology company focused on leveraging our Pfenex Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented Pfenex Expression Technology platform, we have created an advanced pipeline of therapeutic equivalents, vaccines, biologics and biosimilars. The Company also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines. Our lead product candidates are PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis, and our novel anthrax vaccine candidates, Px563L and RPA563, funded through an advanced development contract with the U.S. government. In addition, we are developing hematology/oncology products, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, in collaboration with Jazz Pharmaceuticals. Furthermore, our pipeline includes biosimilar candidates to Lucentis® and Neulasta®.

### **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 SIPL, including its potential to receive annual fees, milestone payments and future royalties. 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, Pfenex's ability to successfully demonstrate the efficacy and safety of its product candidates; the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates or may require Pfenex to conduct additional clinical trials or modify ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; difficulties in achieving and demonstrating biosimilarity in formulations; 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; litigation and other proceedings regarding intellectual property rights, including potential future litigation by Eli Lilly and Company with respect to PF708; and difficulties in obtaining and maintaining intellectual property protection for its product candidates. 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, 2018 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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