



## **Pfenex Announces Positive European CHMP Opinion for PF708 (EU Brand Name: Livogiva™) and New Partnership in Latin America, and Provides CRM197 Business Update**

- ***Positive Opinion from Committee for Medicinal Products for Human Use (CHMP) for Livogiva marks important first step toward marketing authorization***
- ***Pfenex's commercial partner Adalvo entered into commercialization agreement in Latin America for PF708 with a large, multinational pharmaceutical firm***
- ***Serum Institute of India is awarded first UNICEF supply agreement for Pneumosil®***
- ***Merck announces safety and immunogenicity objectives were met in two initial Phase 3 studies for its MRK-V114 Pneumococcal Conjugate Vaccine candidate***

**SAN DIEGO, June 26, 2020** — Pfenex Inc. (NYSE American: PFNX) announced today the achievement of several significant milestones across their business portfolio. Theramex, the European commercialization partner for Pfenex and Adalvo (formerly Alvogen B2B), received a positive opinion for PF708 (branded in Europe as Livogiva™) from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Additionally, Adalvo recently entered into a commercialization agreement with a multinational pharmaceutical company to commercialize PF708, upon receipt of marketing authorization, in certain countries in Latin America.

Merck recently announced that V114, its investigational 15-valent pneumococcal conjugate vaccine met safety and immunogenicity objectives in initial Phase 3 studies in adults. Also, Serum Institute of India announced its first supply agreement with UNICEF for Pneumosil™, a 10-valent pneumococcal vaccine developed to address pneumococcal infection in low- and middle-income countries. Both V114 and Pneumosil contain CRM197 produced via license agreements to the Pfenex Expression Technology, pursuant to which Pfenex may earn development milestone payments and royalties on net product sales.

“This is an exciting time for Pfenex as we continue to achieve meaningful clinical, regulatory and commercial milestones across our pipeline, highlighted today by the positive opinion on Livogiva from the CHMP and the announcement of positive results in two of Merck’s Phase 3 studies for the Merck V114 vaccine,” said Pfenex CEO Eef Schimmelpennink. “Over the past few years, we have had a relentless, laser like focus on our core portfolio and we believe those efforts are paying off.”

“With Alvogen’s U.S. launch of Teriparatide Injection and Serum Institute of India’s Pneumosil supply agreement with UNICEF, we now have two royalty bearing commercial products, a critical milestone as we continue our transition towards novel biopharmaceutical development,” said Mr. Schimmelpennink.

Earlier today, StreetAccount issued a release that erroneously described Livogiva as a Teva product. In order to address this incorrect information, Pfenex asked the NYSE to temporarily halt trading in Pfenex’s stock.

### **PF708: CHMP Positive Opinion & Latin America Commercial Partner**

The Committee for Medicinal Products for Human Use has adopted a positive opinion recommending marketing authorization for PF708, which will be branded in Europe as Livogiva™ (teriparatide injection), a biosimilar product candidate to the reference medicine Forsteo® (teriparatide injection) indicated for uses including in postmenopausal women with osteoporosis who are at high risk for having bone fractures. The CHMP’s recommendation will now be considered by the European Commission, which typically issues a decision within 67 days of CHMP’s recommendation.

If the European Commission affirms the CHMP opinion, it will grant a marketing authorization with unified labeling that is valid in the more than 25 countries that are members of the European Union, as well as European Economic Area members, Iceland, Liechtenstein and Norway. The version of Livogiva that is approved for marketing in the United States is Teriparatide Injection (previously referred to as PF708, as well as Bonsity), which the U.S. Food and Drug Administration (FDA) continues to evaluate for therapeutic equivalence to its reference drug Forsteo®.

In addition, Pfenex announced Adalvo has partnered with a large, multinational pharmaceutical firm to commercialize PF708, upon receipt of marketing authorization, in Brazil, Columbia, Mexico, Ecuador, Paraguay, and Peru in Latin America.

“The CHMP positive opinion on Livogiva and the addition of a global, distinguished partner in Latin America are each important steps in our global regulatory and commercial plans that aim to provide a teriparatide product to patients in European and Latin American markets in a cost effective manner,” said Faysal Kalmoua, Alvogen’s Executive Vice President of Portfolio.

## **CRM197: Serum Institute of India Supply Arrangement**

Serum Institute of India announced a new arrangement with UNICEF to supply ten million doses of Pneumosil, a 10-valent pneumococcal conjugate vaccine, annually for a period of ten years. The supply arrangement will allow low- and middle-income countries to access the drug. Pneumococcus bacterium is a leading cause of severe pneumonia and major cause of morbidity and mortality worldwide. The arrangement was contracted under UNICEF's Vaccine Alliance's Advance Market Commitment and represented the first such arrangement between UNICEF and a developing country manufacturer. Serum Institute currently has a license to the Pfenex Expression Technology for the production of the carrier protein CRM197 a key component of the Pneumosil vaccine. In accordance with the license agreement, Pfenex is eligible to receive royalties on net sales.

## **CRM197: Merck V114 Phase 3 Study Readouts**

Merck and Co. Inc. announced results from two initial Phase 3 studies evaluating the safety, tolerability and immunogenicity of V114, the company's investigational 15-valent pneumococcal conjugate vaccine and were published via the International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) online digital library. Merck also announced its plans to continue to work with the FDA and other regulatory authorities around the world on filing plans for licensure of this vaccine as additional data from the Phase 3 program become available. Merck currently has a license to the Pfenex Expression Technology for the production of the carrier protein CRM197 a key component of the V114 vaccine. In accordance with the license agreement Pfenex is eligible to receive milestone payments and royalties on net sales.

## **About PF708**

PF708 was approved in the U.S. under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug, and commercially launched as Teriparatide Injection. Teriparatide Injection is indicated, among other uses, for the treatment of osteoporosis in certain patients at high risk for fracture. Pursuant to the Development and License Agreement with Alvogen, Pfenex has transferred the new drug application (NDA) for Teriparatide Injection to Alvogen, and Alvogen is responsible for manufacturing and commercializing the product in the U.S. and for fulfilling all regulatory requirements associated with maintaining the Teriparatide Injection NDA. Alvogen also has exclusive rights to commercialize and manufacture PF708 in the European Union (EU), certain countries in the Middle East and North Africa (MENA), and the Rest of World (ROW) territories (the latter defined as all countries outside of the EU, U.S. and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). A marketing authorization application for PF708, which will be branded in

Europe as Livogiva, has been filed and accepted with the EMA using the biosimilar pathway with Forsteo® as the reference medicinal product, and the CHMP has issued a positive opinion; and a marketing authorization application for PF708 has been filed with the Kingdom of Saudi Arabia's SFDA.

Pursuant to the Development and License Agreement with China NT Pharma Group Company Limited (NT Pharma), we granted an exclusive license to NT Pharma to commercialize PF708 in Mainland China, Hong Kong, Singapore, Malaysia and Thailand and a non-exclusive license to conduct development activities in such territories with respect to PF708. Effective April 2020, Pfenex entered into a Deed of Assignment and Amendment with NT Pharma. Pursuant to the Deed of Assignment, Pfenex agreed to allow NT Pharma to assign its rights and obligations under the NT Pharma agreement with Pfenex to Beijing Kangchen Biological Technology Co., Ltd. (Kangchen), a wholly-owned subsidiary of Beijing Konruns Pharmaceutical Co., Ltd.

Forteo® and Forsteo® are approved and marketed by Eli Lilly and Company for the treatment of osteoporosis in certain patients with a high risk for fracture. Forteo® and Forsteo® achieved \$1.4 billion in global product sales in 2019.

### **About Pfenex Inc.**

Pfenex is a development and licensing biotechnology company with commercial products focused on leveraging its proprietary protein production platform, Pfenex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. Using the patented Pfenex Expression Technology platform, Pfenex has created a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration (FDA) approved, next generation and novel biopharmaceutical products. Pfenex's lead product is Teriparatide Injection (previously referred to as PF708 and Bonsity™), a therapeutic equivalent candidate to Forteo® (teriparatide injection). Teriparatide Injection has been commercialized in the U.S. for, among other uses, 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 hematologic oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a recombinant Erwinia asparaginase, and PF745, a half-life extended recombinant Erwinia asparaginase. Pfenex also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein for use in prophylactic and therapeutic vaccines.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (<http://www.pfenex.com/>), its investor relations website (<http://pfenex.investorroom.com/>), press releases, SEC filings, public conference calls, corporate Twitter account (<https://twitter.com/pfenex>), Facebook page (<https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/>), and LinkedIn page

(<https://www.linkedin.com/company/pfenex-inc>) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

### **Cautionary Note Regarding Forward-Looking Statements**

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 the future potential of Pfenex's developed products, product candidates, and the company in general, including the potential to obtain marketing authorization in the European Union for PF708 (branded in Europe as Livogiva™); the expected timing of marketing authorization in Europe; the potential to improve patient access; the potential benefits of PF708; Pfenex's expectations with respect to the cost of PF708; potential market opportunities for PF708; the potential to receive 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 various factors, including: the European Commission may not affirm the CHMP opinion and grant a centralized marketing authorization; the FDA may not grant an "A" therapeutic equivalence designation for Teriparatide Injection; 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; Pfenex's ability to manage operating expenses; impacts related to the COVID-19 pandemic; 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; 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 quarter ended March 31, 2020 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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