



Pfenex and Alvogen Announce European Medicines Agency Accepts Marketing Authorization Application for PF708

Distribution and promotion by established regional partner Theramex

SAN DIEGO, May 30, 2019 —Pfenex Inc. (NYSE American: PFNX) and Alvogen today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) submitted by our partner Alvogen for PF708 (teriparatide). The product is proposed as a therapeutic equivalent in the treatment of osteoporosis to Forteo®. The product is filed with the EMA as a biosimilar in the treatment of osteoporosis to Forsteo®, which achieved \$289 million sales in the E.U. and \$1.6 billion in global product sales in 2018. This acceptance means the EMA considers the MAA to be complete and initiates the EMA's formal review process.

“The acceptance of the PF708 MAA filing is an important milestone for Pfenex and Alvogen and demonstrates that through our collaborative partnership, we continue making progress towards potential approvals beyond the United States,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex. “Subject to applicable regulatory approvals, for Europe, PF708 will be commercialized by Theramex, a leading global specialty pharmaceutical company dedicated to Women’s Health.”

“We are very pleased with the EMA’s acceptance of the MAA for review. This is an important milestone and underlines the successful and valuable partnership between Pfenex and Alvogen to bring biosimilar Teriparatide to market and deliver on our mission to provide high quality, affordable healthcare for patients. The EMA will review the application under the centralized marketing authorization procedure. If approved by the EMA, biosimilar Teriparatide would receive marketing authorization in all 28 member states of the European Union (E.U.), as well as in Iceland, Liechtenstein and Norway,” stated Faysal Kalmoua, Executive Vice President of Alvogen’s Global Portfolio.

About PF708

PF708 is being developed by Pfenex as a therapeutic equivalent candidate to Forteo®, which is approved and marketed by Eli Lilly and Company for the treatment of osteoporosis in certain patients with a high risk of fracture. Forteo achieved \$1.6 billion in global product sales in 2018. PF708 is being developed pursuant to the 505(b)(2) regulatory pathway in the U.S. and references Forteo® as the Reference Listed Drug. PF708 has been filed with EMA using the biosimilar pathway and references Forsteo® as the Reference Drug.

About Pfenex Inc.

Pfenex is a clinical-stage development and licensing biotechnology company focused on leveraging its *Pfēnex* Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented *Pfēnex* Expression Technology platform, the Company has created an advanced pipeline of potential therapeutic equivalents, novel biologics, vaccine and vaccine components, and biosimilars. The Company's lead product candidate is PF708, under development as a therapeutic equivalent drug candidate to Forteo® (teriparatide) indicated for the treatment of osteoporosis. In addition, the Company is developing hematology/oncology products, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension, in collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz). Both PF743 and PF745 are being developed for the treatment of Acute Lymphoblastic Leukemia (ALL). We also use our *Pfēnex* Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates under development by third parties.

Pfenex investors and others should note that we announce material information to the public about the Company through a variety of means, including our website (<http://www.pfenex.com/>), our 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 our disclosure obligations under Regulation FD. We encourage our investors and others to monitor and review the information we make 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.

About Alvogen

Alvogen is a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brand, over-the-counter brands (OTC) and biosimilar products for patients around the world. The company has commercial operations in 35 countries with 2,800 employees and operates four manufacturing and development hubs in the U.S., Romania, Korea and Taiwan. North America is Alvogen's single largest market and other key markets include: South Korea, Russia, Romania, Hungary, Ukraine, Taiwan, Japan and China. Learn more about Alvogen at www.alvogen.com.

About Theramex

Theramex is leading, global specialty pharmaceutical company dedicated to women and their health. With a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis, we support women at every stage of their lives. Our commitment is to listen and understand our patients, serve their needs, and offer healthcare solutions to help improve their lives. Our vision is to be a lifetime partner for women and the healthcare professionals who treat them by providing innovative, effect solutions that care for and support women as they advance through each stage of their lives.

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 the future potential of Pfenex's product candidates and the company in general, including future plans to advance, develop, manufacture and commercialize its product candidates; the possibility of the potential commercial US launch of PF708 as early as the fourth quarter of 2019; and Pfenex's belief that through its collaborative partnership with Alvogen it could potentially receive approvals beyond the US for PF708. 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; 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; 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, 2019 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.

Company Contact:

Susan A. Knudson
Chief Financial Officer
(858) 352-4324
sknudson@pfenex.com