Pfenex Submits New Drug Application to U.S. FDA Seeking Approval of PF708 for the Treatment of Osteoporosis

Submitted as a 505(b)(2) NDA with an Expected Ten-Month Review

SAN DIEGO, December 10, 2018-- Pfenex Inc. (NYSE American: PFNX) today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of PF708 for the treatment of osteoporosis. The application is submitted as a 505(b)(2) NDA and references Eli Lilly and Company's Forteo® (teriparatide) as the Reference Listed Drug.

"We are pleased to submit to the FDA an NDA for PF708 as a proposed therapeutic equivalent to Forteo®, which achieved $1.7 billion in global sales in 2017," said Eef Schimmelpennink, Chief Executive Officer of Pfenex. "We believe the timing of the NDA submission for PF708 could allow for a potential commercial launch as early as the fourth quarter of 2019 in the U.S., subject to FDA acceptance, approval and other factors. We continue to work closely with Alvogen to support the overall plans for commercialization of PF708 in the U.S."

The NDA submission for PF708 is based on positive data from the PF708-301 Phase III clinical study announced earlier this year, which showed comparable overall profiles between PF708 and Forteo® after 24 weeks of daily injection in osteoporosis patients. In addition, the NDA includes data from the PF708-101 study, a single-dose, 2-way crossover study comparing the pharmacokinetics of PF708 and Forteo® in healthy subjects.

About PF708

PF708 is being developed 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 $1.7 billion in global product sales in 2017. PF708 is being developed pursuant to the 505(b)(2) regulatory pathway in the U.S. and references Forteo® as the Reference Listed Drug.

About Pfenex Inc.

We are a clinical-stage development and licensing biotechnology company focused on leveraging our *Pf*ēnex Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented *Pf*ēnex 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®.

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.

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; the likelihood of FDA approving PF708 as a therapeutic equivalent to Forteo®; Pfenex's expectations regarding the size of the potential market for PF708, if approved; and the expected timing of the FDA review period 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 and regulatory approval process, including, without limitation, Pfenex's ability to successfully demonstrate the efficacy and safety of PF708 to the FDA; the FDA may decide not to accept for filing Pfenex's NDA for PF708; despite prior advice, the FDA may determine that additional trials or data are necessary in order to file for or obtain approval; even if PF708 is successfully approved, it may only be approved or used to treat a subset of the patient population; 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 its products, including PF708; 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 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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