# Pfenex Announces FDA Acceptance of NDA for PF708

*FDA Sets PDUFA Date of October 7, 2019*

**SAN DIEGO, February 19, 2019** —Pfenex Inc. (NYSE American: PFNX) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the 505(b)(2) New Drug Application (NDA) for the Company's lead product candidate, PF708, a Forteo® therapeutic equivalent in the treatment of osteoporosis, which achieved $1.6 billion in global product sales in 2018. The acceptance of the NDA indicates the application is sufficiently complete to permit a substantive review by the FDA. The FDA set a target goal date under the Prescription Drug User Fee Act (PDUFA) of October 7, 2019. Additionally, the Day-74 letter did not indicate that FDA is planning to hold an advisory committee meeting to discuss the NDA.

"The acceptance of the PF708 NDA filing is an important milestone for Pfenex as it brings us one step closer to the potential approval and U.S. commercial launch of PF708. We are pleased to achieve this stage in the U.S. regulatory pathway for PF708," said Eef Schimmelpennink, Chief Executive Officer of Pfenex. "We believe PF708 remains on track to enter the U.S. market as early as the fourth quarter of 2019, subject to FDA approval and other factors."

**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 $1.6 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.

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

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