# Pfenex Receives U.S. FDA Approval for PF708 to Treat Osteoporosis

*Pfenex earns a $2.5M milestone payment from Alvogen for U.S. approval*

*Comparative human factors study report expected to be submitted to FDA as early as the second half of October 2019*

**SAN DIEGO, October 7, 2019** — Pfenex Inc. (NYSE American: PFNX) announced today that the U.S. Food and Drug Administration (FDA) has approved the new drug application ("NDA") for PF708 submitted under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. Like Forteo, the FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture.

"The FDA's approval of PF708 marks a major milestone in Pfenex's history as our first approved commercial product and further validates our Pfēnex Expression Technology platform. We look forward to continuing to work with our commercialization partner Alvogen to launch PF708 in the U.S. We believe PF708 has the potential to significantly enhance patient access to an important therapy as a cost-effective alternative to Forteo, which had $1.6 billion in global sales in 2018," said Eef Schimmelpennink, Chief Executive Officer of Pfenex.

Pfenex is also asking the FDA to designate PF708 as therapeutically equivalent ("A" rated) to Forteo, which would permit PF708 to be automatically substituted for Forteo in many states. To further support an "A" rating, Pfenex is conducting a comparative human factors study between PF708 and Forteo as requested by FDA. Pfenex anticipates submitting the final study report to the FDA as early as the second half of October 2019 and believes that this completes the information package required by the FDA to evaluate the therapeutic equivalence of PF708.

"Looking ahead, we are confident in the planning that Alvogen has done thus far in preparation for the commercial launch of PF708 and their established sales and marketing teams are excited to bring PF708 to market. To optimize patient and payer impact, we currently expect our commercial partner Alvogen to launch PF708 upon an FDA decision on the therapeutic equivalence rating," concluded Mr. Schimmelpennink.

**About PF708**

PF708 is approved in the U.S. under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. The U.S. approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture. Pursuant to the Development and License Agreement with Alvogen, Alvogen is responsible for commercializing and manufacturing PF708 in the U.S. and for fulfilling all regulatory requirements associated with maintaining the PF708 NDA. Alvogen also has exclusive rights to commercialize and manufacture PF708 in the 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). PF708 has been filed and accepted with the EMA using the biosimilar pathway with Forsteo® as the reference medicinal product. Forteo® and Forsteo® are approved and marketed by Eli Lilly companies 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.

**About Pfenex Inc.**

Pfenex is a 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, Pfenex has created an advanced pipeline of potential therapeutic equivalents, vaccines, biologics and biosimilars. Pfenex's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide injection) which has been approved in the U.S. for the treatment of osteoporosis in certain patients at high risk of osteoporosis, and for which marketing authorization applications are pending in other jurisdictions. In addition, Pfenex is developing hematology/oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology. Pfenex also uses its Pfēnex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used 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 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; Pfenex’s expectations with regard to future milestones and royalty payments from Pfenex’s collaboration with Alvogen statements relating to PF708, including but not limited to potential market opportunities and the benefits of use of PF708; the timing of the potential commercial launch of PF708 in the U.S.; and Pfenex’s expectations regarding the timing and advancement of the human factors study, including the submission of the study report to the FDA and Pfenex’s belief that such report completes the information package required by the FDA to evaluate therapeutic equivalence. 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 quarter ended June 30, 2019 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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