Pfenex Reports Positive Results for PF708 Comparative Use Human Factors Study

Study results found that the FDA-approved PF708 product is noninferior to Forteo® based on a pre-specified statistical analysis of critical patient and caregiver tasks

Pfenex believes the study report completes the information package required by the FDA to evaluate the FDA-approved PF708 product for therapeutic equivalence

SAN DIEGO, October 14, 2019 — Pfenex Inc. (NYSE American: PFNX) announced today it has successfully completed the PF708 comparative use human factors (HF) study and submitted the final study report to the FDA. The study found that the user interface of the FDA-approved PF708 product was noninferior to that of Forteo® for each critical user task evaluated in the study. Pfenex believes this submission completes the information package required by the FDA to evaluate the therapeutic equivalence of the PF708 product. Pfenex is seeking FDA designation of the recently-approved product as therapeutically equivalent ("A" rated) to Forteo, which would permit PF708 to be automatically substituted for Forteo in many states.

"We are very pleased with the outcome of the human factors study, which we believe demonstrates noninferiority between the user interfaces of our product and Forteo," said Eef Schimmelpennink, Chief Executive Officer of Pfenex. "We look forward to the FDA's review of the study report, along with the bioequivalence and pharmaceutical equivalence data in our recently approved NDA. We believe these results complete the information package required by the FDA to evaluate therapeutic equivalence of our PF708 product," commented Mr. Schimmelpennink.

The comparative use HF study was a simulated use study intended to evaluate the effect of each product's delivery device and user interface on critical task performance by untrained osteoporosis patients and caregivers. The study used a paired design of the FDA-approved PF708 and the Forteo products.

A total of 102 untrained participants, 52 osteoporosis patients and 50 caregivers, completed the study. For 67% (12 of 18) of critical tasks performed in the patient user group, and 83% (15 of 18) performed in the caregiver group, PF708 had fewer or equal user errors when compared to Forteo. Importantly, in each of the instances where PF708 had marginally higher user error rates (33% and 17 % of critical tasks among patients and caregivers, respectively), the magnitude of the differences was such that no error difference in either user group exceeded the predetermined maximum allowable difference. For these reasons, Pfenex believes the study data demonstrate that the user interface of the FDA-approved PF708 product is noninferior to that of Forteo. With

submission of the final study report to FDA, the agency can begin its review of the relevant data to make a therapeutic equivalence determination.

About PF708

PF708 was approved in the U.S. under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. The FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk of 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). A marketing authorization application for PF708 has been filed and accepted with the EMA using the biosimilar pathway with Forsteo® as the reference medicinal product and has been filed with the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Pursuant to the Development and License Agreement with NT Pharma Group Company Ltd. (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. 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® and Forsteo® 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). PF708 has been approved in the U.S. for the treatment of osteoporosis in certain patients at high risk of fracture, and 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; and Pfenex’s belief that the comparative use human factors study 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, the FDA may disagree that the human factors study report completes the information package and is sufficient to evaluate therapeutic equivalence; the FDA may not agree with Pfenex's interpretation of the results of the human factors study and may not grant an “A” therapeutic equivalence designation for PF708; 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; 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.

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