Pfenex Reports Positive Top-Line Bioequivalence Data for PF708

SAN DIEGO, May 9, 2016 /PRNewswire/ -- Pfenex Inc. (NYSE MKT: PFNX), a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics, including high value and difficult to manufacture proteins, today reported positive top-line bioequivalence data for PF708.

"Today we are excited to announce the positive top-line data from our initial bioequivalence study in healthy subjects for PF708. As we disclosed previously, we are developing PF708 as a therapeutic equivalent to Forteo, through the 505(b)(2) regulatory path in the US. Based on the feedback we have received from FDA, and the positive data announced today, we expect to satisfy the 505(b)(2) filing requirements with an additional immunogenicity/pharmacokinetic study in subjects with osteoporosis," stated Bertrand C. Liang, chief executive officer of Pfenex. "The clinical program is anticipated to initiate by year-end."

The bioequivalence study in healthy subjects for PF708, our peptide product candidate being developed as a therapeutic equivalent to Forteo, met the primary outcome measures. This initial bioequivalence study for PF708 was designed as a double blind, randomized two treatment cross over in 70 healthy adult subjects. Half of the subjects were randomized to receive PF708 first and then Forteo second while the other half was randomized to receive Forteo first and then PF708 second. The primary outcome measures were serum area-under-the-curve (AUC) and serum maximum concentration (Cmax) of PF708 and Forteo. The 90% confidence intervals of the geometric mean ratios for PF708 compared to Forteo, for both AUC and Cmax, fall within the limits of 80%-125%.

Below, both the graphical and tabular formats of the data are presented.

In addition to the positive bioequivalence study announced today, the pivotal PF708 clinical program will include an immunogenicity/pharmacokinetic study in subjects with osteoporosis and is anticipated to initiate by the end of 2016. We believe that the clinical program in the US can be leveraged for regulatory filings in other geographies and additional updates will be provided over the course of 2016.

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 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, including future plans to develop, manufacture and commercialize its product candidates; Pfenex's expectations regarding the timing of additional clinical trials and the types of future clinical trials for its product candidates, including PF708; Pfenex's expectations regarding the expected regulatory pathways for its product candidates, including the development of PF708 pursuant to the 505(b)(2) regulatory pathway; and Pfenex's expectations regarding the sufficiency of its clinical trials to satisfy regulatory requirements and to leverage regulatory filings in additional geographies. 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; 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 Annual Report on Form 10-K for the year ended December 31, 2015 and in Pfenex's subsequent reports on Form 10-Q and Form 8-K, filed with the Securities and Exchange Commission. Additional information will also be set forth in Pfenex's Quarterly Report on Form 10-Q for the period ended March 31, 2016 to be filed 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.

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 Pfenex Inc.

Pfenex Inc. is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics and high-value and difficult to manufacture proteins. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab), for the potential treatment of patients with retinal diseases. Pfenex has leveraged its *Pf*ēnex Expression Technology® platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, therapeutic equivalents to reference listed drug products, and next generation biologics.

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