Pfenex Announces FDA Requests Additional Comparative Use Human Factors Data in Experienced Users in order to Complete PF708 Therapeutic Equivalence Determination

FDA review for a Therapeutic Equivalency rating for PF708 continues

SAN DIEGO, April 14, 2020 -- Pfenex Inc. (NYSE American: PFNX) announced today that the U.S. Food and Drug Administration (FDA), informed Alvogen Malta Operations Ltd., the Company's commercialization partner for PF708, via a General Advice letter that additional comparative use human factors (CUHF) data, specifically from Forteo® (teriparatide injection) experienced users, would be required before PF708 Therapeutic Equivalence (TE) could be determined.

"While the previously submitted CUHF study included Forteo-experienced patients and caregivers, the FDA requested that a larger number of experienced subjects be studied," stated Eef Schimmelpennink, Chief Executive Officer of Pfenex. "In the correspondence the FDA has indicated that the review of the PF708 TE package continues and provided guidance on study methodology to generate this additional comparative use human factors data, which we are confident can be met. We intend to work closely with Alvogen and the FDA to expeditiously move toward a solution addressing the Agency's expressed views, so that we can submit additional data as soon as possible. Additionally, we will continue to support Alvogen with its commercial strategy planning in the U.S. while continuing to seek "A" therapeutic equivalence designation."

About Pfenex Inc.

Pfenex is a development and licensing biotechnology company focused on leveraging its proprietary protein production platform, Pfenex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. Using the patented Pfenex Expression Technology platform, Pfenex has created a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration (FDA) approved, next generation and novel biopharmaceutical products. 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 for fracture, and marketing authorization applications are pending in other jurisdictions. In addition, Pfenex is developing hematologic oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a recombinant Erwinia asparaginase, and PF745, a half-life extended recombinant Erwinia asparaginase. Pfenex also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein for use 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 expectations to submit additional human factors data to FDA, the potential commercial launch of PF708 in the U.S., and expectations with respect to a comparative use human factor study that addresses the FDA’s views. 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 not agree with Pfenex's protocol for a 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; 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, manufacturing, 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 Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 11, 2020 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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