# Pfenex Provides Update for PF708 Outside the United States

*New Exclusive Commercialization Agreements in South Korea, Canada, and Israel*

*Submission of Marketing Authorization Application for PF708 in Saudi Arabia*

*Potential approval of PF708 in the EU as early as the second half of 2020*

**SAN DIEGO, October [11], 2019** — Pfenex Inc. (NYSE American: PFNX) today announced that its partner Alvogen has entered into exclusive commercialization agreements for PF708 with PharmBio Korea in South Korea, JAMP Pharma in Canada and Kamada Ltd. in Israel. Furthermore, Alvogen's partner in the Middle East and North Africa (MENA) region, SAJA, submitted a Marketing Authorization Application (MAA) to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Additionally, the accepted MAA for PF708 under review by the European Medicines Agency (EMA) continues to make progress and Pfenex believes that PF708 could be approved in the European Union (EU) as early as the second half of 2020, pending marketing authorization by the European Commission under the EU centralized procedure and other factors.

"The new commercialization agreements in South Korea, Canada, and Israel, the filing of the PF708 MAA with the Saudi Food and Drug Authority, and the progress on Alvogen's submission in Europe are important milestones for the PF708 commercialization program," said Eef Schimmelpennink, Chief Executive Officer of Pfenex. "These are just the latest steps forward in our global commercialization strategy for PF708 as we continue to build positive momentum with our commercial partner, Alvogen."

Faysal Kalmoua, Executive Vice President of Alvogen's Global Portfolio, added, "We are very pleased with the latest submissions for PF708 and new commercial agreements with our partners in Canada, South Korea and Israel. Through our strong marketing network and growing pipeline of biosimilars, we can continue to deliver on our mission to provide high quality, affordable healthcare for patients."

Subject to applicable regulatory approvals, PF708 will be commercialized by PharmBio Korea in Korea, JAMP Pharma in Canada, and Kamada in Israel. Under the terms of the agreements, Alvogen will be responsible for overseeing the local activities through PharmBio Korea, JAMP Pharma and Kamada. Pfenex will be eligible to receive milestone payments and a percentage of net sales or transfer price.

PharmBio Korea was founded in 1999 by Mr. Bong-Kil Nam, its Chairman and CEO. With innovative marketing strategies and constructive partnerships, PharmBio Korea has developed a pipeline of innovative products and has licensed and marketed products in collaboration with pharmaceutical companies in the EU, Japan, and U.S.

JAMP Pharma is a private Canadian company that was established in 1988 in British Columbia. Its current headquarters is in Quebec. JAMP Pharma is a key player in the generic pharmaceutical industry and one of the fastest growing pharmaceutical companies in Canada.

Kamada Ltd. is a biopharmaceutical company specializing in the development, manufacture and marketing of proteins as pharmaceuticals. The Company's headquarters and laboratories are located in the park of Kiryat Weizmann Institute of Science in Rehovot, Israel.

**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 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). 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; the possibility that PF708 could be approved in the EU as early as second half of 2020; and Pfenex's development and commercialization strategy for PF708 in collaboration with Alvogen and others. 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,; 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 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