



**Pfenex and Alvogen Expand Development and Commercialization Collaboration for PF708, a Therapeutic Equivalent Candidate to Forteo®/Forsteo®, to the EU, MENA, and ROW**

**Distribution and Promotion by established regional players Theramex and Tamer Group (SAJA)**

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**SAN DIEGO, February 28, 2019** —Pfenex Inc. (NYSE American: PFNX) and Alvogen Ltd. today announced entering into agreements expanding their collaboration to develop and commercialize Pfenex’s lead product candidate, PF708, a proprietary teriparatide therapeutic equivalent candidate to Eli Lilly & Company’s Forteo®/Forsteo®, to the EU, to certain countries in Middle East and North Africa (MENA) the ROW territories (the latter defined as all countries outside of the EU, US and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). This collaboration leverages Alvogen’s established international experience and expertise in regulatory, IP and supply chain activities, as well as its established network of specialty marketing and sales pharmaceutical companies in these regions. Subject to applicable regulatory approvals, PF708 will be commercialized in Europe and Switzerland by Theramex, a leading global specialty pharmaceutical company dedicated to Women’s Health, in MENA by SAJA, a Tamer Group company, and in ROW by Alvogen’s current and/or future commercialization partners. Under the terms of the agreements, Alvogen will be responsible for the local activities through Theramex, SAJA and its other commercialization partners and for overseeing any clinical development, regulatory, litigation, commercial manufacturing and commercialization. Pfenex will be eligible to receive additional upfront and milestone payments of \$2.5 million for EU and MENA and additional potential milestone payments for ROW. For EU, MENA and ROW, Pfenex may also be eligible to receive a gross profit split of up to 60% on product sales, depending on geography and cost of goods sold.

“Collaborating with Alvogen in Europe, MENA and ROW centralizes the development, regulatory and commercialization activities of PF708 and leverages Alvogen’s global supply chain and market access experience to maximize potential of commercial success in these markets. Combining these operational capabilities with the favorable financial terms of the agreements, makes partnering on regional commercialization for PF708 the optimal strategy,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex. “We believe working with Alvogen, coupled with the established and credible commercial partnerships with Theramex, Tamer Group (SAJA) and its other commercialization partners significantly enhances our commercialization strategy. We chose to expand our relationship with Alvogen on PF708 because the overall deal terms proposed were superior to the other regional players that we considered.”

“We continue to be excited by the market opportunity that PF708 offers as a therapeutic equivalent candidate to Forteo®. We believe this new collaboration in the EU, MENA and ROW will allow us to leverage our commercialization efforts in the U.S. and capture a larger piece of the teriparatide global market, which was approximately \$1.6 billion in global sales in 2018,” stated Robert Wessman, Chief Executive Officer of Alvogen.

Anish Mehta, Chief Executive Officer at Theramex said, “As a leading women’s health company, we are delighted to be commercializing Pfenex’s proprietary teriparatide across Europe and Switzerland. The addition of teriparatide to our already broad portfolio of medications for the treatment of osteoporosis reinforces our commitment to helping women manage this potentially debilitating condition.”

“As part of SAJA’s long-stated vision to strategically invest in long-term partnerships with global pharma/biotech companies to bring solutions to patients in the MENA region, we are thrilled to welcome Pfenex/Alvogen as our new collaborator to bring new solutions to patients in the MENA region,” stated Riad Fanus, CEO of SAJA.

PF708 is being developed as a therapeutic equivalent to Forteo®. In December 2018, we submitted our new drug application (NDA) for PF708 to the FDA and the FDA accepted the submission in February 2019, leading to potential launch in the U.S., if approved by regulators, as early as the fourth quarter of 2019, subject to regulatory approval and other factors. The NDA submission for PF708 is based on positive data from the PF708-301 Phase III clinical study announced in 2018, which showed comparable overall profiles between PF708 and Forteo after 24 weeks of daily injection in osteoporosis patients. In addition, the NDA includes data from the PF708-101 study, a single-dose, 2-way crossover study comparing the pharmacokinetics of PF708 and Forteo in healthy subjects.

### **About Alvogen**

Alvogen is a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brand, over-the-counter brands (OTC) and biosimilar products for patients around the world. The company has commercial operations in 35 countries with 2,800 employees and operates four manufacturing and development hubs in the U.S., Romania, Korea and Taiwan. North America is Alvogen’s single largest market and other key markets include: South Korea, Russia, Romania, Hungary, Ukraine, Taiwan, Japan and China on top of this Alvogen covers rest of the world markets through strategic partnerships lead by B2B operation headquartered in Malta with the teams spread in the world. Learn more about Alvogen on [www.alvogen.com](http://www.alvogen.com).

### **About Pfenex Inc.**

Pfenex is a clinical-stage 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 therapeutic equivalents, vaccines, biologics and biosimilars. Pfenex also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines. Pfenex’s lead product candidates are PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis, and its novel anthrax vaccine candidates, Px563L and RPA563, funded through an advanced development contract with the U.S. government. In addition, Pfenex is developing hematology/oncology products, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, in collaboration with Jazz Pharmaceuticals. Furthermore, Pfenex’s pipeline includes biosimilar candidates to Lucentis® and Neulasta®.

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.

## **About Theramex**

Theramex is a leading global specialty pharmaceutical company dedicated to women and their health. With a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis, the company supports women as they progress through the different stages of their life. Theramex broad portfolio of osteoporosis therapies includes Actonel®, Actonel GR®, Alpha D3® and Cacit®. For more information visit [www.theramex.com](http://www.theramex.com)

## **About Tamer (SAJA)**

SAJA is a joint-venture between two leading Japanese Pharmaceutical companies, Astellas and Daiichi-Sankyo and the premier healthcare company, TAMER Group, managing a portfolio of more than USD 4.0 billion and serves many of the world leading pharmaceutical companies, SAJA is well established in the MENA region with two manufacturing facility in Saudi Arabia and Egypt and sales, marketing, regulatory, and supply chain teams effectively covering MENA Region.

## **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 in collaboration with Alvogen, Theramex, and Tamer; the potential benefits of the collaboration with Alvogen, Theramex, and Tamer; the possibility of the potential commercial US launch of PF708 as early as the fourth quarter of 2019; Pfenex's expectations with respect to future market sizes for PF708 and the ability of Pfenex and its collaboration partners to capture a large piece of the market; and Pfenex's expectations regarding potential future milestones and royalties with respect to PF708. 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; 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 period ended September 30, 2018 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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