



Press release – 29 May 2019

Alvogen and Pfenex Announce European Medicines Agency Accepts Marketing Authorization Application for PF708

Pine Brook, New Jersey – 29 May 2019, Alvogen and Pfenex Inc. (NYSE American: PFINX) today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) submitted for PF708 (Teriparatide). The product is filed as a biosimilar in the treatment of osteoporosis to Forsteo[®], which achieved \$289 million sales in the E.U. and \$1.6 billion in global product sales in 2018. This acceptance means the EMA considers the MAA to be complete and initiates the EMA's formal review process.

Faysal Kalmoua, Executive Vice President of Alvogen's Global Portfolio, commented: "We are very pleased with the EMA's acceptance of the MAA for review. This is an important milestone and underlines the successful and valuable partnership between Alvogen and Pfenex to bring biosimilar Teriparatide to market and deliver on our mission to provide high quality, affordable healthcare for patients. The EMA will review the application under the centralized marketing authorization procedure. If approved by the EMA, biosimilar Teriparatide would receive marketing authorization in all 28 member states of the European Union (EU), as well as in Iceland, Liechtenstein and Norway."

Eef Schimmelpennink, Chief Executive Officer of Pfenex added, "The acceptance of the PF708 MAA filing is an important milestone for Pfenex and Alvogen and demonstrates that through our collaborative partnership, we continue making progress towards potential approvals beyond the United States. Subject to applicable regulatory approvals, for Europe, PF708 will be commercialized by Theramex, a leading global specialty pharmaceutical company dedicated to Women's Health."

About PF708

PF708 is being developed by Pfenex as a therapeutic equivalent candidate to Forteo[®], which is approved and marketed by Eli Lilly and Company for the treatment of osteoporosis in certain patients with a high risk of fracture. Forteo[®]/ Forsteo[®] achieved \$1.6 billion in global product sales in 2018. PF708 is being developed pursuant to the 505(b)(2) regulatory pathway in the U.S. and references Forteo[®] as the Reference Listed Drug. PF708 has been filed with the EMA using the biosimilar pathway and references Forsteo[®] as the Reference Drug.

* Forteo[®]/ Forteo[®] are trademarks of Eli Lilly

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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.

Learn more about Alvogen on 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, the Company has created an advanced pipeline of potential therapeutic equivalents, novel biologics, vaccine and vaccine components, and biosimilars. The Company's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis. In addition, in collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz) the Company is developing hematologic oncology products, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension. Both PF743 and PF745 are being developed for the treatment of Acute Lymphoblastic Leukemia (ALL). We also use our *Pfēnex* Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates under development by third parties.

About Theramex

Theramex is 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, we support women at every stage of their lives. Our commitment is to listen and understand our patients, serve their needs, and offer healthcare solutions to help improve their lives. Our vision is to be a lifetime partner for women and the healthcare professionals who treat them by providing innovative, effect solutions that care for and support women as they advance through each stage of their lives.

Learn more about Theramex on www.theramex.com