For Immediate Release

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2018 Report: A Year of Successful US FDA Submissions

Germantown, MD, USA (March 06, 2019) – Amarex's Regulatory Affairs Department is pleased to announce a record year for new regulatory submissions to the US FDA. In 2018, Amarex submitted 13 Investigational New Drug (IND) applications, one Investigational Device Exemption (IDE) application, and one 510K application. Amarex also filed over 50 amendments to existing regulatory submissions in 2018.

Amarex President & CEO, Dr. Kazem Kazempour has 25+ years of experience working with the US FDA, beginning with his tenure as a Senior Staff Fellow, Mathematical Statistician at the FDA. Dr. Kazem Kazempour stated that, "Amarex's Regulatory Affairs department continues to offer a competitive regulatory strategy to clients, which is our basis for maintaining successful interactions with the FDA and foreign regulatory bodies. We approach regulatory affairs holistically, rather than viewing it as simply a process of jumping through hoops. In 2018, we experienced a number of changes to the drug approval process, including new eSubmission requirements, and we expect to see additional changes related to Digital Health that will require a new regulatory framework."

Amarex's regulatory experts are available to outline product development strategies that are efficient and cost effective, to manage FDA meetings, and to prepare and submit regulatory applications in North America, Europe, and Asia. Amarex has also established an eCTD submission system in order to comply with new FDA eSubmission requirements.

About Amarex
Amarex is a global, full service Contract Research Organization (CRO), whose leadership team has significant expertise conducting biomedical research, and whose combined experience includes the design and conduct of several hundred clinical research projects in many therapeutic indications. Amarex provides comprehensive services in Project Management (Phase I-IV, BE/BA, PK/PD), Regulatory Affairs, FDA Applications and Submissions, Applications and Submissions to international Health Authorities, GxP Compliance Audits, Clinical Operations, Adaptive Study Designs, Statistical Analysis, Data Management and General Consulting. Amarex has taken clients' products through the entire approval process from writing the initial product approval strategy to the marketing approval application with a growing list of approved products. Amarex is committed to cost effective, high quality clinical product development. For more information, visit www.amarexcro.com.

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