



Xendo announces partnership with QPS for the conduct of early phase radiolabelled studies in man

Groningen, the Netherlands, April 13, 2010: Xendo Drug Development BV, a European contract research organization (CRO), announced its latest collaboration with QPS LLC. As part of this collaboration, Xendo will partner with QPS to conduct and support early phase human radiolabelled studies.

Johan Wemer, M.D., Ph.D, Xendo's Chief Medical & Scientific Officer, stated: "This new partnership is an exciting new collaboration. QPS's reputation is world-renowned for their conduct of studies determining absorption, distribution, metabolism and excretion (ADME) patterns in laboratory animals (incl. those employing radiolabelled investigational products) and humans. These studies are employed at the discovery, candidate selection, investigational new drug (IND) enabling and new drug application (NDA) stages of a development program. In addition to conducting animal pharmacokinetic (PK) studies, QPS performs a comprehensive series of biotransformation and quantitative whole-body autoradiography (QWBA) studies.

All clinical aspects including submission and review procedures for radiolabelled studies in man, dosimetry calculations and submission of clinical trial application (CTA) to the local EC and Dutch Competent Authority of the radiolabelled studies will be performed by Xendo.

The complementary preclinical radiolabel and DMPK strengths of QPS add a new dimension to the CRO services that Xendo already provides, continuing to demonstrate our commitment to providing our clients with the highest standard of quality and expertise."

Xendo has a dedicated 24-bed clinical pharmacology unit (CPU) located at the premises of the University Medical Center Groningen (UMCG), a leading medical faculty in the Netherlands. Established in 2004, the CPU of Xendo has performed more than 100 clinical pharmacology studies - many of them first entry into man (FIM) studies - across all major therapeutic areas with an emphasis on CNS. With many years of experience, Xendo has robust processes in place and its hospital-based location provides a full suite of safety monitoring with 24/7 access to hospital-based crash teams and hospital specialists for therapeutic area expertise and patient recruitment. In addition, Xendo offers an extensive database of healthy volunteers and other patient populations.

The DMPK group at QPS, Newark, Delaware, have been screening many new chemical entities (NCEs) using the discovery pharmacokinetics (PK) approach for more than 8 years, resulting in more efficient identification of candidates with the most desired ADME properties.



Xendo's long pedigree in clinical pharmacology and expertise in early phase human radiolabelled ADME (including microdosing) studies combined with QPS's preclinical radiolabel capabilities are poised to provide the industry with a complete ADME data package that will fully support regulatory IND and NDA submissions.

The facilities of Xendo include a GMP clean room at the radiopharmacy of the UMCG, licensed for the manufacture as well as extemporaneous of radiolabelled drug products, including aseptic products for parenteral use. The close proximity of Xendo's own ionising radiation laboratory, also located in the UMCG, allows a rapid turn around of radioactivity data (within 24 hours). Human metabolites can be characterized by QPS by liquid chromatography with accurate mass, mass spectroscopy and concurrent radio-detection.

Company profiles:

About Xendo: Established in 1999, Xendo Drug Development BV is a European CRO with extensive experience conducting and staffing international Phase I to Phase IV clinical trials across a broad range of therapeutic areas for a wide variety of clients. Xendo employs approximately 100 people. Xendo provides early & late phase clinical development, data management, biometrics, medical writing, bioanalysis and resourcing solutions services. Further information is available at www.xendo.com.

About QPS: Established in 1995, QPS provides GLP/GCP-compliant preclinical and clinical research services to pharmaceutical and biotechnology clients worldwide in the areas of bioanalysis, DMPK, translational medicine research, early-phase clinical research, and clinical research services. Our regional laboratories are located at Newark, Delaware; Springfield, Missouri; and Taipei, Taiwan. Further information is available at www.qps-usa.com.

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