



CiToxLAB and KaLy-Cell join forces to offer *in vitro* and *ex vivo* testing for hepatotoxicity and metabolism

Evreux and Plobsheim, France, June 15, 2017 – CiToxLAB, a leading CRO in the field of non-clinical research, announces today its partnership with KaLy-Cell, a company specialized in the evaluation of hepatic toxicity and *in vitro* and *ex vivo* metabolism tests. This partnership will allow both companies to meet the growing demand from clients in the pharmaceutical, biotech and chemical industries for predictive tests to evaluate hepatotoxicity and to perform metabolism studies during product development.

KaLy-Cell was founded in 2003 by Professor Lysiane Richert. It offers *in vitro* and *ex vivo* studies to evaluate hepatotoxicity and detect potential drug-drug interactions. This unique expertise is documented in numerous scientific publications and is acknowledged by international pharmaceutical companies. KaLy-Cell is a partner in a number of European projects (such as EuroTransBio and IMI), bringing together hospitals, pharmaceutical companies and renowned university laboratories. It also contributes to the validation of regulatory tests in collaboration with EURL-ECVAM, the European reference laboratory for alternatives to animal testing.

With this partnership, *in vitro* and *ex vivo* testing (using hepatocytes and liver microsomes) will allow companies to evaluate hepatotoxicity and the potential effects linked to hepatic metabolism disorders; at early stages and during preclinical and clinical phases of development. The use of cultured multi-species hepatocytes will allow companies - to evaluate *in vitro* hepatic clearance (metabolite stability), - to identify the structure of resulting metabolites (Qtrap Orbitrap- Q exactive™), - to identify potential drug-drug interactions (cytochrome P450 and transporters), - to determine endocrine disrupting potential (i.e. thyroid and steroidal hormones), - to investigate the mechanisms using transcriptomics (Affymetrix™ technology or RT-PCR).

Dr. Jean-François Le Bigot, Chairman of CiToxLAB Group said: “We identified KaLy-Cell as a strategic partner, given that hepatotoxicity is still one of the most common causes for terminating a candidate drug’s development process and a significant factor in the refusal of marketing authorization for a drug or for restrictions on its use. Predicting potential toxicity during drug development is therefore a major issue for our clients. Early knowledge of drug metabolism through cellular models of animal and human hepatocytes is essential and contributes to rational choices, particularly the choice of the non-rodent species used during preclinical development.”

Pr. Lysiane Richert, Scientific Director of KaLy-Cell added: “We are particularly proud of this exciting partnership with the CiToxLAB Group. CiToxLAB offers testing capabilities in many preclinical models and state-of-the-art platforms in bioanalysis and metabolites characterization, along with a transcriptomic approach. This partnership will enable us to offer clients a full range of *in vitro* and *ex vivo* hepatotoxicity and metabolism tests in a comprehensive and integrated manner. KaLy-Cell’s large library of human hepatocytes will also allow integration of the notion of genetic polymorphism in the evaluation of a compound’s toxicological risk.”

About CiToxLAB

With six facilities located in France (Evreux, Saint-Nazaire), Canada (Montreal), Denmark (Copenhagen) and Hungary (Veszprem), the CiToxLAB Group offers a comprehensive range of preclinical services to meet the needs of pharmaceutical, biotechnology and chemical companies worldwide. CiToxLAB carries out studies in general and reproductive toxicology, carcinogenicity, immunology, pharmacology, pharmacokinetics and bioanalysis/biomarkers. Through Atlanbio (Saint-Nazaire, France), CiToxLAB offers both preclinical and clinical bioanalysis and biomarker services. With AccelLAB's entry into the Group, CiToxLAB now offers efficacy and safety studies in the area of medical devices (cardiology, ENT, orthopedics, dermatology and regenerative medicine). A partnership with Stemina (Madison, USA) allows the Group to offer screening services using human embryonic stem cell models. Today, CiToxLAB has more than 1,000 employees working at six sites representing 65,000 sq meters of state-of-the-art facilities. The company has a world-class, top-level management team in scientific, financial and business activities.

www.citoxlab.com

About KaLy-Cell

KaLy-Cell has decades of experience in hepatocyte isolation, cryopreservation and culturing as well as *in vitro* and *ex vivo* ADME-Tox and Metabolism assays. By combining scientific expertise in cell and molecular biology, toxicology and analytics, KaLy-Cell has been instrumental in advancing the understanding of *in vitro* models and in improving predictions of toxicity, drug-drug interactions and safety assessments. KaLy-Cell produces high quality hepatocytes of both human and animal origin. It offers them in fresh and cryopreserved formats along with the appropriate media for use in preclinical *in vitro* ADME-Tox applications. KaLy-Cell also offers a variety of contract research services to the pharmaceutical industries for drug candidate safety evaluation.

www.kaly-cell.com

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