

Qualyst Transporter Solutions and Kaly-Cell Announce the Transporter Certification™ of Human Cryopreserved Hepatocytes

Transporter Certification™ of Kaly-Cell cryopreserved hepatocytes

Research Triangle Park, NC, 18 June 2013 – Qualyst Transporter Solutions, LLC, has completed its Transporter Certified™ process on two high-quality, plateable cryopreserved human hepatocytes from Kaly-Cell. The Transporter Certified™ process uses the patented B-CLEAR® technology to assess hepatocytes for uptake and efflux transporter function, endogenous bile acid formation, as well as metabolic activity. Using Transporter Certified™ hepatocytes means that users can be sure that their cells will maintain a fully-functioning complement of hepatic transporters, reflect *in vivo*-relevant intracellular concentrations of drugs, and produce *in vivo* relevant results.

Transporter certification provides confidence in choosing cryopreserved hepatocytes, and, these cells can be used in Qualyst Transporter Solutions-approved B-CLEAR® studies. Instead of purchasing fresh B-CLEAR® kits, now cryopreserved hepatocytes can be purchased separately and used for all hepatocyte studies, including B-CLEAR® work. All that is required is a media-based Cell-Less B-CLEAR® Kits to perform any B-CLEAR® studies. “Here is another example of where partnering with a key hepatocyte supplier has allowed us to offer customers more options to access the B-CLEAR® technology and obtain human hepatocytes with acceptable quality for B-CLEAR® studies,” said Dr. Christopher Black, CEO of Qualyst Transporter Solutions. “We are fortunate to be able to partner with such a high-quality provider of human hepatocytes,” said Dr. Black.

Kaly-Cell’s cryopreserved human hepatocyte lots, S1099 and S1163, have been Transporter Certified™. Aside from the confidence Transporter Certified™ brings, using cryopreserved hepatocytes also offers clients the ability to perform studies on their own schedule. In addition, the variability from donor-to-donor is eliminated if one donor is available for multiple experiments and multiple compounds. Although Transporter Certified™ cryopreserved hepatocytes are essential in studying hepatic drug transporters, having transporter function in other hepatic studies is critical since these proteins dictate what the intracellular concentration of a drug and its metabolites will be. “Some examples of studies where this is critical, outside of studying transporters, include hepatotoxicity, P450 induction, and metabolism studies,” said Dr. Kenneth Brouwer, CSO of Qualyst Transporter Solutions.

The Cell-Less B-CLEAR® Kits, along with the standard fresh hepatocyte kits, are available from Qualyst Transporter Solutions. Transporter Certified™ cryopreserved hepatocyte lots S1099 and S1163, are available from Kaly-Cell.

About Qualyst Transporter Solutions, LLC

Qualyst Transporter Solutions is the world’s exclusive provider of hepatic drug transporter products and contract research services utilizing the patented B-CLEAR® technology. Qualyst Transporter Solutions commercializes novel and proprietary drug transport and

hepatobiliary disposition assay services and products for drug discovery and development. The technology, in conjunction with human and animal hepatocytes, provides a fully integrated, unique physiologic model that combines uptake and efflux transporters with hepatic metabolism. This integrated model can address questions related to compound clearance, drug transporter interactions, and cholestatic/hepatotoxic potential. For additional information, please refer to the company's web site at www.qualyst.com or call +1 (919) 313-6500.

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 assays. By combining scientific expertise in cell and molecular biology, toxicology and analytical, 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, both human and animal origin, and offers them in fresh and cryopreserved formats along with the appropriate media for use in pre-clinical *in vitro* ADME-Tox applications. Kaly-Cell also offers a variety of contract research services to the pharmaceutical industries for drug candidate safety evaluation. For additional information, please refer to the company's website at www.kaly-cell.com or call +33-388-108-830.

Media Contact

For more information, contact Qualyst Transporter Solutions, (919) 313-6500, marketing@qualyst.com

##END##