

Qualyst Transporter Solutions Announces New License Deal with Bioreliance® on New Transporter Knock-out Products and Services

The first integrated hepatocyte system to knock-out specific drug transporters

Research Triangle Park, NC, 20 April 2015 – Qualyst Transporter Solutions (QTS) is pleased to announce the completion of a non-exclusive license agreement with BioReliance®, Sigma-Aldrich Corporation's (NASDAQ: SIAL) biologics and early-development services business under SAFC® Commercial (www.sigmaaldrich.com/safc) to allow QTS' proprietary B-CLEAR® Technology to be used in their new transporter knock-out products and in HepaRG™-related contract research services. These products aim to exclude key drug transporters, such as BSEP, OATPs, and P-gp, from the hepatic HepaRG cell line in order to assess their impact in drug disposition and drug interactions. The B-CLEAR® Technology was used in the development of these cell line products to ensure proper transporter function and it can also be used by end-users after purchasing the products.

QTS' B-CLEAR® technology refers to a patented methodology that, when applied to properly functioning hepatic cells, opens the bile pockets (analogous to bile canaliculi *in vivo*), allowing material that has been transported from inside the cell to be measured. Measuring biliary efflux allows for the evaluation of biliary clearance, transporter interactions, and intracellular concentration. The B-CLEAR® technology is patented in over 45 countries worldwide.

Sigma has generated transporter knock-out cell lines using the CompoZr® Zinc Finger Nuclease (ZFN) technology in HepaRG™ cells which will allow researchers to discern effects from a single transporter. This has historically been a challenge as primary hepatocytes, and HepaRG cells, express all of the hepatic transporters, which means that isolating effects from a single transporter has been very difficult. QTS has been able to provide the means, through B-CLEAR®, to measure compound uptake and efflux into the bile pocket. In addition, the method can evaluate the overall integrated effect of transporters and metabolism together by measuring the intracellular concentration of a compound. The intracellular concentration is the result of the balance of all of these processes and the driving force for everything that happens inside a hepatocyte.

“We are extremely excited about the use of B-CLEAR® in these innovative HepaRG transporter products since it means researchers will now have a way to study single transporters within a complex, whole cell system. We see applications from transporter screening all the way to definitive transporter drug interactions testing,” said Dr. Christopher Black, CEO for Qualyst Transporter Solutions.

“Because the B-CLEAR® Technology exclusively allows you to measure compound in the bile pocket, we provide the only way to measure physiologic intracellular concentrations. Whether you are interested in uptake transporter knock-outs or efflux transporter knock-outs, measuring changes in intracellular concentration is the perfect read-out to understand their effects,” said Dr. Kenneth Brouwer, CSO for Qualyst Transporter Solutions.

About Qualyst Transporter Solutions, LLC

Qualyst Transporter Solutions commercializes novel and proprietary drug transport and hepatobiliary disposition products for research in drug induced liver injury, hepatotoxicity, drug interactions and drug metabolism. Qualyst Transporter Solutions products and contract services provide clinically-relevant answers to liver-related questions through the use of a proprietary technology, B-CLEAR[®], that yields physiologic intracellular concentrations by ensuring proper metabolism and transport function. In addition, Qualyst Transporter Solutions has pioneered and an industry-accepted standard of hepatocyte function for cryopreserved human hepatocytes called Transporter Certified™, which is available from most hepatocyte providers. The B-CLEAR[®] technology is covered by US (# 6780580), EU (#1163517) and JP (#4451570) patents issued and pending. For additional information, please refer to the company's web site at www.qualyst.com or call (919) 313-6500.

About BioReliance by SAFC: As part of the Sigma-Aldrich Corporation, operating under the SAFC Commercial business unit, BioReliance is a key component of the company's commercial life science services portfolio. With locations worldwide, BioReliance offers more than 1,000 tests and complementary services related to biologics safety testing and specialized toxicology. For more information, visit www.bioreliance.com.

About SAFC: [SAFC Commercial](http://www.sigma-aldrich.com/safc), the custom manufacturing and services business unit of Sigma-Aldrich Corporation, is recognized as a top 10 global specialty chemicals and biologics supplier. As a trusted manufacturer for the life science and high-technology industries, SAFC works closely with customers to resolve development challenges and accelerate the product pipeline using its global "Centers of Excellence" and dedicated manufacturing facilities. Its rich portfolio includes high-purity inorganic materials for high-technology applications, critical raw materials and extensive biologics safety testing services for biopharmaceutical manufacturing, and complex, high-potent APIs and key intermediates for pharmaceutical manufacturing. For more information, visit www.sigma-aldrich.com/safc

Media Contact

Qualyst Transporter Solutions, Christopher Black, Ph.D. Chief Executive Officer, (919) 313-6511, information@qualyst.com

##END##