

Qualyst Transporter Solutions Announces Herbal-Drug Interactions Testing Strategy with P&G

Utilizing the B-CLEAR[®] technology in order to predict clinical herbal-drug interactions (HDI)

Research Triangle Park, NC, 30 March 2015 – Qualyst Transporter Solutions is pleased to announce the launch of a new program in conjunction with Procter & Gamble (P&G) aimed at utilizing B-CLEAR[®] technology to assess potential herbal cytotoxicity and herbal-drug interactions. Herb-drug interactions are not a new concept to the industry but trying to assess and predict these potentially serious drug interactions using complex herbal mixtures has proven to be a difficult task. Many of these interactions occur in the liver, the primary site of both drug and herb metabolism. One of the primary obstacles has been identifying a liver model system that integrates all of the major hepatic processes and provides confidence in the prediction of potential *in vivo* interactions.

As the use of herbal medicines increases, herbs are often administered in combination with conventional drugs, thereby, increasing the potential for herb-drug interactions. Herbal-drug interactions have been known for decades and include some commonly available products like St. John's Wort as well as foods such as grapefruit juice. These herbals or foods can interact with or change how the body metabolizes many drugs, potentially resulting in inactivity of the drug or worse, toxicity. For example, changes in drug metabolism by the use of some herbal products or foods can result in insufficient levels of contraceptives leading to unplanned pregnancies. In the case of critical cancer or retroviral treatments, a loss in drug efficacy can be the difference between life and death. Because of these potentially life-threatening interactions, understanding, predicting, and informing consumers is of paramount importance.

B-CLEAR[®] technology uses liver-derived cells called hepatocytes and allows researchers to culture them in a way that mimics function in the human liver. "The key for our hepatic model is that all of the basic functions remain intact, including uptake into the cell, metabolism inside the cell, and efflux out of the cell," said Dr. Christopher Black, CEO of Qualyst Transporter Solutions. "Since our primary goal is to predict *in vivo* hepatic disposition, a model that integrates everything together is key," said Dr. Black. This model has been selected by P&G in order to screen their portfolio of herbals and extracts for potential drug interactions. Data from these studies will be used to inform consumers on product labels regarding the safe use of these products as well as help direct appropriate follow-up safety work.

The cornerstone to the B-CLEAR[®] technology is using high-quality hepatocytes that have been certified by Qualyst Transporter Solutions. Cells that have received this certification are labeled Transporter Certified™ and are appropriate for use in all types of drug transport, metabolism, drug interaction, and liver toxicity studies. "Multiple processes including transport and metabolism can be involved in these interactions, and evaluation in a system that integrates these processes is critical for clinical predictions," said Dr. Kenneth R. Brouwer, CSO Qualyst Transporter Solutions. "Transporter Certified™ hepatocytes and our patented B-CLEAR[®] technology provide an optimal system to predict these interactions," said Dr. Brouwer.

P&G, and its wholly-owned subsidiary New Chapter, have a number of herbal products that are eligible for this type of testing. "Our goal with this program is two-fold. First, we want to help inform the consumer as it relates to the usage and safety of our products. Second, if we have to do additional or expanded safety testing in order to provide more information to the consumer, we would like to know how to focus those efforts using predictive data," said Dr. Amy Roe, Director of Metabolism & Pharmacokinetics at P&G. "We are excited about this program and also about establishing a new paradigm for the industry in safety testing for herbal products," said Dr. Roe.

About Qualyst Transporter Solutions, LLC

Qualyst Transporter Solutions commercializes novel and proprietary drug transport and hepatobiliary disposition products for drug discovery and development. Qualyst Transporter Solutions products provide answers to transporter questions that arise in drug discovery and development. For additional information, please refer to the company's web site at www.qualyst.com or call (919) 313-6500.

About Procter & Gamble

P&G serves nearly five billion people around the world with its brands. The Company has one of the strongest portfolios of trusted, quality, leadership brands, including Always®, Ambi Pur®, Ariel®, Bounty®, Charmin®, Crest®, Dawn®, Downy®, Fairy®, Febreze®, Gain®, Gillette®, Head & Shoulders®, Lenor®, Olay®, Oral-B®, Pampers®, Pantene®, SK-II®, Tide®, Vicks®, Wella® and Whisper®. The P&G community includes operations in approximately 70 countries worldwide. Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

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