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# **Cryoport Partners with KCAS Bioanalytical and Biomarker Services and Heat Biologics on Comprehensive Logistics Study for Bioanalytical and Clinical Trial Materials**

IRVINE, Calif., Aug. 29, 2016 /PRNewswire/ -- Cryoport, Inc. (NASDAQ: CYRX, CYRXW) ("Company"), the world's leading temperature-controlled logistics company serving the life sciences industry, today announced that it has initiated a novel and comprehensive logistics study to evaluate the impact of temperature and transport packaging at deep frozen temperatures on critical biomarkers and cell-therapy cancer vaccines, respectively, in conjunction with partners KCAS Bioanalytical and Biomarker Services ("KCAS") and Heat Biologics, Inc. ("Heat").



**SCIENCE. LOGISTICS. CERTAINTY.**

Very little is documented about the impact of dynamic transportation conditions and temperature on critical bioanalytical materials and their influence on the data generated and required to support drug development programs. Cryoport, in conjunction with KCAS and Heat, has initiated a broad based study to scientifically compare the effect of logistics shipping systems and temperature on bioanalytical sample quality, assay performance and stability of investigational cell therapeutics. This study will evaluate the use of dry ice in various packaging configurations as well as Cryoport Express® Dry Vapor Shippers.

The packaging configurations selected for this study will utilize Cryoport's advanced Smart Pak II™ Condition Monitoring System to evaluate the condition and impact of dynamic transit conditions on the stability and bioanalytical recovery of 30 different plasma biomarkers as well as the cell viability and assay performance of *ImPACT*® allogeneic cancer vaccines. The goal of this study is to better understand how various logistics choices, as well as dynamic transport conditions, such as deviation from estimated transit times, temperature excursions and carrier handling, impact the condition and efficacy of the commodities shipped.

Michael Lanman, Vice President of Operations at KCAS, commented, "Data integrity supporting the bioanalytical process has always been of critical importance to KCAS. We

have experienced, first hand, the impact of poor logistics decisions on the quality of inbound frozen clinical samples. This study is crucial to the future of bioanalytical development as it will provide guidance on which temperatures and packaging provide the optimal conditions to maintain sample reliability during secured transport. We are pleased to be working with Cryoport to gain a better understanding of the impact of global transportation on critical biomarkers used in evaluating efficacy of therapeutics in clinical trials."

Taylor Schreiber, M.D., Ph.D., Heat's Chief Scientific Officer, commented, "We are pleased to continue working with Cryoport in our current trials and during our ramp-up for Phase 3 for HS-410, as they are a global leader in supporting logistics in the cell therapy space. The data generated from this study will be instrumental to our Phase 3 planning, and by leveraging these data and Cryoport's capabilities, we believe that we can maximize the benefits of our off-the-shelf *ImPACT* cancer immunotherapy."

"We are pleased that we have two very committed partners working with us to better understand the impact of temperature and/or transport on the integrity of materials critical to bioanalytical development and the clinical trial process. These studies will not only assist us in improving our understanding of the impact of transportation choices, it will be a strong educational tool to the entire biopharma industry. Cryoport is dedicated to providing data-derived and scientifically supported solutions in the logistics space, and these studies are expected to significantly augment our current understanding," commented Mark Sawicki, Ph.D., Chief Commercial Officer of Cryoport, Inc.

#### **About Cryoport, Inc.**

Cryoport is the premier provider of cryogenic logistics solutions to the life sciences industry through its purpose-built proprietary packaging, information technology and specialized cold chain logistics expertise. The Company provides leading edge logistics solutions for biologic materials, such as immunotherapies, stem cells, CAR-T cells and reproductive cells for clients worldwide. Cryoport actively supports points-of-care, CRO's, central laboratories, pharmaceutical companies, contract manufacturers and university researchers. For more information, visit [www.cryoport.com](http://www.cryoport.com).

To download Cryoport's investor relations app, which offers access to SEC documents, press releases, videos, audiocasts and more, please click to download from your [iPhone and iPad](#) or [Android mobile device](#).

#### **About Heat Biologics, Inc.**

Heat Biologics, Inc. (Nasdaq: HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumacel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). For more information, please visit [www.heatbio.com](http://www.heatbio.com).

## About KCAS

KCAS Bioanalytical & Biomarker Services is a contract laboratory with 36+ years of bioanalytical expertise. Centrally located in Kansas City, KCAS provides small- and large-molecule PK, immunogenicity, and biomarker analysis operating a variety of equipment platforms to service a wide range of therapeutic areas. KCAS' team leverages a highly scientific staff with an average tenure of 14 years at the company to provide clients of all sizes with expertise in robust assay development, validation, and sample analysis under non-GLP, GLP, and GCP conditions for discovery, preclinical and clinical studies. Our teams have developed and validated more than 5,500 bioanalytical assays and have undergone 15 FDA inspections. Learn more at: [www.kcasbio.com](http://www.kcasbio.com)

## Forward Looking Statements

*Statements in this news release which are not purely historical, including statements regarding Cryoport, Inc.'s intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, risks and uncertainties associated with the effect of changing economic conditions, trends in the products markets, variations in the company's cash flow, market acceptance risks, and technical development risks. The company's business could be affected by a number of other factors, including the risk factors listed from time to time in the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended March 31, 2016. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Cryoport, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.*

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/cryoport-partners-with-kcas-bioanalytical-and-biomarker-services-and-heat-biologics-on-comprehensive-logistics-study-for-bioanalytical-and-clinical-trial-materials-300318983.html>

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