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Global Genomics proposes state-of-the-art performance standards for FDA pharmacogenomics initiative

Global Genomics has proposed state-of-the-art performance standards for gene expression profiling in a response to the recent draft document, “Guidance for Industry: Pharmacogenomics Data Submissions”, from the United States Food and Drug Administration (FDA).

Global Genomics AB is a Swedish-based biotechnology company developing tools for research into functional genomics. Dr. Ulf Boberg, CEO at Global Genomics, explained the importance of the FDA initiative, “Pharmacogenomic research deals with small genetic differences that can explain why individuals respond differently to a therapeutic drug. Such studies have the potential to enable development of individualized therapies by predicting which individuals have a greater chance of benefit or risk. With an estimated 2 million cases of adverse drug reactions in US hospitals annually and an estimated cost to the US economy in drug-related morbidity and mortality of $177 billion, there are clear financial and social advantages in maximizing the efficacy and safety of drug treatment.”

Dr. Boberg continued, “Genes and their expression are a central focus of these studies; they act as blueprints for the millions of proteins that serve as messengers and activators of healthy and abnormal biological processes. We believe that it is essential to establish key gene expression technology standards in order to elevate the quality of gene expression analysis data and promote the best scientific research. Our own research and development plans are focused towards producing the highest possible quality and information content. We recently introduced tangerine gene expression profiling, a technology that provides a comprehensive whole genome expression profile in a single experiment. Unlike microarray technologies, our solution enables the study of gene regulation in any disease or eukaryotic model since there is no prerequisite for sequence data. High coverage and high sensitivity produce a reliable and complete profile of expressed genes, giving unique insights into processes taking place in healthy, diseased or drug-treated cells. Tools of this type are essential to enable biotechnology and pharmaceutical firms to develop more effective, targeted therapies and FDA guidelines should reflect the optimum test systems and techniques available”.

Detailed information about Global Genomics and the FDA initiative is available in the press room at www.globalgenomics.com

About Global Genomics

Global Genomics drives drug discovery. The company combines molecular biology and computational analysis to develop innovative tools that reveal the mechanisms involved in disease and therapeutic treatment.

The company's first product tangerine gene expression profiling is a proprietary solution that provides comprehensive gene expression profiles of any disease in any species, with no requirement for initial sequence information. Detailed information from tangerine profiling gives a unique insight into processes taking place in healthy, diseased or drug-treated cells. Incorporating such comprehensive gene expression profiling at key stages in drug discovery significantly improves selection of targets and lead compounds, leading to well-validated drug candidates and expediting development of a strong pharmaceuticals portfolio.

Investors include HealthCap KB, HBM Bioventures AG, Karolinska Investment Fund AB and ABN AMRO Participaties B.V.

Global Genomics is headquartered at the Karolinska Science Park in Stockholm, Sweden.

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