EPISTEM PLC AND ASTRAZENECA COMPLETE PLUCKED HAIR BIOMARKER STUDY FOR ONCOLOGY DRUG DEVELOPMENT

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The companies have demonstrated that single plucked hairs sampled over multiple time points provide effective levels of RNA for gene expression measurement. The study also showed that the process was well tolerated by subjects and samples proved robust during shipment and storage. Over 85% of hairs sampled were evaluable for measurement. Further analysis of single hairs also established reliable detection of over 13,000 genes in single hairs, which can be used to establish 'core gene sets' for biomarker drug discovery, validation and patient selection. A joint scientific abstract of the study was recently presented at the AACR-NCI-EORTC meeting in San Francisco.

The hair biomarker provides the industry with a potentially powerful tool to measure the effects of new cancer treatments and their translation from preclinical through to clinical phases, enabling more informed go/no go decisions to be undertaken at an earlier stage. The identification of appropriate biomarkers within drug development is gaining greater importance with the launch last year of The Biomarkers Consortium founded by The Foundation for the National Institutes of Health (FNIH), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). AstraZeneca is an active member of the consortium, with the consortium's aim to identify new biomarkers that could accelerate the delivery of new clinical treatments and medicines for prevention, early diagnosis, and treatment of disease.

Epistem and AstraZeneca plan to explore hair follicle core gene sets based on drug-induced gene expression in pathways of interest for specific therapeutics. Identified gene expression changes in the hair follicle will be linked to changes in tumours to determine drug exposure, toxicity and dose response leading to patient selection.

Matthew Walls, CEO, Epistem stated: “We are excited at the initial results that our companies have made in developing an RNA based biomarker for drug development. AstraZeneca was the first of the top tier pharmaceutical companies to begin feasibility studies for the use of our hair biomarker platform and the successful completion of these studies bodes well for the proposed next steps in our joint development collaboration.”.

Professor Andrew Hughes, Clinical Director of Discovery Medicine, AstraZeneca commented “Epistem are clearly at the forefront of understanding gene expression profiling in plucked human hair and its utility to drug development. Our published results clearly demonstrate that the method is both feasible and practical; and offers the promise of providing insights into both dose and patient selection.”