Epistem presents GenetRx™ clinical data on the use of scalp hair to assess androgen receptor directed therapies and to identify novel pharmacodynamic markers for an antisense molecule, at the AACR-NCI-EORTC meeting in Boston

MANCHESTER, UNITED KINGDOM -- (Marketwire-November 9, 2009) - Epistem plc (LSE: EHP), the leading biotechnology company, will present results from two recently completed clinical studies. The first study, with a leading pharmaceutical company, demonstrates androgen receptor pathway activity in hair from elderly volunteers. In the second phase I study, novel pharmacodynamic markers for Enzon Pharmaceuticals Inc’s survivin messenger ribonucleic acid (mRNA) antagonist were identified from hair follicle analysis. Data will be presented in poster sessions at the AACR-NCI-EORTC “Molecular Targets and Cancer Therapeutics” Conference, Boston on Monday 16th November and Wednesday 18th November 2009.

The first study was completed successfully in 12 healthy normal volunteer elderly men and involved collection of plucked eyebrow and scalp hair. Dr Ged Brady will present data which demonstrates plucked human scalp hairs as a preferred tissue for assessing androgen receptor directed therapies. Quantitative PCR analysis identified a panel of 7 genes which were reliably expressed in most scalp hairs. This gene panel could be used to monitor drug induced gene expression change for compounds targeting the androgen receptor pathway, whilst using single plucked hair as a surrogate tissue with a minimally invasive sampling process. Data will be presented in:
Poster Session C, Abstract C130: Plucked human scalp hairs are a suitable tissue for assessing androgen receptor directed therapies. Wednesday 18th November 12:30 pm - 2.30 pm

In the second Phase I dose escalation study in cancer patients, hair follicle analysis was used to identify novel pharmacodynamic markers to support dose scheduling decisions for Enzon Pharmaceutical Inc’s compound EZN-3042 (a novel survivin messenger ribonucleic acid (mRNA) antagonist). These results will be presented in:
Poster Session A, Abstract A99: EZN-3042 (E), a novel survivin messenger ribonucleic acid (mRNA) antagonist, administered as a single agent (SA) or with docetaxel (D): results of a Phase 1, first-in-human, pharmacokinetic (PK), combination after single agent (CASA) dose-escalation study. Monday 16th November 12.30 pm - 2.30 pm

Epistem has previously presented data on the use of GenetRx™ technology to monitor the effects of a range of different classes of drugs including: erlotinib, an epidermal growth factor receptor inhibitor; gemcitabine, commonly known as Gemzar and a c-Met inhibitor. These positive new data confirm the clinical utility of GenetRx™ to monitor drug induced changes in epithelial tissue. Epistem is active in collaborations with partners developing compounds which modulate the Notch, c-Met and Hedgehog signalling pathways.

“We are extremely pleased that our technology is sufficiently sensitive to identify a panel of genes applicable for further clinical investigation using plucked hair. We are encouraged that we were able to identify a robust gene set with low variability by generating a large sample set from just 3 individual scalp hairs per timepoint, per subject.” said Lydia Meyer-Turkson, Vice President of the Biomarker Division at Epistem plc. “In addition, the survivin antagonist data validates our technology for the assessment of antisense molecules in the clinic. Data from these studies strongly supports the case for plucked hair as a valuable surrogate tissue, with broad utility, to measure transcriptional changes and pharmacodynamic response for a range of oncology therapies”. 
The posters will be available on request following presentation. For further information on the Company please visit www.epistem.co.uk or contact:

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Notes to Editors:

About Epistem

Epistem is a biotechnology company commercialising its expertise in epithelial stem cells in the areas of oncology, gastrointestinal diseases and dermatological applications. Epistem develops innovative therapeutics and biomarkers and provides contract research services to drug development companies. The Group’s expertise is focused on the regulation of adult stem cells located in epithelial tissue, which includes the gastrointestinal tract, skin, hair follicles, breast and prostate. Epistem does not conduct research in the areas of embryonic stem cells or stem cell transplantation.

Epistem operates three business divisions, Biomarker, Contract Research Services, Novel Therapies.

The Biomarker division, with offices in Manchester, England and Cambridge, MA collaborates with drug development companies to identify and validate novel biomarkers, using Epistem’s innovative GenetRx™ technology. GenetRx™ is the company’s cDNA gene expression profiling technology which has the ability to analyse individual plucked hairs, blood and other tissue samples which are traditionally difficult or too small to analyse by other methods. This includes the bulb of cells at the base of the hair follicle, providing a simple, robust means of measuring biological response in epithelial tissue. Changes in gene expression can be detected within hours of treatment with low levels of chemotherapy or radiation.