Ember Trial: Evaluation of Multiple Protein and Molecular Biomarkers to Estimate Risk in Gynecology Patients Presenting with a Pelvic Mass

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** Cross Section of Ember System

** Plan View of Ember System

** Captured CTCs Blood Flow White blood cells Red blood cells pass through Patented step

** Comparison of ROC-AUCs for single and all combinations of genes. a) For protein serum biomarkers to discriminate between benign (n=104) versus cancer (n=62) showed that a multivariate model combining the expression levels of 8 genes and 4 serum protein biomarkers achieved the highest AUC (91.7%). b) This combined rare cell gene expression and serum biomarker model significantly outperformed models using: HE4 & CA125 (AUC = 86.9%, p<0.005); CA125, prealbumin, apo-A1, transferrin & β2-microglobulin (AUC = 87.4%, p<0.001); and CA125, transferrin, apo-A1, FSH & HE4 (AUC = 89.9%, p<0.017) (see Figure 3).

** The combination of rare cell gene expression & serum protein biomarker model achieved an AUC of 88.3% for patients with stage 1-2 EOC and 88.8% for patients with stage 3-4 EOC (Figure 4.

** Data Analysis: Univariate and multivariate logistic regression analyses of the gene expression and serum protein marker data were conducted, and ROC curves constructed and compared (Figures 3 & 4).

** The unique rare cell gene expression profile coupled with the serum protein expression levels provided complementary insights which significantly improve the detection of cancer in women with a pelvic mass compared to the use of the current serum biomarker approach alone.

** Optimization of this combined approach is currently underway, with evaluation of additional gene targets and protein markers in further studies being planned.

** The Ember System is a novel method for capturing circulating tumor cells (CTCs) from whole blood without interference from contaminating cells. The system is designed to capture rare CTCs while allowing the passage of most normal cells. The captured CTCs can then be analyzed for gene expression using next-generation sequencing (NGS), providing valuable insights into the biology of the tumor.

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