Flagship Biosciences Further Refines Tumor Heterogeneity Analysis With Presentation at the 2011 San Antonio Breast Cancer Symposium

*Technique evaluates heterogeneity of tumors using novel image analysis algorithms with standard immunohistochemistry techniques*

San Antonio, Texas (PRWEB) December 14, 2011 -- Flagship Biosciences presented a poster at the San Antonio Breast Cancer meeting “Evaluating Tumor Heterogeneity in Immunohistochemistry Stained Breast Cancer Tissue”, which demonstrated a unique approach to quantifying variation in HER2 staining in breast biopsies called HetMap(TM). In this study, Flagship used the Aperio HER2 quantification algorithm, a 510(k) cleared image analysis method already in clinical practice, to sample over 4800 regions of interest in over 200 breast cancer biopsies which had been evaluated by 3 different pathologists for molecular diagnosis. HetMap(TM) combines this or any other digital tissue imaging methodology, along with mathematical equations rooted in the study of ecology, to quantify heterogeneity between neighboring cells and within the entire tissue section.

“As a provider of tissue analytic services and image analysis approaches to quantify biomarkers in clinical tissue, Flagship Biosciences has tremendous experience and expertise in analyzing in situ biomarkers in clinical biopsies of complex tissues such as breast,” stated Dr. Steven Potts, CEO of Flagship Biosciences. "Proper assessment of a biomarker which is used to make patient decisions, such as HER2, is critical to deciding what targeted therapies may be used to treat the patient. HetMap(TM) demonstrates where a sample may require further evaluation by pathologists or reflex testing; or identify samples which may not have been stained properly due to poor tissue quality or sample processing”.

Flagship Biosciences method of evaluating the heterogeneity of HER2 in breast biopsies demonstrated the need for incorporation of such a measurement in the normal clinical use of the assay. In the study presented, Flagship compared the inter-pathologist scores of HER2 scoring for the same samples. In the cases where the pathologists disagreed most, tumor heterogeneity was highest as measured by HetMap®. In these cases with a high HetMap(TM) score, the pathologists frequently disagreed on whether to classify a tumor as a 1+ vs a 2+ score, which is the decision point between whether or not a patient should receive anti-HER2 therapy such as Herceptin®. As well, the highest Hetmap(TM) scores correlated with when pathologists agreed on a 2+ vs 3+ score, which is the cutoff point where HER2 “reflex” FISH testing is required to make a final decision. Both of these situations could have tremendous impact on the patient, as they may not receive anti-HER2 therapy as a result of the differences in these pathologist scores.

“Breast cancer is the one of the most heterogeneous tissues, and demonstrates a wide range of tissue morphologies, stromal and immune infiltrates, and variation in staining patterns for ER, PR, and HER2. The difficulty in scoring patients with significant heterogeneity has led to the implementation of HER2 gene amplification testing, which is currently controversial due to the frequent lack of correlation between HER2 amplification and protein expression, heterogeneity in HER2 FISH results, and clinical studies which show benefits of Herceptin® in patients who were classified as HER2 FISH negative. Clearly, the patient stratification paradigm for HER2 scoring needs to address these issues, and evaluating heterogeneity is a key step.” said Dr. David Young, Chief Pathologist of Flagship Biosciences.

Dr. Joseph Krueger, the Director of Biology for Flagship Biosciences, attended the conference and presented the poster. Dr. Krueger noted that several lectures at the conference discussed genetic heterogeneity in tumors.
Dr. Krueger said “Advances in the technical ability to examine mutations in clinical tissue through nextgen sequencing approaches have been applied evaluating genetic heterogeneity in breast tumors, and the results have surprised everyone. Within a breast tumor, there are in fact several different genotypes, all of which may respond to therapy differently.”

Dr. Krueger noted that much of the current research being performed in academic institutions and pharmaceutical companies places significant emphasis on the use of patient-derived xenograft models for preclinical breast cancer studies, to capture the normal tissue complexity seen in patient samples. This translational research approach is used to predict which types of patients will respond to a new drug candidate to try and define a clinical trial approach. “Because of advances in digital imaging technology, we are able to quantify a biomarker in the actual patient tissue, without the need for using patient-derived xenograft models to make quantitative measurements. In addition to its potential use in existing IHC-based companion diagnostics, HetMap(TM) is a valuable tool for fast-tracking the examination of putative biomarkers in clinical tissue, as well as defining better patient stratifications for ongoing trials relying on a companion diagnostic approach. I expect to see many drug companies relying on a tumor heterogeneity measurement as part of their strategy in the future”.

The patent pending approach is used for research purposes and pharmaceutical drug development only. The presentation “Evaluating Tumor Heterogeneity in Immunohistochemistry Stained Breast Cancer Tissue” is available on-line.

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