Docket #: S19-458

Biomarkers Predict Response to HER2-Targeted Breast Cancer Therapies

Researchers at Stanford have leveraged spatial proteomic analysis to identify biomarkers with immediate implications for HER2-positive breast cancer treatment decision making and patient stratification. By comparing protein marker levels in the on-treatment "run-in" biopsy versus the pre-treatment "baseline" biopsy, they have demonstrated that they can predict response to neoadjuvant HER2-targeted therapy in HER2- positive breast cancer, thus determining which patients will achieve a pathologic complete response (pCR) and which will not after just one cycle of targeted therapy. Currently, there are no available biomarkers apart from the HER2 oncogene itself to predict patient outcomes during neoadjuvant HER2- targeted therapy. Such biomarkers could be used to escalate/de-escalate or change therapy and address a pressing clinical need. Importantly, the biomarkers reported here could be assessed (and likely re-discovered) using conventional immunohistochemistry which can readily be deployed in a clinical setting.

Stage of Development
In vivo. The researchers continue to validate their findings in additional clinical trial samples and using other methods (e.g., standard and multiplexed immunohistochemistry).

Applications

- Biomarkers to inform the development of an in vitro diagnostic assay based on proteomic analysis of breast tumor biopsies

Advantages

- There is critical need to identify biomarkers that predict response before or early in the course of therapy
- Could enable clinicians to tailor and potentially adapt/alter therapy

Publications

- McNamara, Katherine L., et al. "Spatial proteomic characterization of HER2-positive breast tumors through neoadjuvant therapy predicts response." *Nature Cancer* 2.4 (2021): 400-413.

Patents

- Published Application: WO2021087167
- Published Application: 20230047712

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