Docket #: S19-380

Methods of treatment based on molecular characterization of breast cancer

Stanford researchers have formulated a statistical model to determine the risk of breast cancer recurrence with unprecedented accuracy in women 5 – 20 years after initial diagnosis. By categorizing distinct genome-driven subsets of breast cancer, inventors were able to determine the rate, route, and location of tumor metastasis with utmost precision. Currently, doctors rely on the size/grade of the tumor and the degree of lymph node spread but the exact course of the tumor is unknown especially after the patient was considered cured (after 5 yrs post diagnosis). This leaves doctors with no full-proof way to plan careful clinical follow-ups--ultimately missing critical cancer recurrences.

After following over 3000 women diagnosed with breast cancer (between 1977 and 2005), researchers discovered that certain molecular components of tumor tissue could be categorized into specific, distinct tumors which helped to provide a chronology of tumor metastasis. More specifically, 25% of women categorized as estrogen receptor positive and HER2 negative have a 42-55% chance of late relapse within 20 years. Further, researchers found that women with the aggressive and difficult to treat triple-negative breast cancers were able to be divided into defining subgroups.

This discovery allows practitioners to drastically improve upon clinical management and outcome by honing-in on targeted therapies and eventual drug delivery systems for millions of women with precision and confidence – solving a huge, unmet clinical need worldwide (please refer to list of applications and advantages).

Stage of Development:
Prediction models have been verified and continued research will confirm the clinical, therapeutic, and diagnostic use, and possible drug therapies with both in

vivo and in vitro data

Applications

- **Targeted therapy**– able to identify and direct clinical decision-making
  - Monitor high risk patients who need ongoing therapies
  - Adjust therapeutics -- use of chemotherapy and/or extended endocrine therapy
  - Identify genomic defects in tumor, then direct treatment
- **Drug development** –drugs produced to directly cater towards specific tumors as inventors found specified gene targets

Advantages

- **Unmet medical need –** Extreme accuracy in prediction of breast cancer late recurrence risk (5 yrs and up to 20 yrs from diagnosis)
  - Compared to other commercially available multigene signatures
- **Identification of key factors**
  - 25% of estrogen receptor positive and HER2 negative women have a 42-55% chance of late relapse within 20 years
  - **Patterns of tumor metastasis:** route, rate, and location in the body
- **Classification of breast cancers**
  - 11 distinct diseases
  - For example, triple-negative breast cancer (known to have poor prognosis) has two different sub types with one that can be treated successfully
- **Huge, impactful reach –** In the United States alone, according to the **U.S. Breast Cancer Statistics**, about **1 in 8 U.S. women** (~ 12%) will develop invasive breast cancer over the course of her lifetime

Publications

- Hokyung K. Chung, Xinzhi Zou, Bryce T. Bajar, Veronica R. Brand, Yunwen Huo, Javier F. Alcudia,James E. Ferrell Jr., Michael Z. Lin, A compact synthetic pathway rewires cancer signaling to therapeutic effector release, Science (published 03 May 2019).

Patents

- Published Application: WO2021055517
- Published Application: 20220359084

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