

# Targeting Treatment for ER-Positive Breast Cancers

## Category

Technology: Biomarker and Diagnostic

## Problem

There is an unmet need to identification of effective therapy for breast cancer patients based on their hormone receptor status.

## Technology Overview

This technology compares the ratio of estrogen receptor to androgen receptor to determine optimal therapeutic options.

## IP Status

- ▶ Patents issued in US, Europe and Japan
- ▶ US continuation and Canada pending

## Value Proposition

- ▶ Optimizes treatment based on personalized patient profile

## Market Attractions

- ▶ Several drugs in the pipeline
- ▶ Breast and prostate cancer are huge players in R&D

## Contact

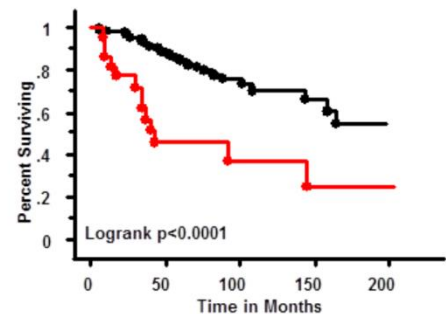
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**Problem:** At its simplest, breast cancer can be divided into two types: estrogen receptor (ER) positive (~70% of all breast cancers) and ER-negative. Endocrine therapies (sometimes called hormonal therapies) target ER-positive cancers, so ER has historically been used as a biomarker to determining whether to treat breast cancer with endocrine therapy or some other non-endocrine based therapy. Recently it has been shown that in breast cancers, the androgen receptor (AR) is more widely expressed than estrogen receptor (ER) alpha or progesterone receptor. Accordingly, AR has recently emerged as a useful marker for the further refinement of breast cancer subtype classification. Among ER+ tumors, some breast cancers respond well to a traditional endocrine therapy while others do not. Currently, there is no reliable method for determining whether a breast cancer will respond better to traditional ER-directed endocrine therapy or an anti-androgen therapy.

**Solution:** University of Colorado researchers led by Jennifer Richer have discovered that tumors that respond to a traditional endocrine (i.e., anti-estrogen or AI) therapy have a positive correlation between AR and ER (e.g., when AR is high, ER is also high and when AR is low, ER is also low), while tumors that respond less well to an endocrine therapy (as measured by shorter time to relapse or shorter disease-free survival) have significantly more percent cells positive for AR than for ER. This discovery enables a method to determine the most effective form of therapy for breast cancer (ER-directed vs AR-directed therapy) by determining the ratio of AR-to-ER in a biopsy or primary tumor resection.

An AR:ER ratio of less than 2, is indicative of a likelihood of a positive response to a traditional ER-directed endocrine therapy. In contrast, a tumor sample that exhibits an AR:ER ratio greater than or equal to 2 has over four-fold increased risk for failure while on tamoxifen. (HR = 4.43).



AR:ER ratio > 2 was strongly predictive of poor outcome.

## Advantages and Value Propositions

A breast cancer tumor with an AR:ER ratio of greater than or equal to 2 suggests that an anti-androgen therapy would be more appropriate, and such agents are currently being tested in clinical trials. This provides the opportunity for a new indication for these anti-androgen medications.

## Additional Documents and Sources:

- "Role of androgen receptor in breast cancer and preclinical analysis of enzalutamide." Breast Cancer Res. 2014 Jan 22;16(1):R7
- "Method for Determining Breast Cancer Treatment." US Patent No. 10,175,240
- "Method for Determining Breast Cancer Treatment." JP Patent No. 6153613
- "Targeting Treatment for ER-Positive Breast Cancers: A method to predict response to estrogen or androgen pathway inhibitors in breast cancer." EP Patent No. 2888594

## About CU Innovations

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