

New target Therapy for Triple Negative Breast Cancer

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HIGHLIGHTS

- ✓ New strategy to inhibit RANK pathway for the treatment of TNBC.
- ✓ RANK is expressed in 40% of TNBC where it was linked with poor clinical outcomes.
- ✓ Cost-effective therapy for TNBC and NSCLC easing the economic burden.

TECH STATUS

- ✓ **TRL:** Technology Concept
- ✓ **IP:** Know-how and Patent on Draft

Problem to be solved

Breast cancer is the most common malignancy among females in the Western world, resulting in approximately half a million deaths annually, mainly due to metastatic disease. TNBC, which lacks estrogen receptor, progesterone receptor and HER2 expression, accounts for approximately 15–20% of all breast cancers.

Despite its sensitivity to chemotherapy, TNBC remains a clinical challenge because of a high rate of relapse, a propensity to form visceral metastasis and the lack of targeted therapies. Lung cancer, with over 1.5 million deaths yearly has become the leading cause of cancer-related mortality worldwide.

One of the main unmet needs in TNBC treatment is the need for more effective treatment options that provide substantial improvement in progression-free survival (PFS) and overall survival (OS).

Background

This new target therapy proof of concept is based on the innovative idea of generating novel small molecules targeting RANK for the treatment of triple negative breast cancer (TNBC) and non-small

cell adenocarcinomas (NSCLC), aggressive subtypes where no targeted therapies are available. Despite encouraging evidences in mouse models, anti-RANKL drugs (the antibody denosumab) have failed to show a benefit preventing recurrence in clinical breast cancer.

Our value proposition: New strategy to inhibit RANK pathway for the treatment of TNBC and NSCLC.

Technology

RANK is expressed in breast and lung tumors, particularly in tumors from the TNBC and NSCLC subtype, where no targeted therapies are available.

Taking into a count that RANK expression associates with prognosis and RANK receptor can signal in the absence of RANKL, our unique insight to solve this problem is a New strategy to inhibit RANK pathway for the treatment of TNBC and NSCLC.

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Applications

The most important benefits of this new therapy are based on

- 1) Medical need to treat TNBC/NSCLC patients
- 2) The economic burden for public health systems generated by standard non-selected and ineffective cancer treatment.

These new RANK inhibitory molecules will improve the current treatments with less side effects

Technology status

The RANK signaling pathway has emerged as a new target in breast and NSCLC. In mouse models have already been performed showing that Rank pathway promotes mammary tumorigenesis and lung metastasis

In silico drug design models will be performed in order to select and validate the NCE (new chemical entity)

Market Opportunity

The growth of the TNBC market in the US and EU5 will be similar to the other markets with a CAGR of 12.4%. Overall, the US market will experience more than a 1.7-fold increase in sales.

All the current branded therapies are expected to go off patent in the US during the forecast period. (2018-2025)

The increase in the incident cases of all types of breast cancer will translate into more, who will be eligible to receive the new branded therapies—

Furthermore, increased awareness of the potential benefit of routine breast screening will lead to more women being diagnosed with breast cancer at earlier stage. This will be particularly true in China, where there is currently no national breast screening program; however, it is worth noting that healthcare reform is underway in China, which will lead to increased awareness of the disease and improve patient diagnosis in this market

The breast cancer market in Japan is expected to increase from \$554M in 2015 to \$1.15B by 2025, at a CAGR of 7.6%. This growth will be partially driven by the increasing incidence of the disease, at an AGR of 2.2%, and the surge of premium-priced products that are set to enter this market over the forecast period. The total share of the Japanese market in 2015 was 10.2%, which is expected to slightly increase to 10.9% by 2025

Business Opportunity

Co-development or investment for spin-off creation

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