PHOENIX MOLECULAR DESIGNS

SABCS* 2020 Poster: A Phase 1 Triple Negative Breast Cancer Clinical Study

A Phase 1/1b multicenter, open-label dose escalation study to assess tolerability of PMD-026, a first-in-class oral RSK inhibitor, in metastatic breast cancer patients

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Status

Recruiting; Find more information at:
clinicaltrials.gov/ct2/show/NCT04115306

Background

- Metastatic breast cancer, especially the subtype triple negative breast cancer (TNBC), is very aggressive and has limited treatment options
- TNBC is particularly hard to treat because it lacks the usual 3 targets for treatment, hence why it is called triple negative breast cancer

This article is most relevant for:

- People with metastatic triple negative breast cancer
- Over the age of 18
- Tried previous standard of care metastatic breast cancer therapies

*San Antonio Breast Cancer Symposium

- PMD-026 is a new “targeted therapy,” which is an oral capsule
- “Targeted therapies” work by seeking and destroying cancer cells with high levels of select proteins, in this case, RSK (pronounced risk), and sparing as many normal cells as possible

Study design

Part 1 (Complete, not enrolling):
A total of 15 patients who had metastatic breast cancer and no longer responded to other therapies were enrolled to receive PMD-026 at increasing oral doses from once a day to twice a day. The primary goal was to collect safety data and to select a safe and tolerable dose of PMD-026.

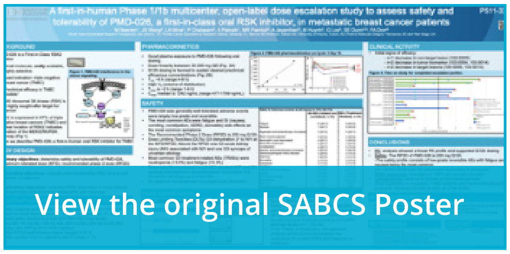
Part 2 (Active, enrolling):
Up to 20 TNBC patients will be enrolled to receive PMD-026 at 200 mg twice a day to collect more data about side effects and clinical activity (the effect of the drug on the body and on the tumor).

Conclusions from part 1 data - dosing of 15 metastatic breast cancer patients

- **Pharmacokinetics (how the drug moves through the body):** A review of the drug levels in the blood from the study patients supports a twice-a-day dosing schedule.
- **Safety:** A review of the side effects from the study supports a dose of 200 mg twice a day.
  - The most common side effects were fatigue (60%) and nausea (40%).
  - There was no hair loss or numbing of hands/feet (peripheral neuropathy)
- **RSK Expression (the drug target):** Before dosing, 100% of patient tumor samples had RSK levels; therefore, RSK looks like a good target for killing this type of tumor cell.
- **Clinical Activity:** The current clinical study data shows initial signs of stabilizing disease in patients with metastatic breast cancer for up to 5 months.

Next steps

- Additional patients will be enrolled to further study the safety, tumor activity and clinical activity of PMD-026 at the 200 mg twice a day dose
- Part 2 is open to enrollment for up to 20 metastatic TNBC patients at 9 clinical sites in the US


A first-in-human Phase 1/1b multicenter, open-label dose escalation study to assess safety and tolerability of PMD-026, a first-in-class oral RSK inhibitor, in metastatic breast cancer patients
View the original SABCS Poster

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