Studies suggest novel targeted therapies may benefit patients with metastatic HR+/ HER2- breast cancer

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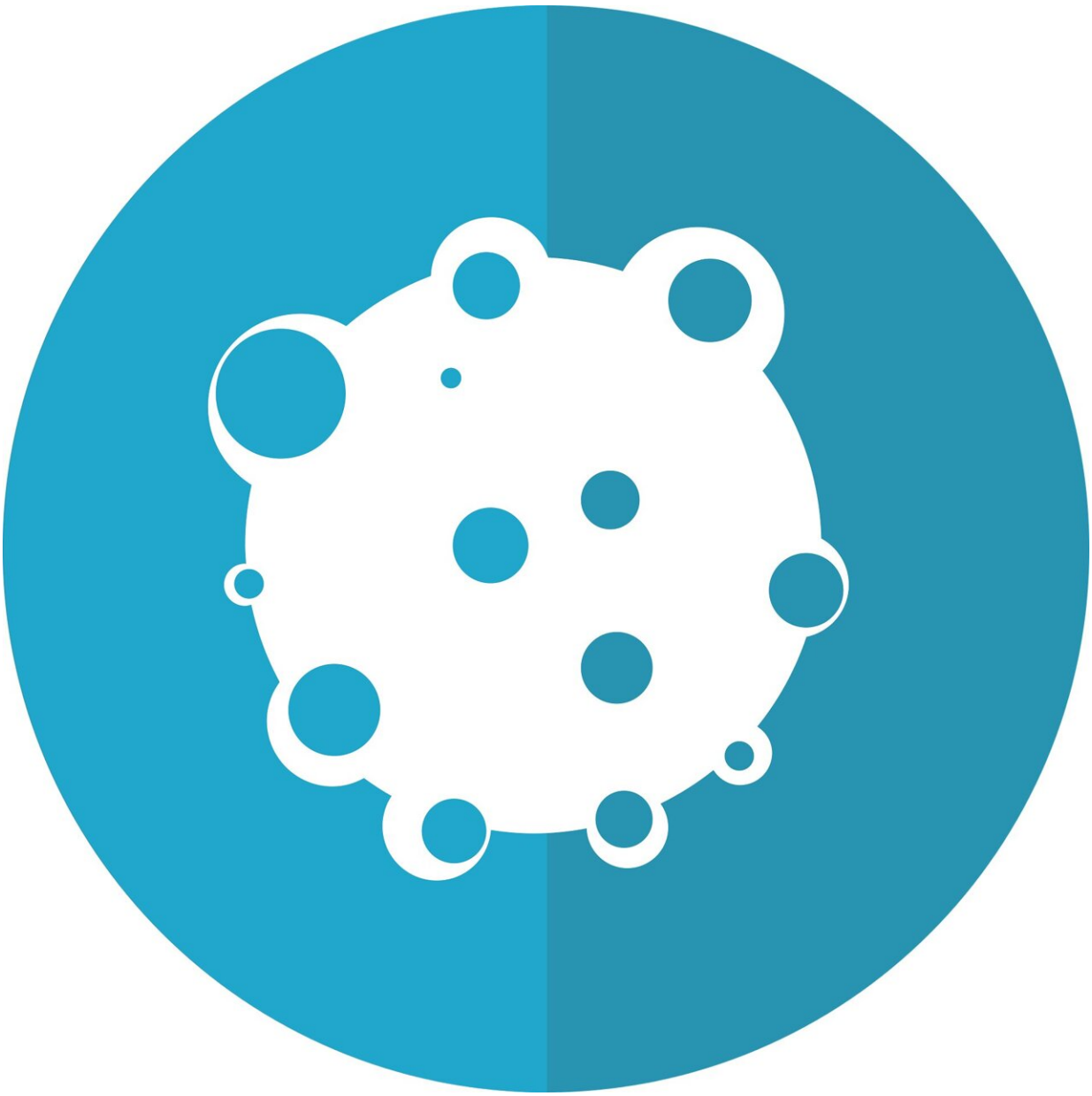

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Two studies led by researchers at The University of Texas MD Anderson Cancer Center demonstrated clinical benefit from novel targeted therapies, which may offer new treatment options for patients with metastatic hormone receptor-positive (HR+)/human epidermal growth factor receptor 2-negative (HER2-) breast cancer. The data will be shared in oral presentations today at the 2023 San Antonio Breast Cancer Symposium (SABCS).

According to the National Cancer Institute, HR+/HER2− breast cancer is the predominant breast cancer subtype in the U.S., constituting nearly 70% of all breast cancer cases. When caught at an early stage before it metastasizes, the disease is very treatable. However, the five-year relative survival rate for metastatic HR+/ HER2- breast cancer is only 34%, underscoring the need for innovative therapeutic approaches.

Futibatinib achieves antitumor activity in advanced breast cancer with FGFR1 amplification (Abstract RF01-04)

The Phase II FOENIX-MBC2 trial, led by Senthil Damodaran, M.D., Ph.D., associate professor of Breast Medical Oncology and Investigational Cancer Therapeutics, achieved early signs of antitumor activity when combining the FGFR inhibitor futibatinib with the hormone therapy fulvestrant in patients with advanced HR+/HER2− breast cancer harboring high-level FGFR1 amplification.

Among 22 patients, the researchers observed a median progression-free survival (PFS) of 7.2 months. The overall response rate (ORR) was 18.2%, including four confirmed partial responses, and the median duration of response was 6.3 months.

"We are encouraged by the antitumor activity of futibatinib and the possibility of offering this targeted therapy to patients who have had their breast cancer progress after CDK4/6 inhibitor treatment," Damodaran said. "We will continue to observe these patients and study further biomarkers of response."

This open-label multicenter trial enrolled patients with locally advanced/metastatic breast cancer harboring FGFR gene amplifications who had progressed on prior CDK4/6 inhibitor treatment. Patients were enrolled in one of four treatment cohorts based on diagnosis and FGFR gene amplification status. Patients were a median age of 58 years, had received a median of three lines of any prior systemic anticancer therapy, and had all received previous CDK4/6 inhibitor treatment.

No treatment-related serious adverse events were reported. The most common treatment-related adverse events were hyperphosphatemia (95.5%), alopecia (54.5%), constipation (45.5%) and dry mouth (40.9%).

The trial was supported by Taiho Oncology, Inc. Damodaran previously served on the Taiho advisory board. A complete list of collaborating authors and their disclosures can be found in the abstract.

Tinengotinib shows clinical benefit in heavily pre-treated patients with metastatic HR+/HER2- or triple-negative breast cancers

Pooled data from two trials led by Sarina Piha-Paul, M.D., associate professor of Investigational Cancer Therapeutics, demonstrated clinical benefit with manageable side effects from tinengotinib, either alone or in combination with nab-paclitaxel, in heavily pre-treated patients with metastatic HR+/HER2- or triple-negative breast cancers.

In 11 patients with HR+/HER2- breast cancer, tinengotinib monotherapy achieved an ORR of 45.5%, a clinical benefit rate (CBR) of 64% and a median progression-free survival (mPFS) of 5.68 months. The 17 patients with triple-negative breast cancer had an ORR of 23.5%, a CBR of 29.4% and a mPFS of 2.73 months. Of note, partial responses were seen in three patients designated as HER2-zero and in two patients designated HER2-low.

"Tinengotinib has showcased clinical benefit for individuals facing refractory metastatic HR+/HER2- or triple-negative breast cancers, potentially elevating treatment outcomes," Piha-Paul said. "This positive impact was also observed among subgroups, including patients with HER2-zero and HER2-low disease."

The presentation pooled data from a Phase I study and a Phase Ib/II study. Among the 36 patients treated across both trials, 30 patients were treated with tinengotinib alone and six were treated with tinengotinib plus nab-paclitaxel. Twenty-eight patients receiving tinengotinib monotherapy were evaluated for efficacy. Patients were a median age of 51 years old and had received a median of five lines of prior therapy. All patients had no available standard treatment options.

No treatment-related serious adverse events were reported. The most common treatment-related adverse events of tinengotinib monotherapy were hypertension (60.0%), stomatitis (50.0%), palmar-plantar erythrodysesthesia syndrome (46.7%) and diarrhea (20.0%). The most common treatment-related adverse events of tinengotinib in combination

with nab-paclitaxel were neutrophil count decreased/neutropenia (50.0%), stomatitis (50.0%), hypertension (33.3%), hyponatremia (33.3%), hypokalemia (33.3%), and nausea (33.3%). One patient on the combination had a grade-five pulmonary hemorrhage.

The trial was supported by TransThera Sciences (Nanjing), Inc. Piha-Paul reports research support from TransThera Bio. A complete list of collaborating authors and their disclosures can be found in the abstract.

Provided by University of Texas M. D. Anderson Cancer Center

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