MedicalXpress

Study tests new breast cancer drug in African American women

July 6 2016

The first clinical trial to test a newly approved breast cancer drug specifically in African American patients is now enrolling at Georgetown Lombardi Comprehensive Cancer Center and will begin soon at five other institutions in Washington, DC, Maryland, Alabama and New Jersey.

The phase II study will evaluate the safety of palbociclib (Ibrance) in African American patients, including those who may have a low white blood cell count due to "benign ethnic neutropenia." This condition is common in African-Americans, but it is unclear whether it increases a patient's risk of infection while taking palbociclib, says the study's leader, Filipa Lynce, MD, a physician researcher at Georgetown Lombardi Comprehensive Cancer Center.

The U.S. Food and Drug Administration approved palbociclib in February 2016 for ER+ HER2- breast cancer that has spread.

Because about three-fourths of the 1,137 patients tested in earlier clinical trials of palbociclib developed neutropenia (low white blood cell count)—including half of the patients who developed a more serious form of the disorder—the FDA guidelines for palbociclib use require the patient to have a normal white blood cell count.

That threshold forces the elimination of African-American women who have "benign ethnic neutropenia," or a lower than normal white blood cell count, from receiving the drug.

The study Lynce is conducting explores the safety of the drug in all African American women, knowing that some may have benign ethnic neutropenia. "The assumption that African American women with this common condition could not safely use this drug needs to be fully tested," says Lynce.

The study will enroll 35 patients with metastatic breast cancer at Georgetown Lombardi/MedStar Georgetown University Hospital (Washington, DC), MedStar Washington Hospital Center (Washington, DC), MedStar Union Memorial Hospital (Baltimore, MD) and MedStar Good Samaritan Hospital (Baltimore, MD), the University of Alabama at Birmingham Comprehensive Cancer Center, and at the John Theurer Cancer Center at Hackensack University Medical Center (Hackensack, New Jersey).

All patients will be given palbociclib and letrozole (Femara). Both agents are pills that are taken once daily. Participants will be enrolled in the study for a maximum of 13 months.

The usual standard of care services required to monitor and treat the cancer—including examinations, scans and laboratory tests—will be performed as part of the study and billed to a patient's insurance. The primary study drug, palbociclib, will be provided free of charge on the study, but the second drug, letrozole, will also be billed to insurance.

Lynce applied and received a $600,000 grant from Pfizer, Inc., the developer of palbociclib, to test the agent in African Americans.

I think this award shows how committed the company is to look at the safety of their drugs in minorities," says Lynce. "One focus area of my research is to look at the safety and efficacy of medications used to treat breast cancer in populations that have not been included in clinical trials.

Provided by Georgetown University Medical Center