# BREAST CANCER: A STORY HALF TOLD

"Patients with metastatic breast cancer have unique needs. First of all, they realize they're probably always going to be in treatment to keep this disease stable for as long as possible. The mission is control, and not cure, and that can be a hard thing to have to wrap your mind around. We owe it to these women to make sure society as a whole understands their situation and how they are coping with it and what help and support they need. These women are warriors, and I look at them in awe."

**LILLIE SHOCKNEY, RN**
ADMINISTRATIVE DIRECTOR
JOHNS HOPKINS BREAST CENTER

and a 22-year breast cancer survivor

## IBRANCE® (PALBOCICLIB) APPROVED BY THE U.S. FDA

On February 3, 2015, the U.S. Food and Drug Administration (FDA) granted accelerated approval of Ibrance® (palbociclib), in combination with letrozole, for the treatment of post-menopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer as initial endocrine-based therapy for their metastatic disease. Ibrance, an oral kinase inhibitor, was reviewed and approved under the FDA's Breakthrough Therapy designation and Priority Review programs.

The FDA approval of Ibrance is based on the final results of the Phase 2 PALOMA-1 trial. The study demonstrated that the combination of Ibrance and letrozole prolonged progression-free survival compared with letrozole alone, a standard of care, in post-menopausal women with ER+/HER2- locally advanced or metastatic breast cancer. Detailed results from the PALOMA-1 trial have been published in *The Lancet Oncology*.

Prior to the FDA approval of Ibrance, patients with ER+/HER2- advanced breast cancer had not seen a first-line treatment advance in more than 10 years. This is the most common type of advanced breast cancer, affecting an estimated 60 percent of patients.

Ibrance selectively inhibits cyclin-dependent kinases (CDKs) 4 and 6, key regulators of the cell cycle, to regain cell cycle control and block tumor cell proliferation. Ibrance is being developed by Pfizer in ER+/HER2- breast cancer across stages and treatment settings, and several Phase 3 studies are underway globally. In addition, Pfizer has initiated external collaborations to evaluate Ibrance in other tumor types.

**PRIOR TO IBRANCE, METASTATIC BREAST CANCER PATIENTS HAD NOT SEEN A FIRST-LINE TREATMENT ADVANCE IN MORE THAN**

**10 YEARS**