

# Oncology



Few words in health care can have such a devastating impact on patients and their families as “cancer.” That motivates us to bring innovative treatments to the forefront and drives us to harness the power of the latest in targeted treatments for our oncology patients.

## Introducing a New Class of Cancer Treatments in Europe

Pfizer’s Ibrance® (palbociclib) received approval from the European Medicines Agency (EMA) in late 2016, for the treatment of women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer. The approval is for Ibrance to be used in combination with an aromatase inhibitor and also covers the use of Ibrance in combination with fulvestrant in women who have received prior endocrine therapy. This milestone follows the initial approval of Ibrance from the U.S. Food and Drug Administration (FDA) in 2015 and its expanded approval in early 2016. Ibrance is the first CDK 4/6 inhibitor approved in either the United States (U.S.) or Europe, representing a new class of treatments for breast cancer. It is also the first new medicine approved in the first-line setting in nearly a decade for the treatment of women in Europe with this type of metastatic breast cancer. Women with HR+/HER2- metastatic breast cancer represent about 60 percent of all metastatic breast cancer cases.

**>45,000**  
SINCE LAUNCH,  
MORE THAN 45,000  
PATIENTS HAVE  
BEEN PRESCRIBED  
IBRANCE IN THE U.S.

The 10th Annual Prix Galien USA Awards in New York honored Pfizer and Ibrance in 2016 with the prestigious “Best Pharmaceutical Product” Award. Prix Galien USA recognizes exceptional pharmaceutical innovations that have improved health around the globe, and Pfizer’s metastatic breast cancer medicine took the top prize in a category of 22 products.



### Providing Holistic Support to Women with Breast Cancer

**>\$35m**  
 SINCE 2014, PFIZER  
 HAS PROVIDED  
 MORE THAN \$35  
 MILLION TO UNIQUE  
 BREAST CANCER  
 RESEARCH FUNDING  
 PARTNERSHIPS

Many patients with metastatic breast cancer have needs that extend well beyond the hospital treatment room. The **Seeding Progress And Resources for the Cancer Community: Metastatic Breast Cancer Challenge (SPARC)**, an initiative launched by the Union for International Cancer Control (UICC) in partnership with Pfizer, has awarded grants to 20 organizations in 18 countries around the globe who are addressing unmet needs for this patient community. Pfizer continued its support of SPARC in 2016, which included such diverse programs as creating a support group for rural women living with breast cancer in Rwanda, developing an online community for metastatic patients in Mexico and training nurses to educate metastatic breast cancer patients in Bulgaria.

### Advancing the Science for Men with Metastatic Castration-Resistant Prostate Cancer

This year, the FDA approved a supplemental New Drug Application (sNDA) to update the U.S. product labeling for Xtandi® (enzalutamide) capsules to include new clinical data from its TERRAIN study. As published in *The Lancet Oncology*, the data demonstrated a statistically significant increase in radiographic progression-free survival in patients with metastatic castration-resistant prostate cancer (CRPC) who were treated with bicalutamide (Hazard Ratio - 0.44; 95% Confidence Interval, 0.34-0.57; p<0.0001). Importantly, the safety profile of enzalutamide was shown to be consistent with results of earlier enzalutamide trials. We are also exploring potential expanded clinical applications for the drug, including in triple-negative prostate cancer.

### Increasing Treatment Options for People with ROS1-Positive Advanced Non-Small Cell Lung Cancer

The positive news for Pfizer's oncology portfolio continued in 2016, with the FDA and EMA granting approval for Xalkori® (crizotinib) for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC). Xalkori is the first and only approved biomarker-driven therapy for ROS1-positive advanced NSCLC in both the U.S. and the EU. Additional marketing applications for the ROS1-positive NSCLC indication are planned or currently in review in select countries worldwide.

## Reshaping the Field of Oncology

This year, Pfizer also accelerated its work in immuno-oncology (IO), the use of the immune system to treat cancer. Immunotherapies are designed to harness the natural ability of the immune system to fight cancer and are different from other approaches like radiation or chemotherapy. They work on the immune system throughout the body, helping it to recognize cancer cells and potentially produce a response.

We believe the full promise of IO has yet to be discovered. Despite groundbreaking progress in IO, current treatments only help a small population of patients. Therefore, at Pfizer, we are working rapidly in the search for novel technologies to identify solutions across multiple cancer types.

- We currently have 11 IO compounds in the clinic and we are evaluating them as both monotherapies and as combination treatments.
- Our avelumab program with Merck KGaA now has 30 studies ongoing, nine of which are in Phase 3, including two each in lung, gastric and ovarian cancers, and one each in bladder, renal cell carcinoma and locally advanced squamous cell carcinoma of the head and neck (SCCHN).
- This year, we received FDA Priority Review and EMA validation of our regulatory submissions for avelumab in Merkel cell carcinoma, based on Phase 2 data.
- We are leading checkpoint inhibitor registration-enabling Phase 3 studies in ovarian cancer as part of our avelumab program.
- Four of our Phase 3 studies in the avelumab program are for combination with chemotherapy; two for ovarian cancer, one for bladder cancer and one for locally advanced SCCHN.
- We have initiated combination studies of avelumab with immunotherapies, targeted therapies and chemotherapy, including: 4-1BB across various types of tumors, Xalkori and lorlatinib in non-small cell lung cancer, Inlyta® (axitinib) in first-line treatment of renal cell carcinoma, and studies with chemotherapy in ovarian, bladder and head and neck cancers.
- In addition to avelumab, we have studies underway with many other agents in our portfolio including:
  - OX-40 is being studied as a single agent, in combination with 4-1BB and with avelumab in various tumor types.
  - PTK7 is being studied in Phase 1b and combination studies with avelumab expected to commence in 2017.
  - Our IDO1 inhibitor is also in Phase 1 and we expect combination studies to start in 2017.
  - Our clinical allogeneic CAR T cell program with Cellectis and Servier is on track, with recruitment in the United Kingdom ongoing.

## Collaborating to Spur Progress

We know that cancer is a disease that no one should fight alone. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments and licensing partners, Pfizer strives to cure or control cancer with its breakthrough medicines. In 2016, we entered into many [significant partnerships](#).

## Directly Engaging with the Cancer Community

Our work to advance the science of cancer is augmented by our support for outreach programs that connect directly with cancer patients and caregivers. Hearing firsthand the needs of these patients and their families and caregivers deepens our understanding of how best to serve them and enables us to accelerate those programs and treatments that deliver positive impact.

Pfizer also works directly with advocates to ensure the patient perspective is incorporated into therapy management tools we develop for our products. For example, we held patient advocacy advisory boards in 2015 and 2016 to better understand the unmet needs of acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL) patients and caregivers and their treatment priorities. Based on feedback that newly diagnosed patients needed a “first-aid kit” to better understand their disease, we partnered with Patient Power in Europe to develop two acute leukemia video “health centers” that include 88 videos featuring experts explaining AML and ALL. A subsequent version of the hub, to be launched in 2017, will augment the video library with perspectives from both patients and caregivers.

Patient Power Acute Lymphoblastic Leukemia and Acute Myeloid Leukemia video health centers:

- Includes 88 videos featuring interviews with 14 international key opinion leaders in five languages
- Received more than 65,000 views across various channels (Patient Power website, Oncology Tube and YouTube)
- Featured a Twitter handle (@PatientPower) that became the second most influential Twitter account in ALL during the Summer of 2016
- Patient Power in Europe was recognized in the 2016 awards, winning Gold in Communique 2016, EVCOM 2016 and PMEA 2016