ADVANCES IN ONCOLOGY

We understand the urgency that cancer patients face. Our scientists are hard at work seeking to turn promising research into important medicines and making strides in innovative fields such as immuno-oncology as we build a pipeline of potential next-generation therapies so people with cancer may live longer, fuller lives.

IBRANCE® REACHES PATIENTS

We continue to invest in research at the forefront of developing new treatment options for people living with breast cancer. In early 2015, we received U.S. Food and Drug Administration accelerated approval for 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 has been approved in several other countries around the world based on results from the Phase 2 PALOMA-1 clinical trial. Results from the first Ibrance Phase 3 trial, PALOMA-3, were reported in 2015 and additional Phase 3 studies are ongoing. We filed a marketing application in Europe in mid-2015, and we have also initiated plans for additional global submissions in order to bring this innovative medicine to patients worldwide.
Seeking Additional Indications

In addition to demonstrating efficacy in treating a relatively common type of metastatic breast cancer (ER+/HER2−), palbociclib is being tested in numerous clinical trials in other subsets of breast cancer and in other cancers such as head and neck cancer and pancreatic cancer, both on its own and in combination with other therapies.

The largest breast cancer trial for Ibrance to date, the PALbociclib CoLlaborative Adjuvant Study, or PALLAS, launched in August 2015. This Phase 3 trial for patients with early stage hormone receptor-positive (HR+)/HER2− breast cancer is designed to evaluate whether the addition of palbociclib to adjuvant endocrine therapy will improve disease-free survival and prevent the disease from recurring when compared with endocrine therapy alone (standard-of-care). A clinical research collaboration, the PALLAS trial is being conducted along with multiple research entities across Europe and other regions, including the Austrian Breast & Colorectal Cancer Study Group, Breast International Group, German Breast Group, National Surgical Adjuvant Breast and Bowel Project, PIRO, LLC and Alliance Foundation Trials, LLC. Approximately 4,600 people with early breast cancer are expected to enroll in the trial.

GLOBAL PARTNERSHIP TAKES ON METASTATIC BREAST CANCER

In a first-of-its-kind partnership, the Union for International Cancer Control and Pfizer have launched the SPARC initiative to encourage sustainable change for metastatic breast cancer (MBC) worldwide. SPARC stands for Seeding Progress and Resources for the Cancer Community. The program will support projects that address challenges in metastatic breast cancer by providing funding, mentorship and access to best practices to improve unmet needs for the global MBC patient population. The project topics range from raising awareness to addressing systematic gaps in health and public policies, patient access to information, and patient support, with the core focus being improving the lives of patients with MBC around the world. Ultimately, the SPARC initiative aims to empower advocacy groups, hospital networks, support groups and other organizations worldwide as they initiate projects to close the gap in information, support, awareness and policy between MBC and early disease, as well as help reduce the number of women diagnosed at the metastatic stage of breast cancer. From a large pool of 82 applicants from 46 countries, 20 organizations from 18 countries were selected to receive grants amounting to $760,000 (USD) in funding provided by Pfizer. The organizations will share progress and outcomes at the World Cancer Congress in 2016.
“Breast Cancer: A Story Half Told”

We have partnered with multiple breast cancer advocacy groups to chronicle the lives of women with metastatic breast cancer through the lenses of prominent photographers, in order to tell a fuller story of this poorly understood disease and its effects on patients, their families and the larger community we all share. This photo essay initiative is the next chapter of Breast Cancer: A Story Half Told, which was covered in the 2014 Annual Review. Its aim is to identify public misperceptions and gaps in knowledge surrounding metastatic breast cancer, the most advanced form of breast cancer.

The women profiled in this initiative are advocates, bloggers, working professionals, mothers, daughters and/or wives who have shared personal stories. A diverse group of breast cancer advocacy organizations provided counsel and support to bring these very human profiles to life. These include BreastCancer.org, Cancer Support Community, Living Beyond Breast Cancer, Metastatic Breast Cancer Network, and Young Survival Coalition. This photography-based effort encourages the public to share photos and messages of hope using the hashtag #StoryHalfTold, and is featured on the @StoryHalfTold Instagram, Facebook and Twitter accounts, as well as on www.StoryHalfTold.com.


“Pfizer is proud to be working with our advocacy partners and Story Half Told participants to dispel misperceptions, combat stigma and foster a more inclusive metastatic breast cancer conversation going forward.”

— Liz Barrett
President and General Manager, Pfizer Oncology
Global Status of Metastatic Breast Cancer: A Decade Report

In order to support the hundreds of thousands of women living with metastatic breast cancer around the world, we worked collaboratively with the European School of Oncology, within the scope of the Advanced Breast Cancer Third International Consensus Conference (ABC3), to release the Global Status of Metastatic Breast Cancer (MBC): A 2005–2015 Decade Report. This report was developed with guidance from a global steering committee of multidisciplinary leaders in the MBC community. The report is the most comprehensive analysis to date of the global landscape for advanced and metastatic breast cancer over the past decade and revealed both areas of improvement and substantial gaps in care, access to resources and support, and treatment outcomes for women with MBC.

In response to these findings, the European School of Oncology and members of the breast cancer community are calling for policymakers, advocates and the medical community to unite to develop a global charter as a call-to-action toward changing and improving MBC outcomes by the year 2025.


NO CURE YET

Global Status of Metastatic Breast Cancer (MBC): A 2005–2015 Decade Report found that 48%–76% of respondents from the general public in 14 countries believe that metastatic breast cancer is curable. However, there is currently no cure for metastatic disease.
Our oncology strategy — redefining life with cancer

We intend to be acknowledged leaders in the fight against cancer, developing medicines that provide meaningful impact and help to restore patient health and well-being. We look to bring these medicines to patients as quickly and safely as possible, and to establish their value so patients everywhere can access them. By bringing potentially life-changing therapies and support to patients, we aim to redefine life with cancer until we cure it.

Today we have eight approved cancer medicines, four of them launched in the last four years. Our large and growing investigational portfolio takes a multi-pronged attack on cancer, including drug candidates designed to kill tumor cells and immunotherapies designed to stimulate the immune system to mount a stronger defense against cancer. Research continues.

Our goal: launch at least one new cancer therapy each year from 2017 through 2022.

Breakthrough Therapy designation for acute lymphoblastic leukemia (ALL)

Our investigational antibody-drug conjugate, inotuzumab ozogamicin, received Breakthrough Therapy designation in the U.S. for the treatment of acute lymphoblastic leukemia (ALL). The designation was based on the results of the Phase 3 INO-VATE ALL trial, which compared inotuzumab ozogamicin to standard-of-care chemotherapy.

I’m working on...

Barbra Sasu
Senior Director, T-cell Engineering

Watch Video
We are particularly encouraged by our growing strength and presence in immuno-oncology, with a broad investigational portfolio that spans numerous mechanisms of action. At the close of 2015, we had five immunotherapeutic agents in the clinic and plan to have up to 10 by the end of 2016. Key targets for these agents include PD-1, PD-L1, OX40, 4-1BB, CCR2 and Vaccine Based Immuno-therapy Regimen (VBIR) pathways that either stimulate or inhibit the immune system’s response to tumors.
## IMMUNOTHERAPY ASSETS IN THE CLINIC

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<th>Asset</th>
<th>Phase</th>
<th>Indication</th>
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<tbody>
<tr>
<td>avelumab</td>
<td>Phase 3</td>
<td>Non-small cell lung cancer 1st line</td>
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<tr>
<td>avelumab</td>
<td>Phase 3</td>
<td>Non-small cell lung cancer 2nd line</td>
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<td>avelumab</td>
<td>Phase 2</td>
<td>Metastatic Merkel cell carcinoma</td>
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<tr>
<td>avelumab</td>
<td>Phase 3</td>
<td>Metastatic gastric/gastro-esophageal junction cancers 1st line</td>
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<td>avelumab</td>
<td>Phase 3</td>
<td>Metastatic gastric/gastro-esophageal junction cancers 3rd line</td>
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<td>avelumab</td>
<td>Phase 3</td>
<td>Platinum-resistant/refractory ovarian cancer</td>
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<td>avelumab</td>
<td>Phase 3</td>
<td>Locally advanced or metastatic urothelial cancer 1st line</td>
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<td>avelumab + Inlyta</td>
<td>Phase 1b</td>
<td>Advanced renal cell cancer</td>
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<td>avelumab + 41BB or Xalkori</td>
<td>Phase 1</td>
<td>Non-small cell lung cancer</td>
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<td>4-1BB + CCR4 (in collaboration with Kyowa Hakko Kirin)</td>
<td>Phase 1</td>
<td>Cancer</td>
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<td>CCR2</td>
<td>Phase 1</td>
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<td>OX40</td>
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<td>VBIR</td>
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<td>Prostate cancer</td>
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In 2015, avelumab, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody being co-developed with Merck KGaA, Darmstadt, Germany (Merck KGaA) was granted Orphan Drug designation in the U.S. and the EU, and Fast Track and Breakthrough Therapy designations in the U.S. for the treatment of metastatic Merkel cell carcinoma, a rare and aggressive type of skin cancer. If successful, the first potential commercial launch of avelumab is anticipated in 2017. As of December 31, 2015, the clinical development program for avelumab included more than 1,500 patients who had been treated across more than 15 tumor types, including breast cancer, gastric/gastro-esophageal junction cancers, head and neck cancer, Merkel cell carcinoma, melanoma, non-small cell lung cancer, ovarian cancer, renal cell carcinoma and urothelial (i.e., bladder) cancer. The alliance has initiated six pivotal trials, reaching its goal for 2015, with additional trials expected to initiate in 2016. Pfizer and Merck KGaA presented data from six studies evaluating the potential role of PD-L1 inhibition and avelumab’s safety and efficacy at the European Cancer Congress 2015.

Combination therapy holds perhaps the greatest potential within immuno-oncology. Our broad portfolio of immuno-oncology, small molecule and antibody-drug conjugate oncology assets affords us the opportunity to test a wide range of combination regimens on our own and with one of our current collaborators, Merck KGaA, and others. We continue to grow our footprint in immuno-oncology through such collaborations, including a CAR-T with Cellectis and Servier, and an IDO1 with iTEOS. Our collaboration with Kyowa Hakko Kirin to combine our 4-1BB with their anti-CCR4 antibody has already led to a Phase 1 study.

We believe our immuno-oncology portfolio, along with our skilled scientists and focused partnerships, should help enable Pfizer to be a formidable player in this vital, high opportunity area going forward.