

Pfizer to Showcase Diverse and Growing Oncology Portfolio at the American Society of Clinical Oncology (ASCO) 2016 Annual Meeting

Wednesday, May 18, 2016 - 01:00pm

More than 40 accepted abstracts highlight innovation in immuno-oncology and other novel modalities across multiple tumor types Pfizer invites public to view and listen to webcast of conference call with analysts on Wednesday, June 8 at 10 a.m. EDT to review oncology business and ASCO data presentations

“Immunotherapy is revolutionizing the treatment of cancer, and Pfizer is advancing a diverse immuno-oncology pipeline with promise for patients with numerous types of cancer”

Pfizer Inc. (NYSE:PFE) today announced that the company will have its largest presence to date at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago from June 3-7, with more than 40 abstracts spanning a diverse and growing portfolio seeking to tackle numerous cancers and mechanisms of action. Presentations include eight oral presentations and five poster discussions that span Pfizer’s internal and collaborative scientific advances. Highlights include the first presentation of a novel immunotherapy combination study involving a 4-1BB agonist and checkpoint inhibitor as a potential new immunotherapy strategy and new clinical data featuring breakthrough treatments IBRANCE® (palbociclib) and XALKORI® (crizotinib), as well as investigational assets avelumab, an anti-PD-L1 IgG1 monoclonal antibody that is being developed in collaboration with Merck KGaA, Darmstadt, Germany, and lorlatinib, a next-generation ALK/ROS1 tyrosine kinase inhibitor.

“Our significant presence at ASCO underscores our long-term commitment to oncology, cutting-edge science and the strength of collaborations to help bring forward potential new medicines that address the serious and complex needs of people battling cancer,” said Liz Barrett, global president and general manager, Pfizer Oncology. “We look forward to sharing our findings with the entire oncology community with the hope that our collective efforts will continue to advance innovative approaches and redefine life with cancer.”

Immuno-Oncology Highlights

New clinical data from Pfizer’s growing immuno-oncology portfolio features an oral presentation on utomilumab (the proposed generic name for PF-05082566), Pfizer’s novel 4-1BB agonist, in combination with pembrolizumab, a PD-1 inhibitor, in patients with a variety of advanced solid tumors. Numerous other presentations offer new insights from the JAVELIN clinical development program of avelumab, the proposed nonproprietary name for the anti-PD-L1 mAb (also known as MSB0010718C), including new data from the registrational, Phase 2 trial in second-line metastatic Merkel cell carcinoma (MCC).

“Immunotherapy is revolutionizing the treatment of cancer, and Pfizer is advancing a diverse immuno-oncology pipeline with promise for patients with numerous types of cancer,” said Chris Boshoff, vice president and head of early development, translational and immuno-oncology for Pfizer Oncology.

Key oral immuno-oncology presentations include:

- Phase 1b study of PF-05082566 in combination with pembrolizumab in patients with advanced solid tumors (Tolcher et al)
- Avelumab (MSB0010718C; anti-PD-L1) in patients with metastatic Merkel cell carcinoma previously treated with chemotherapy: Results of the Phase 2 JAVELIN Merkel 200 trial (Kaufman et al)
- Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced unresectable mesothelioma from the JAVELIN solid tumor phase 1b trial: Safety, clinical activity, and PD-L1 expression (Hassan et al)

Breast Cancer Highlights

IBRANCE data to be presented at ASCO demonstrate Pfizer’s continued leadership in breast cancer and add to the growing body of knowledge around this first-in-class CDK 4/6 inhibitor in metastatic breast cancer. Since its FDA approval in February 2015, more than 28,000 women have been prescribed IBRANCE by more than 6,800 prescribers in the U.S. IBRANCE is the only CDK 4/6 inhibitor with Phase 3 data in this disease. New Phase 3 PALOMA-2 data to be presented at ASCO represent the third randomized pivotal study of IBRANCE in combination with endocrine therapy to demonstrate clinical benefit for women with HR+, HER2- metastatic breast cancer.

Key abstracts include:

- PALOMA-2: Primary results from a phase III trial of palbociclib with letrozole compared with letrozole alone in postmenopausal women with ER+/HER2- advanced breast cancer (Finn et al)
- Efficacy of palbociclib plus fulvestrant in patients with metastatic breast cancer and ESR1 mutations in circulating tumor DNA (Turner et al)

Lung Cancer Highlights

Pfizer’s continuing leadership in biomarker-driven treatments for lung cancer will be represented by new data on XALKORI and next-generation investigational treatment lorlatinib, the proposed generic name for PF-06463922.

Key abstracts include:

- Safety and efficacy of lorlatinib (PF-06463922) from the dose-escalation component of a study in patients with advanced ALK+ or ROS1+ non-small cell lung cancer (Solomon et al)
- Phase II study of crizotinib in East Asian patients with ROS1-positive advanced non-small cell lung cancer (Goto et al)
- Efficacy and safety of crizotinib in patients with advanced MET Exon 14-altered non-small cell lung cancer (Drilon et al)

Pfizer Oral Presentation Planner

Title/Abstract Number	Date/Time (CDT)	Location
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<p>(Abstract 512) Efficacy of palbociclib plus fulvestrant (P+F) in patients with metastatic breast cancer and ESR1 mutations in circulating tumor DNA</p> <p>Turner N</p>	<p>Friday, June 3</p> <p>5:18 – 5:30 p.m.</p>	<p>Hall D1</p>
<p>(Abstract 3002) Phase 1b study of PF-05082566 in combination with pembrolizumab in patients with advanced solid tumors</p> <p>Tolcher A</p>	<p>Saturday, June 4</p> <p>1:39 – 1:51 p.m.</p>	<p>Hall B1</p>
<p>(Abstract 8503) Avelumab* (MSB0010718C; anti-PD-L1) in patients with advanced unresectable mesothelioma from the JAVELIN solid tumor phase 1b trial: Safety, clinical activity, and PD-L1 expression</p> <p>Hassan R</p>	<p>Sunday, June 5</p> <p>8:58 – 9:10 a.m.</p>	<p>Arie Crown Theater</p>
<p>(Abstract 11509) Crizotinib in children and adolescents with advanced ROS1, MET, or ALK-rearranged cancer: Results of the AcSé phase II trial</p> <p>Vassal G</p>	<p>Monday, June 6</p> <p>9:45 – 9:57 a.m.</p>	<p>S404</p>
<p>(Abstract 108) Efficacy and safety of crizotinib in patients with advanced MET Exon 14-altered non-small cell lung cancer</p> <p>Drilon A</p>	<p>Monday, June 6</p> <p>10:09 – 10:21 a.m.</p>	<p>Hall D1</p>
<p>(Abstract 9009) Safety and efficacy of lorlatinib (PF-06463922) from the dose-escalation component of a study in patients with advanced ALK+ or ROS1+ non-small cell lung cancer</p> <p>Solomon B</p>	<p>Monday, June 6</p> <p>1:15 – 1:27 p.m.</p>	<p>Hall D2</p>
<p>(Abstract 507)</p> <p>PALOMA-2: Primary results from a phase III trial of palbociclib with letrozole compared with letrozole alone in postmenopausal women with ER+/HER2- advanced breast cancer</p> <p>Slamon D</p>	<p>Monday, June 6</p> <p>3:27 – 3:39 pm</p>	<p>Hall D1</p>

(Abstract 9508)

Avelumab* (MSB0010718C; anti-PD-L1) in patients with metastatic Merkel cell carcinoma previously treated with chemotherapy: Results of the phase 2 JAVELIN Merkel 200 trial

Kaufman H

Monday,
June 6
3:39 – 3:51
p.m.
Arie Crown
Theater

* Avelumab is being developed through an alliance between Merck KGaA, Darmstadt, Germany, and Pfizer

For a complete list of Pfizer-sponsored abstracts featuring data on our broad pipeline of biologics and small molecules, please visit:

http://www.pfizer.com/files/news/asco/ASCO2016_FactSheet_PfizerOncologyDataPresentations2016.pdf

Learn more about how Pfizer Oncology is applying innovative approaches to improve the outlook for people living with cancer at http://www.pfizer.com/research/therapeutic_areas/oncology.

Post-ASCO Analyst Conference Call

Pfizer invites investors and the general public to view and listen to a webcast of a conference call with investment analysts on Wednesday, June 8, 2016 at 10 a.m. EDT to review Pfizer's oncology business and ASCO data presentations.

To pre-register for and access the webcast and conference call, please visit the For Investors section of www.pfizer.com. You can also listen to the conference call by dialing (855) 895-8759 in the United States and Canada or (503) 343-6044 in other countries. The password is ASCO. The webcast will be archived on www.pfizer.com.

About IBRANCE® (palbociclib) 125mg capsules

IBRANCE is an oral inhibitor of CDKs 4 and 6,ⁱ which are key regulators of the cell cycle that trigger cellular progression.^{ii,iii} IBRANCE is indicated for the treatment of HR+, HER2- advanced or metastatic breast cancer in combination with letrozole as initial endocrine based therapy in postmenopausal women, or fulvestrant in women with disease progression following endocrine therapy.ⁱ The indication in combination with letrozole is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.ⁱ

IBRANCE Important Safety Information

Neutropenia was the most frequently reported adverse reaction in Study 1 (PALOMA-1) (75%) and Study 2 (PALOMA-3) (83%). In Study 1, Grade 3 (57%) or 4 (5%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. In Study 2, Grade 3 (56%) or Grade 4 (11%) decreased neutrophil counts were reported in patients receiving IBRANCE plus fulvestrant. Febrile neutropenia has been reported in about 1% of patients exposed to IBRANCE. One death due to neutropenic sepsis was observed in Study 2. Inform patients to promptly report any fever.

Monitor complete blood count prior to starting IBRANCE, at the beginning of each cycle, on Day 14 of first 2 cycles, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Pulmonary embolism (PE) has been reported at a higher rate in patients treated with IBRANCE plus letrozole in Study 1 (5%) and in patients treated with IBRANCE plus fulvestrant in Study 2 (1%) compared with no cases in patients treated either with letrozole alone or fulvestrant plus placebo. Monitor for signs and symptoms of PE and treat as medically appropriate.

Based on the mechanism of action, IBRANCE can cause **fetal harm**. Advise females of reproductive potential to use effective contraception during IBRANCE treatment and for at least 3 weeks after the last dose. IBRANCE may **impair fertility in males** and has the potential to cause genotoxicity. Advise male patients with female partners of reproductive potential to use effective contraception during IBRANCE treatment and for 3 months after the last dose. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise women **not to breastfeed** during IBRANCE treatment and for 3 weeks after the last dose because of the potential for serious adverse reactions in nursing infants.

The **most common adverse reactions (?10%)** of any grade reported in **Study 1** of IBRANCE plus letrozole vs letrozole alone included neutropenia (75% vs 5%), leukopenia (43% vs 3%), fatigue (41% vs 23%), anemia (35% vs 7%), upper respiratory infection (31% vs 18%), nausea (25% vs 13%), stomatitis (25% vs 7%), alopecia (22% vs 3%), diarrhea (21% vs 10%), thrombocytopenia (17% vs 1%), decreased appetite (16% vs 7%), vomiting (15% vs 4%), asthenia (13% vs 4%), peripheral neuropathy (13% vs 5%), and epistaxis (11% vs 1%).

Grade 3/4 adverse reactions (?10%) in **Study 1** reported at a higher incidence in the IBRANCE plus letrozole group vs the letrozole alone group included neutropenia (54% vs 1%) and leukopenia (19% vs 0%). The most frequently reported serious adverse events in patients receiving IBRANCE plus letrozole were pulmonary embolism (4%) and diarrhea (2%).

Lab abnormalities occurring in **Study 1** (all grades, IBRANCE plus letrozole vs letrozole alone) were decreased WBC (95% vs 26%), decreased neutrophils (94% vs 17%), decreased lymphocytes (81% vs 35%), decreased hemoglobin (83% vs 40%), and decreased platelets (61% vs 16%).

The **most common adverse reactions (?10%)** of any grade reported in **Study 2** of IBRANCE plus fulvestrant vs fulvestrant plus placebo included neutropenia (83% vs 4%), leukopenia (53% vs 5%), infections (47% vs 31%), fatigue (41% vs 29%), nausea (34% vs 28%), anemia (30% vs 13%), stomatitis (28% vs 13%), headache (26% vs 20%), diarrhea (24% vs 19%), thrombocytopenia (23% vs 0%), constipation (20% vs 16%), vomiting (19% vs 15%), alopecia (18% vs 6%), rash (17% vs 6%), decreased appetite (16% vs 8%), and pyrexia (13% vs 5%).

Grade 3/4 adverse reactions (?10%) in **Study 2** reported at a higher incidence in the IBRANCE plus fulvestrant group vs the fulvestrant plus placebo group included neutropenia (66% vs 1%) and leukopenia (31% vs 2%). The most frequently reported serious adverse reactions in patients receiving IBRANCE plus fulvestrant were infections (3%), pyrexia (1%), neutropenia (1%), and pulmonary embolism (1%).

Lab abnormalities occurring in **Study 2** (all grades, IBRANCE plus fulvestrant vs fulvestrant plus placebo) were decreased WBC (99% vs 26%), decreased neutrophils (96% vs 14%), anemia (78% vs 40%), and decreased platelets (62% vs 10%).

Avoid concurrent use of **strong CYP3A inhibitors**. If patients must be administered a strong CYP3A inhibitor, reduce the IBRANCE dose to 75 mg/day. If the strong inhibitor is discontinued, increase the IBRANCE dose (after 3-5 half-lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor. Grapefruit or grapefruit juice may increase plasma concentrations of IBRANCE and should be avoided. Avoid concomitant use of **strong CYP3A inducers**. The dose of **sensitive CYP3A substrates** with a narrow therapeutic index may need to be reduced as IBRANCE may increase their exposure.

IBRANCE **has not been studied** in patients with **moderate to severe hepatic impairment** or in patients with **severe renal impairment** (CrCl <30 mL/min).

The full prescribing information for IBRANCE can be found at www.pfizer.com.

About XALKORI® (crizotinib)

XALKORI is a kinase inhibitor indicated in the U.S. for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test, and for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive. XALKORI was the first ALK inhibitor approved in the U.S. and has been used to treat more than 8,000 patients to date.^{iv}

XALKORI Important Safety Information

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.1% of patients treated with XALKORI across clinical trials (n=1719). Transaminase elevations generally occurred within the first 2 months. Monitor with liver function tests including ALT, AST, and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin in patients who develop transaminase elevations. Permanently discontinue for ALT/AST elevation >3 times ULN with concurrent total bilirubin elevation >1.5 times ULN (in the absence of cholestasis or hemolysis); otherwise, temporarily suspend and dose-reduce XALKORI as indicated.

Interstitial Lung Disease (Pneumonitis): Severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis can occur. Across clinical trials (n=1719), 2.9% of XALKORI-treated patients had any grade ILD, 1.0% had Grade 3/4, and 0.5% had fatal ILD. ILD generally occurred within 3 months after initiation of treatment. Monitor for pulmonary symptoms indicative of ILD/pneumonitis. Exclude other potential causes and permanently discontinue XALKORI in patients with drug-related ILD/pneumonitis.

QT Interval Prolongation: QTc prolongation can occur. Across clinical trials (n=1616), 2.1% of patients had QTcF (corrected QT by the Fridericia method) \geq 500 ms and 5.0% had an increase from baseline QTcF \geq 60 ms by automated machine-read evaluation of ECGs. Avoid use in patients with congenital long QT syndrome. Monitor with ECGs and electrolytes in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that prolong the QT interval. Permanently discontinue XALKORI in patients who develop QTc \geq 500 ms or \geq 60 ms change from baseline with Torsade de pointes, polymorphic ventricular tachycardia, or signs/symptoms of serious arrhythmia. Withhold XALKORI in patients who develop QTc \geq 500 ms on at least 2 separate ECGs until recovery to a QTc \leq 480 ms, then resume at a reduced dose.

Bradycardia: Symptomatic bradycardia can occur. Across clinical trials, bradycardia occurred in 12.7% of patients treated with XALKORI (n=1719). Avoid use in combination with other agents known to cause bradycardia. Monitor heart rate and blood pressure regularly. In cases of symptomatic bradycardia that is not life-threatening, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of \geq 60 bpm, re-evaluate the use of concomitant medications, and adjust the dose of XALKORI. Permanently discontinue for life-threatening bradycardia due to XALKORI; however, if associated with concomitant medications known to cause bradycardia or hypotension, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of \geq 60 bpm. If concomitant medications can be adjusted or discontinued, restart XALKORI at 250 mg once daily with frequent monitoring.

Severe Visual Loss: Across clinical trials, the incidence of Grade 4 visual field defect with vision loss was 0.2% (n=1719). Discontinue XALKORI in patients with new onset of severe visual loss (best corrected vision less than 20/200 in one or both eyes). Perform an ophthalmological evaluation. There is insufficient information to characterize the risks of resumption of XALKORI in patients with a severe visual loss; a decision to resume should consider the potential benefits to the patient.

Vision Disorders: Most commonly visual impairment, photopsia, blurred vision or vitreous floaters, occurred in 63.1% of 1719 patients. The majority (95%) of these patients had Grade 1 visual adverse reactions. 0.8% of patients had Grade 3 and 0.2% had Grade 4 visual impairment. The majority of patients on the XALKORI arms in Studies 1 and 2 (>50%) reported visual disturbances which occurred at a frequency of 4-7 days each week, lasted up to 1 minute, and had mild or no impact on daily activities.

Embryo-Fetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Advise of the potential risk to the fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 45 days (females) or 90 days (males) respectively, following the final dose of XALKORI.

ROS1-positive Metastatic NSCLC: Safety was evaluated in 50 patients with ROS1-positive metastatic NSCLC from a single-arm study, and was generally consistent with the safety profile of XALKORI evaluated in patients with ALK-positive metastatic NSCLC. Vision disorders occurred in 92% of patients in the ROS1 study; 90% of patients had Grade 1 vision disorders and 2% had Grade 2.

Adverse Reactions: Safety was evaluated in a phase 3 study in previously untreated patients with ALK-positive metastatic NSCLC randomized to XALKORI (n=171) or chemotherapy (n=169). Serious adverse events were reported in 34% of patients treated with XALKORI, the most frequent were dyspnea (4.1%) and pulmonary embolism (2.9%). Fatal adverse events in XALKORI-treated patients occurred in 2.3% of patients, consisting of septic shock, acute respiratory failure, and diabetic ketoacidosis. Common adverse reactions (all grades) occurring in ≥25% and more commonly (≥5%) in patients treated with XALKORI vs chemotherapy were vision disorder (71% vs 10%), diarrhea (61% vs 13%), edema (49% vs 12%), vomiting (46% vs 36%), constipation (43% vs 30%), upper respiratory infection (32% vs 12%), dysgeusia (26% vs 5%), and abdominal pain (26% vs 12%). Grade 3/4 reactions occurring at a ≥2% higher incidence with XALKORI vs chemotherapy were QT prolongation (2% vs 0%), and constipation (2% vs 0%). In patients treated with XALKORI vs chemotherapy, the following occurred: elevation of ALT (any grade [79% vs 33%] or Grade 3/4 [15% vs 2%]); elevation of AST (any grade [66% vs 28%] or Grade 3/4 [8% vs 1%]); neutropenia (any grade [52% vs 59%] or Grade 3/4 [11% vs 16%]); lymphopenia (any grade [48% vs 53%] or Grade 3/4 [7% vs 13%]); hypophosphatemia (any grade [32% vs 21%] or Grade 3/4 [10% vs 6%]). In patients treated with XALKORI vs chemotherapy, renal cysts occurred (5% vs 1%). Nausea (56%), decreased appetite (30%), fatigue (29%), and neuropathy (21%) also occurred in patients taking XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Avoid concomitant use of CYP3A substrates with narrow therapeutic range in patients taking XALKORI. If concomitant use of CYP3A substrates with narrow therapeutic range is required in patients taking XALKORI, dose reductions of the CYP3A substrates may be required due to adverse reactions.

Lactation: Because of the potential for adverse reactions in breastfed infants, advise females not to breast feed during treatment with XALKORI and for 45 days after the final dose.

Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma crizotinib concentrations.

Use caution in patients with hepatic impairment.

Renal Impairment: Decreases in estimated glomerular filtration rate occurred in patients treated with XALKORI. Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CL_{cr} <30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

For more information and full Prescribing Information, visit www.XALKORI.com.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for patients worldwide. Our strong pipeline of biologics and small molecules, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information, please visit www.Pfizer.com.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer_News](https://twitter.com/Pfizer_News), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/pfizer), and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of May 18, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's oncology portfolio, including utomilumab (PF-05082566), avelumab (MSB0010718C), IBRANCE (palbociclib), Xalkori (crizotinib) and lorlatinib (PF-06463922), the potential of immuno-oncology and clinical development plans, including their potential benefits that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of Pfizer's oncology products; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential

indications for Pfizer's oncology products and product candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Pfizer's oncology products and product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

ⁱ IBRANCE® (palbociclib) Prescribing Information. New York, NY: Pfizer Inc: 2016.

ⁱⁱ Weinberg RA. pRb and Control of the Cell Cycle Clock. In: Weinberg RA, ed. *The Biology of Cancer*. 2nd ed. New York, NY: Garland Science; 2014:275-329.

ⁱⁱⁱ Sotillo E, Grana X. Escape from Cellular Quiescence. In: Enders GH, ed. *Cell Cycle Deregulation in Cancer*. New York, NY: Humana Press; 2010:3-22.

^{iv} Pfizer. Data on file.

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