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Pfizer Malaysia is among the first in Southeast Asia to launch IBRANCE[®]: One of the first in a new class treatment for Metastatic Breast Cancer

IBRANCE[®] Now Available for Use in Combination with Letrozole as One of the First-Line Treatments of Postmenopausal Women with Estrogen Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative (ER+/HER2-) Metastatic Breast Cancer

KUALA LUMPUR, 5th August 2016 – Today, Pfizer Malaysia has unveiled a new frontier in the treatment of metastatic breast cancer in Malaysia with the launch of a new anti-cancer agent, IBRANCE[®]. IBRANCE[®] first received accelerated approval by the U.S. Food and Drug Administration (FDA) under the *Breakthrough Therapy Designation and Priority Review Programmes* in February 2015 based on its Progression Free Survival (PFS).¹

Malaysia is among the first country in Southeast Asia where IBRANCE[®] is available. Based on the innovation and proven PFS results, the National Pharmaceutical Regulatory Agency in Malaysia has granted regulatory approval via a priority review for IBRANCE[®] earlier in June this year² to enable better access to innovative therapy for metastatic breast cancer treatment.

In Malaysia 5,000 women aged between 30 and 60 are diagnosed with breast cancer every year and it is found that 1 out of 19 Malaysian women are likely to develop breast cancer at some point in her life.³ Up to 30% of all women who have early stage breast cancer are expected to develop metastatic breast cancer despite the right treatment and prevention measures.⁴ Known as the most advanced stage of breast cancer, metastatic breast cancer

¹ FDA: Palbociclib (IBRANCE Capsules), Online: <http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm487080.htm>, Last consultation: 15.06.2016

² NATIONAL PHARMACEUTICAL CONTROL BUREAU: Permohonan Priority Review Untuk Produk Baru, Nama Produk: Ibrance, 29.09.2015

³ Cancer Research Malaysia: Facts and Figures. Online: <http://www.cancerresearch.my/research/breast-cancer/>, Last consultation: 15.06.2016

⁴ PFIZER: Metastatic Breast Cancer, Online: http://www.pfizer.com/files/news/Metastatic_Breast_Cancer_Fact_Sheet_4.15.16.PDF, Last consultation: 15.06.2016

occurs when the cancer has spread to other parts of the body, such as the brain, lungs, bones and liver.⁵

The discovery of IBRANCE[®] marks a pivotal milestone as one of the first medicines in a new class of anti-cancer agents, cyclin-dependent kinase (CDK) 4/6 inhibitors in combination with another hormone-based therapy for metastatic breast cancer patients with improved efficacy as compared to the current option.⁶ It is now available as one of the first-line treatments for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced metastatic breast cancer.⁶ Now this treatment will be available to metastatic breast cancer patients in Malaysia providing them an option to live a better quality of life.

The primary results from the PALOMA-1 study proved the clinical benefit of IBRANCE[®] by confirming the prolonged PFS is 20.2 months (95% CI: 13.8, 27.5) for women treated with the combination of IBRANCE[®] and letrozole compared to the 10.2 months PFS for women treated with letrozole alone (95% CI: 5.7, 12.6) (HR:0.488 [95% CI: 0.319, 0.748]).⁷ This is a ground breaking achievement as IBRANCE[®] in combination with letrozole almost double the PFS as compared to letrozole alone, which the latter is currently the standard of care for this group of patients.

Noor Yang Azwar Kamarudin, Director of Corporate Affairs, Health & Value, Pfizer Malaysia spoke during the launch on the significance of this milestone for breast cancer, “Scientific advancement in metastatic breast cancer has remained minimal in past years. We are proud to bring IBRANCE[®] to the breast cancer patients today as this therapy gives new hope to women suffering from metastatic breast cancer. The clinical result is truly revolutionary as it delays the progression of cancer by twofold as compared to the previous treatment option. This advancement demonstrates the strength of Pfizer’s innovative core and meaningful global partnerships to deliver breakthrough medicines to address patient’s needs. We will continue to advance the frontiers of cancer biology, increase public awareness on metastatic breast cancer and provide support to patients who need it.”

“The prevalence of breast cancer continues to rise as 1.7 million women worldwide are diagnosed with breast cancer annually. However, public awareness on metastatic breast cancer persists to be much lower as compared to breast cancer. In fact, ER+/HER2- is the most common subtype of breast cancer with 60% of patients having advanced breast cancer. In Malaysia, almost 50% of women diagnosed with breast cancer are under 50 years old. Delays in consultation and diagnosis also present serious problems for women in the country but what is more alarming is that 18% of Malaysian women are Stage IV breast cancer patients,” shared Dr. Mastura Md Yusof, Consultant Oncologist at the Cancer Institute of Pantai Hospital Kuala

⁵ IBRANCE[®]: What is Metastatic Breast Cancer?, Online: <https://www.IBRANCE.com/about-metastatic-breast-cancer>, Last consultation: 15.06.2016

⁶ IBRANCE[®] (palbociclib), Online: <https://www.ibrance.com/ibrance-overview>, Last consultation: 15.06.2016

⁷ The Lancet Oncology: The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): a randomised phase 2 study, Online: <http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045%2814%2971159-3.pdf>, Last consultation: 22.07.2016

Lumpur. She added, “This new treatment represents an important advancement that can help bridge the gap between public perception on breast cancer and patients’ experiences by focusing on the untold story of metastatic breast cancer in Malaysia.”

Also present at the launch was Dr. John Low, Consultant Oncologist at the Cancer Institute of Pantai Hospital Kuala Lumpur, who spoke on the future of metastatic breast cancer treatment, “As the chapter of oncology treatment advances, the ultimate goal of treating breast cancer in the metastatic setting is focused on improving patients’ survival times and their quality of life. Although cure for metastatic breast cancer has yet to be found, this novel discovery highlights the significant strides achieved in the domain of ER+/HER2- metastatic breast cancer by bringing us closer to our aim. It is vital for patients to get cancer treated early but more importantly, understanding the options and treatment possibilities as well as having access to it play an even more crucial role in the patient’s survival.”

“With this clinical development, we now have a first-line treatment option with proven results that will greatly improve the outlook for cancer patients worldwide and in Malaysia. Metastatic breast cancer patients make up a community that is in great need of more clinical advances in the treatment of metastatic disease. We strongly believe that patients should have access to the medicines they need and we will work closely with local healthcare professionals and authorities to ensure patient access to new innovative oncology therapies,” said Dr. Mahmood Alam, Pfizer Oncology’s Regional Senior Medical Affairs Lead who spoke at the event.

With its commitment in research and development, Pfizer has been bringing innovative life-saving and live-extending medicines to cancer patients. IBRANCE[®] symbolises an important milestone that demonstrates the strength of the company’s science and provides a significant medicine to patients in need. In order to improve and extend the lives of Stage IV breast cancer patients, Pfizer plans to continue investing significantly in clinical trials of IBRANCE[®] in ER+/HER2- breast cancer across stages and treatment settings.

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About IBRANCE[®] (palbociclib) capsules

IBRANCE[®] is an oral first-in-class inhibitor of cyclin-dependent kinases (CDKs) 4 and 6. CDKs 4 and 6 are key regulators of the cell cycle that trigger cellular progression.^{8,9} IBRANCE[®] was granted a priority review by the National Pharmaceutical Regulatory Agency² for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced metastatic breast cancer.

About Metastatic Breast Cancer (MBC)

⁸ 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.

⁹ 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

MBC occurs when cancer spreads beyond the breast to other parts of the body, including the bones, lungs, liver and brain.⁵ An estimated 1.7 million new cases of breast cancer are diagnosed globally each year.¹⁰ Globally, five to 10 percent of newly diagnosed breast cancer patients will present with metastatic disease, however, in low- and middle-income countries 50-80% are initially diagnosed with advanced disease.^{4,11} In developed countries, approximately 30% of women diagnosed with early breast cancer progress to MBC, and this number may be higher in less developed countries.^{12,13}

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer 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.

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 health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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.

¹⁰ INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC) AND WORLD HEALTH ORGANIZATION (WHO): Latest world cancer statistics Global cancer burden rises to 14.1 million new cases in 2012, Online: https://www.iarc.fr/en/media-centre/pr/2013/pdfs/pr223_E.pdf, Last consultation: 15.06.2016

¹¹ Unger-Saldana K. Challenges to the early diagnosis and treatment of breast cancer in developing countries. *World J Clin Oncol.* 2014;5(3):465-477.

¹² O'Shaughnessy. Extending Survival with Chemotherapy in Metastatic Breast Cancer. *The Oncologist.* 2005;10(suppl 3):20-29

¹³ Agarwal G, et al. Spectrum of Breast Cancer in Asian Women. *World J Surg* 2007; 31:1031-1041.