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Palbociclib demonstrates significant benefits for Asian women with Metastatic Breast Cancer in clinical trial

*The Phase 3 PALOMA-2 clinical trial provides confirmatory evidence demonstrating
the extension of progression-free survival*

KUALA LUMPUR, 16th February 2017 – Palbociclib, an innovative anti-cancer agent for women with metastatic breast cancer (MBC) was made available in Malaysia six months ago. Today, Pfizer Malaysia announced the results from the global PALOMA-2 Phase 3 clinical trial which demonstrates that palbociclib together with letrozole has been found to extend Progression-Free Survival (PFS) in Asian patients by more than 11 months compared with letrozole plus placebo. The term ‘PFS’ means how long women live before their tumour (or cancer) starts growing again. The results have demonstrated that patients treated with palbociclib together with letrozole are able to extend their survival rate without disease progression by more than 24 months or 2 years.

At the media briefing, Pfizer Malaysia presented results of the sub-analysis of the PALOMA-2 trial, where the investigator-assessed median PFS for Asian women who underwent palbociclib plus letrozole treatment was 25.7 months (95% CI, 19.2-not estimable) compared with 13.9 months (95% CI, 7.4-22.0) for women went through the letrozole plus placebo treatment (HR=0.48 [95% CI, 0.27-0.87], 1-sided P=0,007).

“PALOMA-2 is the third clinical trial and the second largest Phase 3 study completed for palbociclib, adding to the robust, positive body of evidence to-date for this first-in-class therapy when used in combination with another endocrine partner. The significant improvement in terms of efficacy of the treatment for Asian patients shown in the PALOMA-2 trial is very encouraging and demonstrates the potential for palbociclib to be a standard of care treatment in Malaysia where 5,000 women aged between 30 and 60 are diagnosed with breast cancer every year.¹” said Noor Yang Azwar Kamarudin, Director of Corporate Affairs, Health & Value, Pfizer Malaysia.

¹ Cancer Research Malaysia: Facts and Figures. Online: <http://www.cancerresearch.my/research/breast-cancer/>, Last consultation: 15.06.2016

In Malaysia, it is found that 1 out of 19 women have a likelihood of developing breast cancer at some point of their lives¹. Despite the right treatments and prevention measures, up to 30% of women who are diagnosed with early stage breast cancer are expected to develop MBC². This is a condition where the cancer has spread to other parts of the body such as the liver, lungs, bones or brain.³ To-date, it remains incurable⁴ and patients face a median survival of 18 to 24 months⁵. Being able to significantly extend the PFS period as demonstrated by the results of PALOMA-2 goes a long way to giving valuable time for patients and the quality of life.

Azwar added at the media briefing, “We are committed as ever to advance the frontier of oncology with precision medicines while continuing our work in increasing disease awareness of advance or metastatic cancer. These results tell us that we are on the right path – pursuing medical breakthroughs by leveraging on the strengths of Pfizer’s innovative core especially in precision medicine and global partnerships to support patients who are counting on us.”

Dr. John Low and Dr. Mastura Md Yusof, Consultant Oncologists at the Cancer Institute of Pantai Hospital Kuala Lumpur were present at the media briefing together with patients. These patients who underwent treatment bravely shared on their journeys – the challenges they faced, how they felt emotionally and what it means for them to have more time and a better quality of life.

84-year-old Yang Teramat Mulia Dato’ Tunku Mukminah Jiwa, who was first diagnosed in September 2014, said, “When I found out that the cancer had spread to my lungs and spine, I remembered fearing what happens next and how this news was going to affect my family. Many women face this situation too, and this is why I am eager to share my journey in hopes that it may inspire and encourage others that there is still hope. So far, I’ve been having a fulfilling journey and continue to take each day at a time.”

Sarina binti Mat Salleh shared, “It is devastating when you find out you have MBC. Your world stops and you start to think about your family and your friends. Every moment I get to spend with my loved ones is something I dearly cherish and appreciate. Having a better quality of life allows me to do that without being weighed down by pain, discomfort or being a burden to my family.”

Dr. John spoke about the importance of the results today, “As the world continues searching for a cure for MBC, the goal of treating it today, is ultimately on improving patients’ survival rates as well as their quality of life. In Malaysia, palbociclib in combination with letrozole, is the first and only approved treatment for ER+, HER2- MBC to exceed two years in median PFS in the

² 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

³ IBRANCE®: What is Metastatic Breast Cancer?, Online: <https://www.IBRANCE.com/about-metastatic-breast-cancer>, Last consultation: 15.06.2016

⁴ Cardoso F, et al. ESO-ESMO 2nd international consensus guidelines for advanced breast cancer (ABC2). The Breast 2014;23:489-502.

⁵ Martino, M. Long-term survival in patients with metastatic breast cancer receiving intensified chemotherapy and stem cell rescue; data from the Italian registry. 2013. U.S. National Library of Medicine, National Institutes of Health. Available at: www.ncbi.nlm.nih.gov/pubmed/22863724.

randomised Phase 3 study. This demonstrates significant strides in the treatment of MBC and provides new options for MBC patients.”

Dr. Mastura stressed on the importance of greater public awareness on MBC saying, “Often viewed with pessimism, MBC remains very much an untold story here in Malaysia despite the improving public awareness on breast cancer. This is a cause for concern as 60% of patients diagnosed with the most common subtype of breast cancer, ER+/HER2-, are having a more advanced stage of breast cancer. In fact, 18% of Malaysian women are Stage IV breast cancer patients. We see improving efforts to encourage early detection and improve treatment for this patient group. However there is still a huge gap between what patients experience and public perception and we need to bridge it. There is still room for greater awareness and greater support for patients diagnosed with MBC.”

Dr. John further explained, “What we have here is a first line treatment option that has proven significant results. MBC patients are a community that is in great need of such clinical advances in their treatment journey. Giving them access to these new innovative oncology therapies is indeed necessary.”

The results of the PALOMA-2 Phase 3 Study represents an important milestone that reinforces Pfizer’s commitment in bringing innovative life-saving and life-extending medicines to cancer patients. Pfizer remains dedicated to the pursuit of improving and extending the lives of Stage IV breast cancer patients and will continue investing in research and development to support patients’ needs.

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About PALOMA-2

PALOMA-2 is a randomized (2:1), multicenter, multinational, double-blind Phase 3 study implemented to assess the PFS rates of palbociclib (125 mg orally once daily for three out of four weeks in repeated cycles) in combination with letrozole (2.5 mg once daily continuously) against letrozole plus placebo as a first-line treatment for postmenopausal women with ER+, HER2- MBC. PALOMA-2 evaluated a total of 666 women (95 of them being Asians) from 186 global sites in 17 countries⁶.

About palbociclib capsules

Palbociclib 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.^{7, 8} Palbociclib was granted a priority review by the National Pharmaceutical Regulatory Agency⁹ for the treatment

⁶ Finn RS, et al. PALOMA-2: Primary results from a phase III trial of palbociclib (P) with letrozole (L) compared with letrozole alone in postmenopausal women with ER+/HER2- advanced breast cancer (ABC). *J Clin Oncol* 34, 2016 (suppl; abstr 507)

⁷ 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.

⁸ 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

⁹ NATIONAL PHARMACEUTICAL CONTROL BUREAU: Permohonan Priority Review Untuk Produk Baru, 29.09.2015

of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced MBC.

About MBC

MBC occurs when cancer spreads beyond the breast to other parts of the body, including the bones, lungs, liver and brain³. 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.^{2,11} 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.