Novartis CDK4/6 inhibitor LEE011 (ribociclib) receives FDA Breakthrough Therapy designation as first-line treatment for HR+/HER2- advanced breast cancer

Novartis International AG /Novartis CDK4/6 inhibitor LEE011 (ribociclib) receives FDA Breakthrough Therapy designation as first-line treatment for HR+/HER2- advanced breast cancer . Processed and transmitted by NASDAQ OMX Corporate Solutions.The issuer is solely responsible for the content of this announcement.

Designation underscores the continuing unmet need of the HR+/HER2- advanced breast cancer population and the potential of LEE011 (ribociclib) as an effective new treatment option Â Results from Phase III MONALEESA-2 trial of LEE011 in combination with letrozole in postmenopausal women who had received no prior treatment will be presented at upcoming medical congress and form the basis of regulatory discussions Â Marks the 11th Breakthrough Therapy designation granted to Novartis demonstrating company's commitment to developing innovative treatments that address unmet medical need Basel, August 3, 2016 - Novartis announced today that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to LEE011 (ribociclib), in combination with letrozole, for the treatment of hormone receptor positive,Â human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced or metastatic breast cancer. LEE011 is a selective cyclin dependent kinase (CDK4/6) inhibitor.

The Breakthrough Therapy designation is based primarily on positive results of the Phase III MONALEESA-2 trial of LEE011 in combination with letrozole in postmenopausal women who had received no prior therapy for their advanced disease[1]. The MONALEESA-2 trial met the primary endpoint of clinically meaningful improvement in progression free survival (PFS) at a pre-planned interim analysis. Results of this study will be presented at an upcoming medical congress and will form the basis of regulatory discussions in the US, Europe and other countries for use in this indication.

"Despite advancements in treatment, an estimated 40,000 individuals in the United States die each year from advanced breast cancer," said Alessandro Riva, MD, Global Head, Oncology Development and Medical Affairs, Novartis Oncology. "This designation shows the potential of LEE011, and we look forward to close collaboration with the FDA and the advanced breast cancer community to provide a new treatment option for

women living with HR+/HER2- advanced breast cancer as quickly as possible."

Up to one-third of patients with early-stage breast cancer will subsequently develop metastatic disease[2]. Metastatic breast cancer is the most serious form of the disease and occurs when the cancer has spread to other parts of the body, such as the brain, bones or liver[3]. Advanced breast cancer comprises metastatic breast cancer (stage 4) and locally advanced breast cancer (stage 3)[3]. Survival rates for women living with advanced breast cancer are lower than those for women with earlier stage disease. The 5-year relative survival rate for stage 3 breast cancer is approximately 72%, while metastatic (stage 4) breast cancer has a 5-year relative survival rate of approximately 22%[4].

According to the FDA, Breakthrough Therapy designation is intended to expedite the development and review of potential new medicines that treat serious or life-threatening conditions, if the therapy has demonstrated substantial improvement over an available therapy on at least one clinically significant endpoint. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program[5].

The LEE011 Breakthrough Therapy designation marks the 11th designation the FDA has granted to Novartis since the agency initiated the program in 2013, demonstrating Novartis' commitment to developing innovative treatments for diseases with a significant unmet medical need.

About LEE011 (ribociclib)LEE011 (ribociclib) is a selective cyclin dependent kinase inhibitor, a new class of drugs that help slow the progression of cancer by inhibiting two proteins called cyclin dependent kinase 4 and 6 (CDK4/6). These proteins, when over-activated in a cell, can enable cancer cells to grow and divide too quickly.

LEE011 has been studied in non-clinical models and is currently being evaluated in combination with additional endocrine agents as part of the MONALEESA (Mammary ONcology Assessment of LEE011's Efficacy and SAfety) clinical trial program. LEE011 is not approved for any indication in any market at this time.

MONALEESA-2 is a Phase III randomized, double blind, placebo controlled, multicenter global registration trial to evaluate the safety and efficacy of LEE011 in combination with letrozole compared to letrozole alone in postmenopausal women with HR+/HER2- advanced breast cancer who received no prior therapy for their

advanced breast cancer[1]. MONALEESA-2 met the primary endpoint of clinically meaningful improvement in PFS at the pre-planned interim analysis and is continuing to assess overall survival data[1].

MONALEESA-3 is a trial evaluating LEE011 in combination with fulvestrant compared to fulvestrant alone in men and post-menopausal women with HR+/HER2- advanced breast cancer who have received no or a maximum of one prior endocrine therapy. MONALEESA-3 is fully enrolled.

MONALEESA-7 is a trial investigating LEE011 in combination with endocrine therapy and goserelin compared to endocrine therapy and goserelin alone in pre-menopausal women with HR+/HER2- advanced breast cancer who have not previously received endocrine therapy. MONALEESA-7 is fully enrolled and is the only Phase III study that focuses solely on pre and perimenopausal women with advanced breast cancer.

LEE011 was developed by Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

About Novartis in advanced breast cancerFor more than 25 years, Novartis has been at the forefront of driving scientific advancements for breast cancer patients and improving clinical practice in partnership with the global community[1]. With one of the most diverse breast cancer pipelines and the largest number of breast cancer compounds in development, Novartis leads the industry in discovery of new therapies and combinations, especially in HR+ advanced breast cancer, the most common form of the disease[1].

DisclaimerThe foregoing release contains forward-looking statements that can be identified by words such as "Breakthrough Therapy designation," "continuing," "potential," "will," "upcoming," "commitment," "look forward to," "Fast Track program," "evaluating," "investigating," "pipelines," or similar terms, or by express or implied discussions regarding potential marketing approvals for LEE011, or regarding potential future revenues from LEE011. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that LEE011 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that LEE011 will be commercially successful in the future. In particular, management's expectations regarding LEE011 could be affected by, among other things, the uncertainties inherent in research and development,

including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; competition in general; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing, safety or quality issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About NovartisNovartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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