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STRICTLY EMBARGOED: 00:01 BST WEDNESDAY 17TH JULY

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Novartis' Kisqali® (ribociclib) receives NICE recommendation for most common form of advanced breast cancer in combination with fulvestrant

- *Advanced breast cancer is an incurable disease - in the UK 85% of women with metastatic breast cancer will not survive for 5 years or more after diagnosis*[1]
- *Kisqali (ribociclib) in combination with fulvestrant is a new and effective second line treatment option for post-menopausal women in England and Wales who are living with the most common form of advanced breast cancer*
- *This combination gives women the possibility of living 5 months longer without their disease worsening compared with fulvestrant alone.*[2]
- *NICE recommends ribociclib in combination with fulvestrant for immediate use on the NHS for hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) locally advanced or metastatic breast cancer in women who have had previous endocrine therapy.*[3]

Camberley, UK, July 17th 2019 – Novartis today announced that Kisqali® (ribociclib) has been recommended by the National Institute for Health and Care Excellence (NICE) for use on the NHS in combination with fulvestrant, where exemestane plus everolimus is the most appropriate alternative, for the treatment of women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) locally advanced or metastatic breast cancer who have received prior endocrine therapy.[2]

In the UK, around 55,000 women are diagnosed with breast cancer each year.[4] 30% of women with earlier stages of breast cancer will develop advanced disease.[5] 85% of women diagnosed with advanced breast cancer will not live longer than 5 years.[1]

Ribociclib in combination with fulvestrant will be available on the NHS with immediate effect, providing approximately 5,300 patients in England and Wales with a new option for their advanced breast cancer.[6] The combination gives women the possibility of living 5 months longer without their disease worsening, than if receiving fulvestrant alone.[2]

The NICE recommendation follows data from the MONALEESA-3 trial showing that ribociclib plus fulvestrant demonstrated superior efficacy, with median progression-free survival (PFS) of 20.5 months vs.12.8 months for placebo plus fulvestrant, among overall study population of first- and second-line post-menopausal patients with HER2 negative advanced breast cancer.[7]

This NICE recommendation is based on the second line subpopulation of MONALEESA-3 where ribociclib plus fulvestrant demonstrated a median PFS of 14.6 months vs 9.1 months with placebo plus fulvestrant.[2]

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The second line subpopulation consisted of patients who had progressed after one line of endocrine treatment for advanced disease or relapsed while on, or within 12 months of completing, neoadjuvant or adjuvant endocrine therapy.

"Here at the Northern Centre for Cancer Care, we took part in the MONALEESA-3 trial that established the efficacy of this combination treatment" said Dr Mark Verrill, Consultant Medical Oncologist. "Ribociclib is already approved alongside an aromatase inhibitor as first treatment for metastatic breast cancer. However, until very recently, we were unable to offer ribociclib or another drug of the same type to women who had already received an aromatase inhibitor and it had stopped working. This restriction meant that around half of the patients who might benefit from ribociclib could not receive it.

It is a vital step forward to be able to offer ribociclib in combination with fulvestrant after an aromatase inhibitor and I anticipate many women benefitting from this approval. Helping women with this incurable disease by controlling it for longer and maintaining quality of life is a significant step forward."

"The recommendation by NICE is an important development for patients with advanced breast cancer who need additional treatment options that can maintain their quality of life, and provide them with more time without disease progression. This now means ribociclib is available in multiple indications through the NHS which, coupled with the recent ASCO data demonstrating increased survival for pre-menopausal women with HR+/HER2- breast cancer, offers real hope to patients" said Mari Scheiffele, Novartis Oncology General Manager, UK & Ireland. "Novartis is reimagining medicine to transform cancer, and this milestone reflects our dedication to driving ongoing innovation in the treatment of breast cancer."

The NICE recommendation has been published in its final draft guidance. Novartis is awaiting the NICE Technology Appraisal Guidance, the final step within the NICE approval process, which is scheduled for publication later this year and will be available via the NICE website. There will be immediate access to the combination treatment in England through the Cancer Drugs Fund (CDF) and in Wales through the Welsh New Treatment Fund, whilst Novartis await the NICE Technology Appraisal.

In 2017, ribociclib was approved in England and Wales for routine baseline commissioning as a first-line treatment in combination with an aromatase inhibitor.[8]

About Kisqali® (ribociclib)[8]
Kisqali (ribociclib) is a selective cyclin-dependent kinase inhibitor, a 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, can enable cancer cells to grow and divide rapidly. Targeting CDK4/6 with enhanced precision may play a role in ensuring that cancer cells do not continue to replicate uncontrollably.[9]

Ribociclib is approved for use in the UK for the treatment of women with HR+/HER2- locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

Ribociclib can be taken with or without food as a once-daily oral dose of 600 mg (three 200 mg tablets) for three weeks, followed by one week off treatment. Ribociclib is taken in combination with four weeks of any aromatase inhibitor, or with 500 mg of fulvestrant that should be given by intramuscular injection on Days 1, 15, 29, and once monthly thereafter. Please refer to the SmPC of fulvestrant for additional details.

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

About MONALEESA-3. [2]
MONALEESA-3 was a randomised, double-blind, placebo-controlled, multi-centre, phase III trial in postmenopausal women with HR+/HER2- mBC who received no or only 1 prior line of endocrine therapy for advanced or metastatic disease. Patients (N=726) were stratified by the presence of liver and/or lung metastases and prior endocrine therapy for advanced or metastatic disease. Patients were randomised (2:1) to receive either KISQALI 600 mg (3 weeks on, 1 week off) and fulvestrant 500 mg (intramuscular injection on Days 1, 15, 29, and once monthly thereafter) or placebo (3 weeks on, 1 week off) and fulvestrant 500 mg (intramuscular injection on Days 1, 15, 29, and once monthly thereafter). The primary end point was PFS using RECIST v1.1; secondary end points included OS, ORR, QOL, and safety.

About Novartis in Advanced Breast Cancer
Novartis tackles breast cancer with superior science, collaboration and a passion for transforming patient care. Our priority over the past 30 years and today is to deliver treatments proven to improve and extend lives for those diagnosed with advanced breast cancer.

About Novartis
Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 130 000 people of nearly 150 nationalities work at Novartis around the world. Find out more at www.novartis.com.

In the UK, we employ approximately 1,500 people to serve healthcare needs across the whole of the UK, as well as supporting the global operations of Novartis. Since 2014, Novartis has invested over £200 million in R&D and is a leading sponsor of clinical trials, in the UK. For more information, please visit www.novartis.co.uk.

Novartis UK is on Twitter. Sign up to follow @NovartisUK at https://twitter.com/novartisuk
For Novartis multimedia content, please visit https://www.novartis.co.uk/news/media-library

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