

Novartis presents new data at SABCS across broad range of breast cancer patient populations, combination treatments and lines of therapy

Nov 14, 2017

- - Presentation of results from the Kisqali® (ribociclib) MONALEESA-7 Phase III trial exclusively studying premenopausal women with HR+/HER2- advanced breast cancer
- - New MONALEESA-2 analyses focused on quality of life, biomarkers and treatment sequencing to be presented
- - Data across portfolio and pipeline address potential of biomarkers and combination treatments in the neoadjuvant and in the advanced first-line and second-line setting

EAST HANOVER, N.J., Nov. 14, 2017 /PRNewswire/ -- Novartis will present data across its breast cancer portfolio and pipeline in a broad range of patient populations, treatment combinations and pathways at the upcoming 40th annual San Antonio Breast Cancer Symposium (SABCS), San Antonio, December 5-9.

"Our presentations at SABCS will address some of the most pressing challenges and questions facing the advanced breast cancer community, including the need to better understand treatment sequencing and biomarkers," said Bruno Strigini, CEO, Novartis Oncology. "At Novartis, we seek to advance scientific understanding of breast cancer with the ultimate goal of improving treatments and outcomes for those affected by the disease. We are pleased to share the latest data from our MONALEESA program, which continues to evaluate the potential of Kisqali treatment in new patient populations."

Results from the Phase III MONALEESA-7 trial in premenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer will be presented for the first time in a late-breaker oral presentation.

- First-line ribociclib vs placebo with goserelin and tamoxifen or a non-steroidal aromatase inhibitor in premenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer: Results from the randomized phase III MONALEESA-7 trial [Abstract #S2-05; Wednesday, December 6, 4:15 – 4:30 PM CST]

Additional abstracts from across the breast cancer portfolio include:

Kisqali® (ribociclib)*

- First-line ribociclib + letrozole in hormone receptor-positive, HER2-negative advanced breast cancer: Efficacy by baseline circulating tumor DNA alterations in MONALEESA-2 [Abstract #PD4-06; Thursday, December 7, 7:00 – 9:00 AM CST]
- Subsequent treatment for postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer who received ribociclib + letrozole vs placebo + letrozole in the phase III MONALEESA-2 study [Abstract #P5-21-18; Friday, December 8, 5:00 – 7:00 PM CST]
- Efficacy and safety of ribociclib plus letrozole in US patients enrolled in the MONALEESA-2 study [Abstract #P5-21-27; Friday, December 8, 5:00 – 7:00 PM CST]

- Quality of life and patient-reported outcomes in US patients enrolled in the MONALEESA-2 study [Abstract #P1-13-12; Wednesday, December 6, 5:00 – 7:00 PM CST]
- EarLEE-2: A phase 3 study of ribociclib + endocrine therapy (ET) for adjuvant treatment of patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), intermediate-risk, early breast cancer (EBC) [Abstract #OT3-05-06; Friday, December 8, 5:00 – 7:00 PM CST]
- Patient-centered initiatives for improving trial participation of diverse patient populations in the open-label phase 3b ComplEEment-1 study of ribociclib plus letrozole in the treatment of HR+/HER2- advanced breast cancer [Abstract #P4-10-07; Friday, December 8, 7:00 – 9:00 AM CST]

Afinitor® (everolimus)

- Serum activin A and outcomes in HR+/HER2- metastatic breast cancer patients treated with everolimus: Results from BOLERO-2 [Abstract #P1-07-09; Wednesday, December 6, 5:00 – 7:00 PM CST]
- Ribociclib in combination with everolimus and exemestane in men and postmenopausal women with HR+/HER2- advanced breast cancer following progression on a CDK4/6 inhibitor: Efficacy and updated safety and pharmacokinetic results from phase 1 of the TRINITI-1 study [Abstract #PD5-11; Thursday, December 7, 5:00 – 7:00 PM CST]

Tykerb® (lapatinib)**

- Copy number aberration analysis to predict response to neoadjuvant anti-HER2 therapy: results from the NeoALTTO phase III trial [Abstract #S1-04; Wednesday, December 6, 10:15 – 10:30 AM CST]
- Circulating tumor DNA in HER2 amplified breast cancer: A translational research substudy of the NeoALTTO phase III trial [Abstract #PD3-03; Thursday, December 7, 7:00 – 9:00 AM CST]

Alpelisib (BYL719)

- BYLieve: A phase 2 study of alpelisib with fulvestrant or letrozole for treatment of PIK3CA mutant, hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer (aBC) progressing on/after cyclin-dependent kinase (CDK)4/6 inhibitor therapy [Abstract #OT3-05-02; Friday, December 8, 5:00 – 7:00 PM CST]
- Alpelisib plus letrozole in estrogen receptor-Positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer (aBC): Safety and preliminary efficacy analysis from a phase 1b trial [Abstract #P5-21-06; Friday, December 8, 5:00 – 7:00 PM CST]

LSZ102

- Phase I/Ib study of the SERD LSZ102 alone or in combination with ribociclib in ER+ breast cancer [Abstract #P5-21-04; Friday, December 8, 5:00 – 7:00 PM CST]

Product Information

Approved indications for products vary by country and not all indications are available in every country. The product safety and efficacy profiles have not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that compounds will become commercially available with additional indications.

For prescribing information, including approved indications and important safety information about marketed products, please visit <https://www.novartis.com/our-work/product-portfolio>.

Alpelisib (BYL719), buparlisib (BKM120) and LSZ102 are investigational compounds. Efficacy and safety have

not been established. There is no guarantee these compounds will become commercially available.

About Novartis in Advanced Breast Cancer

For more than 25 years, Novartis has been at the forefront of driving scientific advancements for breast cancer patients and improving clinical practice in collaboration with the global community. 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.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing 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 Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation is an affiliate of Novartis which 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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 121,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis> and @NovartisCancer at <http://twitter.com/novartiscancer>.

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For questions about the site or required registration, please contact media.relations@novartis.com.

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

** Marketed as Tyverb[®] in Europe and Tykerb[®] in the United States

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