

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis presents new data on targeted combination therapy at SABCS reinforcing commitment to breast cancer patients**

- *More than 50 abstracts will be presented, including data on Afinitor[®] and investigational compounds for advanced breast cancer, showing pipeline strength*
- *Presentations highlight results of combination therapy with targeted agents compared to endocrine therapy in HR+/HER2- advanced breast cancer*
- *Clinical and pre-clinical data show that inhibition of both HR and PI3K/mTOR or CDK 4/6 pathways may play important role in treatment of advanced breast cancer*

Basel, December 2, 2015 – Novartis will present data that highlight advancements in targeted combination therapy research, and underscore the company's continued commitment to bringing innovative treatments to patients living with advanced breast cancer at the 2015 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), December 8-12. Novartis will present 55 abstracts showcasing key real-world data from Afinitor[®] (everolimus), Tykerb[®] (lapatinib) and several investigational compounds in advanced breast cancer¹.

"These data presented at SABCS reinforce the current focus toward combination therapies as the standard treatment for hormone receptor-positive, HER2 negative advanced breast cancer," said Alessandro Riva, MD, Global Head, Novartis Oncology Development and Medical Affairs. "Given the breadth of our portfolio, we are well positioned to explore innovative treatment combinations with the goal of providing the greatest benefit for patients living with advanced breast cancer."

Key Afinitor presentations show real-world data that add to the growing body of evidence demonstrating the benefit of staying on treatment:

- **BOLERO-2:** cfDNA analysis from BOLERO-2 plasma samples identifies a high rate of ESR1 mutations: Exploratory analysis for prognostic and predictive correlation of mutations reveals different efficacy outcomes of endocrine therapy-based regimens (SABCS Oral Poster: #S2-07; December 9, 4:45 PM CST)
- **EVEREXES:** Clinical effectiveness of everolimus and exemestane in advanced breast cancer patients from Asia and Africa: First efficacy and updated safety results from the phase IIIb study (SABCS Abstract #P4-13-09; December 11, 7:30 AM CST)
- **Evaluation of miracle mouthwash (MMW) plus hydrocortisone versus prednisolone mouth rinses as prophylaxis for everolimus-associated stomatitis:** Preliminary results of a randomized phase II study (SABCS Abstract #P1-15-06; December 9, 5:00 PM CST)
- **BALLET:** Stomatitis following everolimus (EVE) plus exemestane (EXE) in patients with hormone receptor-positive (HR+), HER2-advanced breast cancer (ABC) in the BALLET trial (SABCS Abstract #P4-13-10; December 11, 7:30 AM CST)

- BRAWO: Stomatitis in patients treated with everolimus and exemestane - Results of the 3rd interim analysis of the non-interventional trial (SABCS Abstract #P4-13-08; December 11, 7:30 AM CST)
- BRAWO: Impact of physical activity/exercise on adverse events and quality of life during treatment with everolimus and exemestane for ER+ women - Results of the 3rd interim analysis (SABCS Abstract #P4-13-07; December 11, 7:30 AM CST)
- BRAWO: Results of the third interim analysis – Sub-analysis of patients < 70 years and ≥ 70 years (SABCS Abstract #P4-13-06; December 11, 7:30 AM CST)

Investigational data in PI3K/mTOR and CDK 4/6 pathways demonstrate value of inhibiting multiple targets via dual or triplet therapy:

- BELLE-2: PIK3CA status in circulating tumor DNA predicts efficacy of buparlisib plus fulvestrant in postmenopausal women with endocrine-resistant HR+/HER2– advanced breast cancer: First results from the randomized, Phase III BELLE-2 trial (SABCS Oral Presentation #S6-01; December 11, 3:15 PM CST)
- NeoPHOEBE: Phase II, randomized, parallel-cohort study of neoadjuvant buparlisib (BKM120) in combination with trastuzumab and paclitaxel in women with HER2-positive, PIK3CA mutant and PIK3CA wild-type primary breast cancer (SABCS Abstract #P1-14-01; December 9, 5:00pm CST)
- Triplet therapy with ribociclib, everolimus, and exemestane in women with HR+/HER2- advanced breast cancer (SABCS Abstract #P6-13-01; December 12, 7:30 AM CST)
- Phase Ib/II study of ribociclib and alpelisib and letrozole in ER+, HER2- breast cancer: Safety, preliminary efficacy and molecular analysis (SABCS Abstract #P3-14-01; December 10, 5:00 PM CST)

Data from the Make Your Dialogue Count (MYDC) survey, which sought to better understand how to improve communications among advanced breast cancer patients, caregivers and health care professionals, explore emotional effects of advanced breast cancer on caregivers:

- The experience of caregivers of women with metastatic breast cancer: Insights from the MYDC survey (SABCS Abstract #P1-11-06; December 9, 5:00 PM CST)

Other noteworthy data to be presented at SABCS on Tykerb® (lapatinib) and Sandoz proposed biosimilar pegfilgrastim:

- NeoALTTO: Whole exome sequencing of pre-treatment biopsies to identify DNA aberrations associated with response to HER2-targeted therapies in breast cancer (SABCS Oral Poster #S5-01; December 11, 9:30 AM CST)
- NeoALTTO (BIG 1-06): Breast ultrasound (US) and mammography (Mx) and response to neoadjuvant LAP, TRAS and their combination in HER2+ breast cancer (SABCS Abstract #P6-01-04; December 12, 7:30 AM CST)
- ALTTO: The impact of early LAP-induced rash on DFS and OS (SABCS Abstract # PD5-07; December 10, 5:00 PM CST)
- Results from PROTECT 1; A randomized, double-blind trial comparing the efficacy and safety of a proposed biosimilar pegfilgrastim (LA-EP2006) with reference pegfilgrastim in patients with breast cancer (SABCS Abstract #P1-10-01; December 9, 5:00 PM CST)

To read more about the Novartis research approach and perspectives on current trends in the breast cancer treatment landscape, visit www.novartis oncology.com/stories.

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 full prescribing information, including approved indications and important safety information about marketed products, please visit <http://www.novartis oncology.com/products.jsp>.

Because BKM120 (buparlisib), LEE011 (ribociclib), BYL719 (alpelisib) and LA-EP2006 are investigational compounds, the safety and efficacy profiles have not yet been fully established. Access to these investigational compounds is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of the outcome/results of the clinical trials, there is no guarantee that BKM120, LEE011, BYL719 and LA-EP2006 will ever be commercially available anywhere in the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “commitment,” “will,” “investigational,” “pipeline,” “focus,” “well positioned,” “goal,” “growing,” “exploratory,” “to be presented,” “proposed,” “yet,” or similar terms, or by express or implied discussions regarding potential marketing approvals for BKM120, LEE011, BYL719 or LA-EP2006, or regarding potential new indications or labeling for Afinitor or Tykerb, or regarding potential future revenues from such products and investigational compounds. 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 BKM120, LEE011, BYL719 or LA-EP2006 will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Afinitor or Tykerb will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products and investigational compounds will be commercially successful in the future. In particular, management’s expectations regarding such products and investigational compounds 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; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety issues; unexpected manufacturing 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 Novartis

Novartis 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 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 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>.

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

References

1. San Antonio Breast Cancer Symposium. SABCS Annual 2015 Meeting Program. Available at <https://www.sabcs.org/Program/Schedule-at-a-Glance>.

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