# Novartis data at ASH and SABCS show strength of pipeline and portfolio in hematology and oncology

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- - Additional analysis from pivotal Phase III SOLAR-1 clinical trial studying investigational alpha-specific PI3K inhibitor BYL719 (alpelisib) and fulvestrant in patients with PIK3CA-mutated HR+/HER2- advanced or metastatic breast cancer
- - Longer term follow-up from global pivotal clinical trials ELIANA and JULIET to be presented at ASH, reporting clinical impact of Kymriah® in patients with r/r pediatric B-cell ALL and adult DLBCL
- - First data presentation for asciminib (ABL001), a chronic myeloid leukemia compound evaluated in patients who are resistant to nearly all targeted CML therapies
- - New post-hoc analysis of SUSTAIN study of crizanlizumab (SEG101) evaluating the impact of treatment in vaso-occlusive crises in patients with sickle cell disease

EAST HANOVER, N.J., Nov. 2, 2018 /PRNewswire/ -- Novartis will present new research that may transform the way serious blood diseases and a certain type of breast cancer are treated at the upcoming 60$^{th}$ American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, December 1-4 and the 41$^{st}$ Annual San Antonio Breast Cancer Symposium (SABCS), December 4-8. Nearly 150 abstracts will be presented across both congresses, underscoring the strength of the Novartis pipeline and portfolio in hematology and oncology.

"Novartis Oncology has a purpose-driven legacy built on an unwavering commitment to help patients live better and longer lives," said Liz Barrett, CEO, Novartis Oncology. "The breadth and depth of our data at these scientific forums demonstrates how we are acting on our vision to reimagine cancer in a meaningful way for patients by relentlessly pursuing scientific advancements and exploring novel combination treatment options to help those living with hard-to-treat diseases."

Novartis data at the 2018 ASH Annual Meeting will highlight the following:

Updates on outcomes with Kymriah® (tisagenlecleucel) in adult relapsed or refractory (r/r) patients with diffuse large b-cell lymphoma (DLBCL) and pediatric and young adult patients with r/r acute lymphoblastic leukemia (ALL)*:

- Updated analysis of the efficacy and safety of tisagenlecleucel in pediatric and young adult patients with relapsed/refractory acute lymphoblastic leukemia [Abstract #895; Monday, December 3, 4:30 PM PT]
- Sustained disease control for adult patients with relapsed or refractory diffuse large b-cell lymphoma: an updated analysis of JULIET, a global pivotal Phase 2 trial of tisagenlecleucel [Abstract #1684; Saturday, December 1, 6:15 PM PT]

New post-hoc analysis of the SUSTAIN study evaluating crizanlizumab in patients with sickle cell disease:

- Established prevention of vaso-occlusive crises with crizanlizumab is further improved in patients who follow the standard treatment regimen: post-hoc analysis of the Phase II SUSTAIN study [Abstract #1082; Saturday, December 1, 6:15 PM PT]

First reported data for investigational compound asciminib (ABL001) in chronic myeloid leukemia (CML) patients with T315I genetic mutation that causes resistance to most BCR-ABL tyrosine kinase inhibitors (TKIs) approved to treat CML:

- Asciminib (ABL001), a specific allosteric BCR-ABL1 inhibitor, in patients with chronic myeloid leukemia and the T315I mutation in a Phase 1 trial [Abstract #792; Monday, December 3, 4:00 PM PT]

New data evaluating dabrafenib and trametinib combination treatment in hairy cell leukemia (HCL):

- Treatment with combination of dabrafenib and trametinib in patients with recurrent/refractory BRAF V600E–mutated hairy cell leukemia (HCL) [Abstract #391; Sunday, December 2, 12:00 PM PT]

Data evaluating Promacta® (eltrombopag) in patients with immune thrombocytopenia (ITP):

- Bleeding related episodes, thrombotic events and platelet counts among immune thrombocytopenia patients receiving second line therapy [Abstract #2436; Sunday, December 2, 6:00 PM PT]
- Treatment of ITP with eltrombopag in patients who have received prior rituximab: a post hoc analysis of the EXTEND study [Abstract #1152; Saturday, December 1, 6:15 PM PT]

Final results from the ITP World Impact Survey (I-WISh) about the burden of disease and impact of ITP on patient quality of life and productivity:

- Patients with immune thrombocytopenia (ITP) frequently experience severe fatigue but it is under-reported by physicians: Results from the ITP World Impact Survey (I-WISh) [Abstract #2273; Saturday, December 1, 6:15 PM PT]
- Patients with immune thrombocytopenia (ITP) experience impaired quality of life (QoL), with negative effects on their daily activities, social interactions, emotional well-being and working lives: Results from the ITP World Impact Survey (I-WISh) [Abstract #4804; Monday, December 3, 6:00 PM PT]

New analyses evaluating Rydapt® (midostaurin) in patients with FLT3-mutated acute myeloid leukemia (AML):

- Prognostic impact of insertion site in acute myeloid leukemia with FLT3 internal tandem duplication: results from the RATIFY study [Abstract #435; Sunday, December 2, 5:00 PM PT]
- RATIFY: prognostic impact of FLT3 tyrosine kinase domain (TKD) and NPM1 mutation status in patients with newly diagnosed acute myeloid leukemia (AML) treated with midostaurin or placebo plus standard chemotherapy [Abstract #2668; Sunday, December 2, 6:00 PM PT]
- RADIUS: A phase 2 randomized trial investigating standard of care ± midostaurin after allogeneic stem cell transplant in FLT3-ITD–mutated AML [Abstract #662; Monday, December 3, 10:45 AM PT]

New data evaluating Jadenu® (deferasirox) in patients with low- and int-1-risk myelodysplastic syndromes (MDS) and chronic iron overload:

- Safety and efficacy, including event-free survival, of deferasirox versus placebo in iron-overloaded patients with low- and int-1-risk myelodysplastic syndromes (MDS): outcomes from the randomized, double-blind TELESTO study [Abstract #234; Saturday, December 1, 5:15 PM PT]

New data evaluating Jakavi® (ruxolitinib)** for patients with polycythemia vera who are resistant to or intolerant of hydroxyurea:

- Long-term efficacy and safety (5 Years) in RESPONSE, a Phase 3 study comparing ruxolitinib (rux) with best available therapy (BAT) in hydroxyurea (HU)-resistant/intolerant patients (pts) with polycythemia vera (PV) [Abstract #1753; Saturday, December 1, 6:15 PM PT]

Additional data presented at ASH include:

- Complete responses in relapsed/refractory acute myeloid leukemia (AML) patients on a weekly dosing schedule of XmAb14045, a CD123 x CD3 T cell-engaging bispecific antibody: initial results of a phase 1 study [Abstract #763; Monday, December 3, 2:45 PM PT]

Sandoz, a Novartis division and the pioneer and global leader in biosimilars will present data for the company's pegfilgrastim, filgrastim and rituximab biosimilars:

- Cost simulation for the US of febrile neutropenia hospitalization due to pegfilgrastim on-body injector failure compared to single-injection pegfilgrastim and daily injections with reference and biosimilar filgrastim in non-Hodgkin lymphoma [Abstract #2251; Saturday, December 1, 6:15 PM PT]
- Subcutaneous versus intravenous rituximab in non-Hodgkin lymphoma treated with R-CHOP: economic modeling for the US [Abstract #4776; Monday, December 3, 6:00 PM PT]

Novartis data at the 2018 SABCS Annual Symposium will highlight the following:

New data evaluating Kisqali® (ribociclib)*** in broad range of patients with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2–) advanced breast cancer:

- Biomarker analysis by baseline circulating tumor DNA alterations in the MONALEESA-3 study [Abstract #PD2-05; Wednesday, December 5, 5:00 PM CT]
- Ribociclib + endocrine therapy in patients with hormone receptor-positive, HER2-negative advanced breast cancer presenting with visceral metastases: Subgroup analysis of phase III MONALEESA trials [Abstract #P6-18-07; Saturday, December 8, 7:00 AM CT]
- Ribociclib with endocrine therapy for premenopausal patients with hormone receptor-positive, HER2-negative advanced breast cancer: Biomarker analyses from the phase III randomized MONALEESA-7 trial [Abstract #PD2-08; Wednesday, December 5, 5:00 PM CT]
- Ribociclib treatment benefit in patients with advanced breast cancer with ≥1 dose reduction: Data from the MONALEESA-2, -3, and -7 trials [Abstract #P6-18-06; Saturday, December 8, 7:00 AM CT]

Additional updates on investigational treatments, BYL719 (alpelisib) and LSZ102:

- Alpelisib + fulvestrant for advanced breast cancer: Subgroup analyses from the Phase III SOLAR-1 trial [Abstract #GS3-08; Thursday, December 6, 11:15 AM CT]
- Phase 1/1b study of novel oral selective estrogen receptor degrader (SERD) LSZ102 for estrogen receptor-positive (ER+) advanced breast cancer (ABC) with progression on endocrine therapy (ET) [Abstract #PD1-08; Wednesday, December 5, 5:00 PM CT]

Sandoz will present US real-world evidence data surrounding cost-effectiveness through use of the company's biosimilar filgrastim-sndz:

- Potential Medicare beneficiary out-of-pocket cost reductions through use of biosimilar filgrastim-sndz over reference filgrastim among breast cancer patients: a simulation model analysis [Abstract #675; Friday, December 7, 5:00 PM CT]

Throughout the 2018 ASH Annual Meeting and SABCS Annual Symposium, Novartis will host dedicated content on https://www.novartis.com/our-focus/cancer that will feature unique insights and perspectives on emerging areas of cancer care and research.

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 https://www.novartis.com/our-company/global-product-portfolio.

Asciminib (ABL001), crizanlizumab (SEG101), alpelisib (BYL719) and LSZ102 are investigational compounds. Efficacy and safety have not been established. There is no guarantee these compounds will become commercially available.

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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 nearly 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Novartis Pharmaceuticals Corporation, a US affiliate of Novartis, is located in East Hanover, NJ. For more information, please visit https://www.novartis.com.

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*Novartis and the University of Pennsylvania's Perelman School of Medicine (Penn) have a global collaboration to research, develop and commercialize chimeric antigen receptor T cell (CAR-T) therapies for the investigational treatment of cancers.

**Jakavi is a registered trademark of Novartis AG in countries outside the United States. Jakafi is a registered trademark of Incyte Corporation. Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the United States.

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


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