

Novartis presents data at ASH for patients with serious blood disorders like lymphoma, leukemia and sickle cell disease

Nov 01, 2017

- - Primary results of pivotal Kymriah™ Phase II JULIET study in relapsed/refractory DLBCL
- - Post-hoc sub-analysis of crizanlizumab (SEG101, formerly SelG1) SUSTAIN trial evaluating time to first sickle cell pain crisis
- - Outcomes from matched analysis of Molecular Recurrence-free Survival from EURO-SKI and ENESTfreedom trials following Tasigna® vs. imatinib in patients with CML-CP eligible for Treatment-free Remission (TFR)
- - Additional data on Rydapt®, Revolade®/Promacta®, Exjade®/Jadenu® and Jakavi® underscore breadth of Novartis Oncology hematology portfolio

EAST HANOVER, N.J., Nov. 1, 2017 /PRNewswire/ -- Novartis will present new data from across its hematology portfolio at the upcoming 59th American Society of Hematology (ASH) Annual Meeting & Exposition, Atlanta, December 9-12. More than 75 abstracts will be presented, highlighting the robust Novartis development program for serious blood diseases.

"This is an exceptionally productive time in hematology, and the breadth of our Novartis Oncology data and presence at ASH underscore our commitment to this space," said Vas Narasimhan, Global Head Drug Development and Chief Medical Officer, Novartis. "Following the launch of Kymriah, the first FDA-approved CAR-T therapy, we are particularly excited about presenting additional data on this new approach to cancer treatment, as well as a new analysis for crizanlizumab, an investigational treatment for patients with sickle cell disease."

Kymriah™* (tisagenlecleucel) suspension for intravenous infusion is a CD19-directed genetically modified autologous T cell immunotherapy, indicated for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Additional results evaluating Kymriah in pediatric ALL and in relapsed/refractory diffuse large B-cell lymphoma (DLBCL) will be presented.

Data for Kymriah include results from the primary analysis of the JULIET study in adult patients with relapsed or refractory DLBCL, demonstrating sustained complete response rates based on extended follow up, and efficacy and safety findings from additional treated patients compared to a previously presented interim analysis. Additionally, results of a cost-effectiveness analysis of Kymriah for the treatment of relapsed or refractory ALL in the United States will be presented in an oral presentation.

- Primary Analysis of JULIET: A Global, Pivotal, Phase 2 Trial of CTL019 in Adult Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma [Abstract #577; Monday, December 11, 7:00 AM EST]
- Cost-Effectiveness Analysis of CTL019 for the Treatment of Pediatric and Young Adult Patients with Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia in the United States [Abstract #609; Monday, December 11, 7:30 AM EST]

- Patient-Reported Quality of Life (QoL) Following CTL019 Infusion in Adult Patients with Relapsed/Refractory (r/r) Diffuse Large B-cell Lymphoma (DLBCL) [Abstract #5215; publication only]
- Expert Elicitation of Long-Term Survival for Pediatric Acute Lymphoblastic Leukemia Patients Receiving CTL019 in ELIANA Phase II Study [Abstract #3377; Sunday, December 10, 6:00 PM EST]

Outcomes for chimeric antigen receptor T cell (CAR-T) pipeline therapies in other malignant blood cancers will also be shared at ASH:

- Updated Safety and Efficacy of B-cell Maturation Antigen (BCMA)-specific Chimeric Antigen Receptor T Cells (CART-BCMA) for Refractory Multiple Myeloma (MM) [Abstract #505; Sunday, December 10, 4:30 PM EST]
- Durable Remissions with Humanized CD19-Targeted Chimeric Antigen Receptor (CAR)-Modified T Cells in Children and Young Adults with Relapsed/Refractory Acute Lymphoblastic Leukemia, Including After Prior CAR Therapy [Abstract #1319; Saturday, December 9, 5:30 PM EST]

Data from a post-hoc sub-group analysis of the Phase II SUSTAIN investigational trial of crizanlizumab for time to first on-treatment sickle cell pain crisis will be featured:

- Crizanlizumab 5.0 mg/kg Increased the Time to First On-Treatment Sickle Cell Pain Crisis: A Subgroup Analysis of the Phase II SUSTAIN Study [Abstract #613; Monday, December 11, 10:30 AM EST]

A matched comparison of Molecular Recurrence-free Survival (MRecFS) following treatment discontinuation in chronic myeloid leukemia (CML) patients on Tasigna[®] (nilotinib) in ENESTfreedom versus patients on imatinib in the EURO-SKI trials will be presented in addition to updates from ENESTfreedom and ENESTop on Treatment-free Remission (TFR) outcomes:

- Molecular Recurrence-Free Survival (MRecFS) Following Imatinib vs Nilotinib in Patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP): Matched Analysis of Patients in EURO-SKI and ENESTfreedom [Abstract #1601; Saturday, December 9, 5:30 PM EST]
- Impact of Treatment Cessation on Overall Disease Outcomes in Patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) Attempting Treatment-Free Remission (TFR): Findings from ENESTfreedom and ENESTop [Abstract #1598; Saturday, December 9, 5:30 PM EST]
- Treatment-Free Remission (TFR) Among Patients with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) Not Initially Eligible for Treatment Discontinuation Due to Unstable Deep Molecular Response (DMR): ENESTfreedom and ENESTop [Abstract #2878; Sunday, December 10, 6:00 PM EST]

Additionally, new insights will be presented from the pivotal, Phase III RATIFY trial of Rydapt[®] (midostaurin) in adults with FLT3+ acute myeloid leukemia (AML):

- An Analysis of the Maintenance and Post Completion Effect of Midostaurin Therapy in the International Prospective Randomized Placebo-Controlled, Double-Blind Trial (CALGB 10603/RATIFY [Alliance]) for Newly Diagnosed Acute Myeloid Leukemia (AML) Patients with FLT3 Mutations [Abstract #145; Saturday, December 9, 12:00 PM EST]
- The Addition of Midostaurin to Standard Chemotherapy Decreases Cumulative Incidence of Relapse (CIR) in the International Prospective Randomized, Placebo-Controlled, Double-Blind Trial (CALGB 10603/RATIFY [Alliance]) for Newly Diagnosed Acute Myeloid Leukemia (AML) Patients with FLT3 Mutations [Abstract #2580; Sunday, December 10, 6:00 PM EST]
- Prognostic Impact of NPM1/FLT3-ITD Genotypes from Randomized Patients with Acute Myeloid Leukemia (AML) Treated Within the International RATIFY Study [Abstract #467; Sunday, December 10, 5:30 PM EST]

Sandoz, a Novartis division, the pioneer and global leader in biosimilars, will present two studies examining the impact of granulocyte colony-stimulating factor (G-CSF) on patient outcomes, cost savings and expanded access for biosimilars including Zarxio® (filgrastim-sndz).

- Expanded Access to Obinutuzumab from Cost-Savings Generated by Biosimilar Filgrastim (BIOSIM-FIL) in the Prophylaxis of Chemotherapy-Induced (Febrile) Neutropenia: A Simulation Study [Abstract #3380; Sunday, December 10, 6:00 PM EST]
- A Systemic Literature Review of Overall Survival and Delivered Dose Intensity in Cancer Patient Receiving Chemotherapy and G-CSF in Randomized Control Trials [Abstract #3424; Sunday, December 10, 6:00 PM EST]

Additional abstracts of note from the meeting are as follows.

Exjade®/Jadenu® (deferasirox)

- Predicting Serum Ferritin Levels in Patients with Iron Overload Treated with the Film-Coated Tablet of Deferasirox During the ECLIPSE Study [Abstract #3508; Monday, December 11, 6:00 PM EST]

Jakavi® (ruxolitinib)**

- Primary Analysis of JUMP, a Phase 3b, Expanded-Access Study Evaluating the Safety and Efficacy of Ruxolitinib in Patients with Myelofibrosis (N = 2233) [Abstract #4204; Monday, December 11, 6:00 PM EST]
- Results from the 208-Week (4-Year) Follow-Up of Response Trial, a Phase 3 Study Comparing Ruxolitinib (Rux) with Best Available Therapy (BAT) for the Treatment of Polycythemia Vera (PV) [Abstract #322; Sunday, December 10, 7:30 AM EST]
- Role of Symptom Burden in Disability Leave Among Patients with Myeloproliferative Neoplasms (MPNs): Findings from the Living with MPN Patient Survey [Abstract #1637; Saturday, December 9, 5:30 PM EST]

Revolade®/Promacta® (eltrombopag)***

- Occurrence and Management of Cataracts in Patients with Chronic Immune Thrombocytopenia (cITP) During Long-Term Treatment with Eltrombopag (EPAG): Results from the EXTEND Study [Abstract #1053; Saturday, December 9, 5:30 PM EST]
- Eltrombopag (EPAG) Treatment Improved Platelet Counts in Patients with Persistent or Chronic Immune Thrombocytopenia During a 2-Year, Phase IV, Open-Label Study [Abstract #3628; Monday, December 11, 6:00 PM EST]
- A Retrospective Chart Review to Assess Burden of Illness Among Patients with Severe Aplastic Anemia with Insufficient Response to Immunosuppressive Therapy [Abstract #678; Monday, December 11, 10:30 AM EST]

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 oncology.com/news/product-portfolio>.

Crizanlizumab, CART-BCMA and CTL119 are investigational compounds. Efficacy and safety have not been

established. There is no guarantee these compounds will become commercially available.

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 @Novartis Cancer at <http://twitter.com/novartiscancer>

For Novartis multimedia content, please visit www.novartis.com/news/media-library

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

* 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.

*** Marketed as Promacta® in the United States and as Revolade® outside the United States.

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff

Michael Billings

Novartis Global Media Relations

Novartis Oncology Communications

+41 61 324 7999 (direct)

+1 862 778 8656 (direct)

+41 79 593 4202 (mobile)

+1 201 400 1854 (mobile)

eric.althoff@novartis.com

michael.billings@novartis.com

SOURCE Novartis Pharmaceuticals Corporation

Source URL: <https://qa1.novartis.us/news/media-releases/novartis-presents-data-ash-patients-serious-blood-disorders-lymphoma-leukemia-and-sickle-cell-disease>

List of links present in page

1. <https://qa1.novartis.us/news/media-releases/novartis-presents-data-ash-patients-serious-blood-disorders-lymphoma-leukemia-and-sickle-cell-disease>
2. <https://www.novartisoncology.com/news/product-portfolio>
3. <http://www.novartis.com/>
4. <http://twitter.com/novartis>
5. <http://twitter.com/novartiscancer>
6. <http://www.novartis.com/news/media-library>
7. <mailto:media.relations@novartis.com>
8. <mailto:media.relations@novartis.com>
9. <mailto:eric.althoff@novartis.com>
10. <mailto:michael.billings@novartis.com>