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## MEDIA & INVESTOR RELEASE

# New data at ASH to reinforce breadth of Novartis hematology portfolio across multiple blood cancers and serious hematologic diseases

- *Pivotal ASCEMBL study of novel, investigational STAMP inhibitor asciminib (ABL001) vs. bosutinib in CML patients previously treated with two or more TKIs*

- *ELARA results for Kymriah® in relapsed or refractory (r/r) follicular lymphoma, plus long-term JULIET data on response survival and durability at more than three years in r/r DLBCL patients*

- *Detailed Jakavi® analysis from REACH3 in steroid-refractory chronic GvHD, building on previously reported positive REACH2 results in steroid-refractory acute GvHD*

- *New data for sabatolimab (MBG453) and Adakveo® (crizanlizumab) underscore breadth of Novartis innovation in hematology*

**Basel, November 19, 2020** — Novartis announced today that new research data from a broad range of hematology medicines and investigational therapies will be presented at the 62nd American Society of Hematology (ASH) Annual Meeting & Exposition, taking place virtually December 5-8. More than 65 abstracts from Novartis-sponsored and investigator-initiated trials that include results for asciminib (ABL001), Kymriah® (tisagenlecleucel), Jakavi® (ruxolitinib)*, sabatolimab (MBG453) and Adakveo® (crizanlizumab) underscore the Novartis vision to deliver transformative innovation to address unmet medical needs.

“Our research and development strategy focuses on developing transformative treatments with the aspiration of dramatically improving quality of life and addressing the underlying disease process,” said Susanne Schaffert, PhD, President, Novartis Oncology. “The ASH presentations demonstrate how we are pursuing these goals in hematology with research that focuses on developing advanced therapeutic approaches across an array of blood cancers and difficult-to-treat hematologic diseases.”

**Key highlights of data accepted by ASH:**

Novel, investigational STAMP inhibitor asciminib (ABL001) evaluated for safety and efficacy for TKI-resistant and intolerant CML patients:

- Efficacy and Safety Results From ASCEMBL, a Multicenter, Open-label, Phase 3 Study of Asciminib vs Bosutinib (BOS) in Patients (Pts) with Chronic Myeloid Leukemia in Chronic Phase (CML-CP) Previously Treated with ≥2 Tyrosine Kinase Inhibitors (TKIs) [Abstract #LBA-4; oral presentation; Tuesday, December 8, 8:15 AM

PST]
- Asciminib, a First-in-Class STAMP Inhibitor, Provides Durable Molecular Response in Patients (Pts) With Chronic Myeloid Leukemia (CML) Harboring the T315I Mutation: Primary Efficacy and Safety Results From a Phase 1 Trial [Abstract #650; oral presentation: Monday, December 7, 12:15 PM PST]
- Structural and Biochemical Studies Confirming the Mechanism of Action of Asciminib, an Agent Specifically Targeting the ABL Myristoyl Pocket (STAMP) [Abstract #3961; online publication]

New data for the first anti-TIM-3 antibody in hematology, sabatolimab (MBG453):

- Efficacy and Safety of Sabatolimab (MBG453) in Combination With Hypomethylating Agents (HMAs) in Patients With Acute Myeloid Leukemia (AML) and High-risk Myelodysplastic Syndrome (HR-MDS): Updated Results From a Phase 1b Study [Abstract #657; oral presentation: Monday, December 7, 12:30 PM PST]
- Sabatolimab (MBG453) Dose Selection and Dose-Response Analysis in Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML): Population Pharmacokinetics (PK) Modeling and Evaluation of Clinical Efficacy/Safety by Dose [Abstract #2192; poster presentation: Sunday, December 6, 7:00 AM PST]

Kymriah® (tisagenlecleucel) results from the first analysis of the Phase II ELARA trial in r/r follicular lymphoma and a clinical update of 40-month median follow-up from the pivotal JULIET trial in r/r diffuse large B-cell lymphoma (DLBCL):

- Efficacy and Safety of Tisagenlecleucel in Adult Patients With Relapsed/Refractory Follicular Lymphoma: Interim Analysis of the Phase 2 ELARA Trial [Abstract #1149; poster presentation: Saturday, December 5, 7:00 AM PST]
- Myc Expression and Tumor-Infiltrating T Cells Are Associated With Response in Patients (Pts) With Relapsed/Refractory Diffuse Large B-Cell Lymphoma (r/r DLBCL) Treated With Tisagenlecleucel in the JULIET Trial [Abstract #1194; poster presentation: Saturday, December 5, 7:00 AM PST]

Adakveo® (crizanlizumab) results from the SOLACE trial and a post-hoc analysis of the SUSTAIN trial for vaso-occlusive pain crises in sickle cell disease, and extended results from the Sickle Cell World Assessment Survey (SWAY):

- Pharmacokinetics/Pharmacodynamics, Safety and Efficacy of Crizanlizumab in Patients With Sickle Cell Disease and a History of Vaso-Occlusive Crises: Results From the Phase II, Multicenter, Open-Label SOLACE-Adults Study [Abstract #1715; poster presentation: Sunday, December 6, 7:00 AM PST]
- The Effect of Crizanlizumab on the Number of Days Requiring Opioid Use for Management of Pain Associated With Vaso-Occlusive Crises in Patients With Sickle Cell Disease: Results From the SUSTAIN Trial [Abstract #796; poster presentation: Saturday, December 5, 7:00 AM PST]
- Global Treatment Satisfaction Levels and Treatment Patterns From the International Sickle Cell World Assessment Survey (SWAY): Hydroxyurea (HU) Versus No HU [Abstract #17; oral presentation: Saturday, December 5, 8:30 AM PST]

Primary findings from the REACH3 trial for steroid-refractory chronic graft-vs-host disease (GvHD) and additional findings from REACH2 for steroid-refractory acute GvHD treated with Jakavi® (ruxolitinib)*:

- Ruxolitinib vs Best Available Therapy in Patients With Steroid-Refractory/Steroid-Dependent Chronic Graft-vs-Host Disease: Primary Findings From the Phase 3, Randomized REACH3 Study [Abstract #77; oral presentation: Saturday, December 5, 8:00 AM PST]
- Biomarker Analysis in Patients With Steroid-Refractory Acute Graft vs Host Disease Treated With Ruxolitinib or Best Available Therapy in the Randomized, Phase 3 REACH2 Study [Abstract #1519; poster presentation: Saturday, December 5, 7:00 AM PST]
- Safety Analysis of Ruxolitinib (RUX) vs Best Available Therapy in Patients With

Steroid-Refractory Acute Graft-vs-Host Disease in the Randomized Phase 3 REACH2 Study [Abstract #2440; poster presentation: Sunday, December 6, 7:00 AM PST]

Early pipeline results for ianalumab (VAY736) in chronic lymphocytic leukemia:

- Phase Ib Study of Ianalumab (VAY736) and Ibrutinib in Patients With Chronic Lymphocytic Leukemia (CLL) on Ibrutinib Therapy [Abstract #1309; poster presentation: Saturday, December 5, 7:00 AM PST]

**Product Information**

Approved indications for products vary by country and not all indications are available in every country. Safety and efficacy profiles have not been established for investigational compounds or are outside the approved indications for marketed products. Because of the uncertainty of clinical trials, there is no guarantee that compounds will become commercially available or receive additional indications if already marketed.

For full prescribing information including important safety information about marketed products, please visit https://www.novartis.com/our-company/global-product-portfolio.

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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 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at

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