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MEDIA & INVESTOR RELEASE

New data at ASH spotlight Novartis recently approved Scemblix®, next-generation CAR-T platform and expanding hematology portfolio

- *New longer-term efficacy and safety data from pivotal Phase III ASCEMBL study for recently US-approved Scemblix® (asciminib) in patients with PH+ CML-CP*
- *Early findings from YTB323 and PHE885 CAR-T cell therapies highlight the progress in developing the next generation T-Charge™ Platform*
- *Final analysis from Phase Ib study evaluating efficacy and safety of sabatolimab (MBG453) in combination with HMAs in patients with very high/high-risk MDS and AML*
- *12-month data from Phase II study of iptacopan (LNP023), the anticipated first oral monotherapy in adult PNH patients, evaluating the factor B inhibitor's ability to control both intra- and extravascular hemolysis*
- *First analysis of Phase II SOLACE-kids data on Adakveo® (crizanlizumab) in pediatric patients aged 12-17 years old with sickle cell disease*

Basel, November 4, 2021 — Novartis will highlight new data on Scemblix® (asciminib), recently approved by the US Food and Drug Administration, as well as its next-generation CAR-T platform and the latest research results for an array of hematology medicines at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition (December 11-14; Atlanta and virtually). More than 100 abstracts, including 24 oral presentations, will be shared at the meeting.

New data will be presented for Kymriah® (tisagenlecleucel), as well as CAR-T pipeline compounds YTB323 and PHE885, along with sabatolimab (MBG453), Scemblix® (asciminib), iptacopan (LNP023), Adakveo® (crizanlizumab), Jakavi®* (ruxolitinib) and Promacta®/Revolade® (eltrombopag).

"Novartis is relentless in its pursuit of breakthrough innovation for patients with blood cancers and life-threatening blood disorders," said Susanne Schaffert, PhD, President, Novartis Oncology. "The breadth of new data presented at ASH demonstrates the promise of our advanced therapeutic platforms with exciting new approaches in immuno-oncology and CAR-T therapies that aim to transform the lives of patients."

Data highlights include:

Medicine	Abstract Title	Abstract Number/ Presentation Details
CAR-T Therapies		
YTB323	A First-in-Human Study of YTB323, a Novel, Autologous CD19-Directed CAR-T Cell Therapy Manufactured Using the Novel T-Charge™ Platform, for the Treatment of Patients (Pts) With Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL)	Abstract presentation #740 Oral presentation: Monday, December 13, 3:00 PM – 3:15 PM EST
PHE885	Phase I Study of PHE885, a Fully Human BCMA-Directed CAR-T Cell Therapy for Relapsed/Refractory Multiple Myeloma Manufactured in <2 Days Using the T-Charge™ Platform	Abstract presentation #3864 Poster available: Monday, December 13, 6:00 PM – 8:00 PM EST
Kymriah (tisagenlecleucel)	Efficacy of Tisagenlecleucel in Adult Patients (Pts) With High-Risk Relapsed/Refractory Follicular Lymphoma (R/R FL): Subgroup Analysis of the Phase II ELARA Study	Abstract presentation #131 Oral presentation: Saturday, December 11, 1:00 PM – 1:15 PM EST
Kymriah (tisagenlecleucel)	Real-World Outcomes for Pediatric and Young Adult Patients With Relapsed or Refractory (R/R) B-Cell Acute Lymphoblastic Leukemia (ALL) Treated With Tisagenlecleucel: Update From the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry	Abstract presentation #428 Oral presentation: Sunday, December 12, 9:45 AM – 10:00 AM EST
Kymriah (tisagenlecleucel)	Real-World Efficacy and Safety Outcomes for Patients With Relapsed or Refractory (R/R) Aggressive B-Cell Non-Hodgkin's Lymphoma (aBNHL) Treated With Commercial Tisagenlecleucel: Update From the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry	Abstract presentation #429 Oral presentation: Sunday, December 12, 10:00 AM – 10:15 AM EST
Malignant Hematology		
Sabatolimab (MBG453)	Efficacy and Safety of Sabatolimab (MBG453) in Combination With Hypomethylating Agents (HMAs) in Patients (Pts) With Very High/High-Risk Myelodysplastic Syndrome (vHR/HR-MDS) and Acute Myeloid Leukemia (AML): Final Analysis From a Phase Ib Study	Abstract presentation #244 Oral presentation: Saturday, December 11 2:45 PM - 3:00 PM EST
Scemblix (asciminib)	Efficacy and Safety Results from ASCEMBL, a Multicenter, Open-label, Phase 3 Study of Asciminib, a First-in-Class STAMP Inhibitor, vs Bosutinib in Patients With Chronic Myeloid Leukemia in Chronic Phase After ≥2 Prior Tyrosine Kinase Inhibitors: Update After 48 Weeks	Abstract presentation #310 Oral presentation: Saturday, December 11 4:45 PM – 5:00 PM EST
Scemblix (asciminib)	Trial in Progress: A Multicenter, Open Label, Randomized Phase III Study of Asciminib (80 mg Once Daily) vs Investigator-selected TKIs in Newly Diagnosed Adult Patients With Chronic Myeloid Leukemia in Chronic Phase	Abstract presentation #1478 Poster available: Saturday, December 11 5:30 PM – 7:30 PM EST

Scemblix (asciminib)	Trial in Progress: A Multicenter, Open-label, Phase Ib/II Study to Determine the Dose and Safety of Asciminib in Pediatric Patients With Philadelphia Chromosome–positive Chronic Myeloid Leukemia in Chronic Phase Treated With ≥1 Prior Tyrosine Kinase Inhibitor	Abstract presentation #2561 Poster available: Sunday, December 12 6:00 PM – 8:00 PM EST
Jakavi* (ruxolitinib)	Patient-Reported Outcomes (PROs) Among Patients With Steroid-Refractory or -Dependent Chronic Graft-vs-Host Disease (cGVHD) Randomized to Ruxolitinib (RUX) vs Best Available Therapy (BAT)	Abstract presentation # 3909 Poster available: Monday, December 13, 6:00 PM – 8:00 PM EST
Non-Malignant Hematology		
Iptacopan (LNP023)	12-Month Analysis of a Phase 2 Study of Iptacopan (LNP023) Monotherapy for Paroxysmal Nocturnal Hemoglobinuria	Abstract presentation #2173 Poster available: Sunday, December 12 6:00 PM – 8:00 PM EST
Adakveo (crizanlizumab)	Initial Safety and Efficacy Results From the Phase II, Multicenter, Open-Label SOLACE-Kids Trial of Crizanlizumab in Adolescents With Sickle Cell Disease (SCD)	Abstract presentation #12 Oral presentation: Saturday, December 11, 10:45 AM – 11:00 AM EST
Adakveo (crizanlizumab)	Characterization of Two Anti-P-Selectin Monoclonal Antibodies (mAbs): Crizanlizumab Shows Comparable or Stronger Effects Versus Inclacumab Across Cell Adhesion Assays In Vitro	Abstract presentation #2032 Poster available: Sunday, December 12 6:00 PM – 8:00 PM EST
Promacta/Revolade (eltrombopag)	Efficacy and Safety of Eltrombopag Combined With Cyclosporine as First-Line Therapy in Adults With Severe Acquired Aplastic Anemia: Results of the Interventional Phase 2 Single-Arm SOAR Study	Abstract presentation #2174 Poster available: Sunday, December 12 6:00 PM – 8:00 PM EST
Adakveo (crizanlizumab)	Early Evaluation of the Use of Crizanlizumab in Sickle Cell Disease: A National Alliance of Sickle Cell Centers Study	Abstract presentation #3113 Poster available: Monday, December 13 6:00 PM – 8:00 PM 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.novartisoncology.com/news/product-portfolio.

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generally be identified by words such as “potential,” “can,” “will,” “plan,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “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; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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 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 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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