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PRESS RELEASE

Novartis Scemblix® receives positive CHMP opinion for the treatment of adults with newly diagnosed CML

- *If approved, Scemblix will be indicated for adults with chronic myeloid leukemia (CML), both newly diagnosed and previously treated, expanding access to four times as many patients in Europe*
- *Scemblix is the only CML treatment with a superior efficacy and favorable safety and tolerability profile versus available first-line treatments*[1,2]
- *Despite available first-line treatments, 50% of patients newly diagnosed with CML miss treatment goals within one year, many of whom experience adherence challenges due to treatment tolerability*[3,4]

Basel, October 17, 2025 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion and recommended granting marketing authorization for Scemblix® (asciminib) for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) in all lines of treatment.

“For people living with CML, long-term therapy can be physically and emotionally demanding, and many face challenges in reaching treatment milestones without compromising quality of life,” said David FitzGerald, Member of the CML Advocates Network. “The availability of more treatment options earlier in the care pathway is a welcome development that brings forward additional possibilities for patients and their healthcare teams to choose approaches that best support both clinical goals and patient well-being.”

The positive CHMP opinion is based on data from the Phase III ASC4FIRST trial, which compared Scemblix with investigators’ choice of tyrosine kinase inhibitor (TKI) treatment in patients with newly diagnosed Ph+ CML-CP[1,2]. In the trial, Scemblix demonstrated superior major molecular response (MMR) rates when compared against all TKIs (imatinib, nilotinib, dasatinib and bosutinib) and also when compared against imatinib alone[1,2]. Patients treated with Scemblix also required fewer dose reductions and experienced half the rate of adverse events leading to discontinuation[1,2].

"To give patients newly diagnosed with CML the best chance to reach key efficacy milestones while maintaining quality of life, it is critical to intervene early with a more selective treatment that combines superior efficacy with tolerability," said Professor Andreas Hochhaus, Head of the Department of Hematology and Medical Oncology at Jena University Hospital, Germany. "If approved, Scemblix could provide patients with a well-tolerated option that may deliver faster, deeper and longer-lasting molecular response with fewer treatment discontinuations due to adverse events, compared with available first-line treatments — potentially paving the way for more patients to reach treatment-free remission."

Scemblix is approved in earlier lines in more than 20 countries, including the US, Japan and China[5,6]. Scemblix is recommended for the treatment of patients with newly diagnosed Ph+ CML-CP by the 2025 European LeukemiaNet recommendations for the management of CML and by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[7,8]. Since 2021, Scemblix has been a standard of care (SoC) in more than 80 countries for patients previously treated with two or more TKIs[5,6,9].

“People newly diagnosed with CML need treatments that deliver both better efficacy and excellent tolerability to achieve early, deep molecular response, which is critical to achieve long-term outcomes like treatment-free remission,” said Patrick Horber, M.D., President, International, Novartis. “Scemblix is the only treatment that has demonstrated superior efficacy and tolerability compared to current first-line treatments. Today’s positive CHMP opinion marks a major milestone in our 25-year journey to improve CML care and could help establish a new standard of care in Europe."

Following the CHMP’s recommendation to approve Scemblix for the treatment of adults with Ph+ CML-CP in all lines of treatment, the European Commission (EC) will make a final decision within two months.

About ASC4FIRST
ASC4FIRST (NCT04971226) is a Phase III, head-to-head, multi-center, open-label, randomized study of oral Scemblix® 80 mg QD vs. investigator-selected first- or second-generation TKIs (imatinib, nilotinib, dasatinib or bosutinib) in 405 adult patients with newly diagnosed Ph+ CML-CP[10]. The trial met both primary endpoints with Scemblix demonstrating superior MMR rates at week 48 vs. investigator-selected SoC TKIs (67.7% vs. 49.0%) and imatinib alone (69.3% vs. 40.2%)[1,10]. Additionally, Scemblix showed a numerical improvement versus the 2G TKI stratum (66% vs. 57.8%)[1,10]. At week 96, Scemblix demonstrated sustained superior MMR vs. all investigator-selected TKIs (74.1% vs. 52%) and vs. imatinib alone (76.2% vs. 47.1%)[2].47.1%), meeting both ASC4FIRST key secondary endpoints[2].

About Scemblix® (asciminib)
Scemblix® is the first CML treatment that works by Specifically Targeting the ABL Myristoyl Pocket (referred to as a STAMP inhibitor in scientific literature)[11-13]. Other currently approved CML treatments are TKIs that target the ATP-binding site (ATP-competitive)[13].

Scemblix is approved to treat newly diagnosed adults with Ph+ CML-CP in more than 20 countries, including the US, Japan and China[4,5]. It is also approved in more than 80 countries, including the EU, to treat those with Ph+ CML-CP who have previously been treated with two or more TKIs [5,6,7]. In some countries, including the US, Scemblix is also approved in patients with Ph+ CML-CP with the T315I mutation[5-7].

Scemblix has been studied across multiple treatment lines for Ph+ CML-CP, both as a monotherapy and as a combination therapy[5,6,10-12,14-26].

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,” “may,” “could,” “would,” “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; 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; 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 an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach nearly 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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