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PRESS RELEASE

Scemblix® continued to show superior efficacy and favorable safety and tolerability profile at week 144 in newly diagnosed CML

- *Growing improvement in major molecular response (MMR) rates demonstrated with Scemblix vs. all standard-of-care TKIs including imatinib and second generation (2G) TKIs[1]*
- *Clinically relevant 15.2% higher MMR rate achieved with Scemblix vs. 2G TKIs[1]*
- *Fewer grade ≥3 AEs and less than half the discontinuation rate due to AEs seen with Scemblix vs. imatinib and 2G TKIs[1]*

Basel, June 1, 2026 – Novartis today announced positive 144-week data from the pivotal ASC4FIRST trial of Scemblix® (asciminib) presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting. These results provide longer-term evidence that Scemblix demonstrated increasingly superior molecular responses at week 144 compared with established tyrosine kinase inhibitors (TKIs), strengthening confidence in its sustained response[1].

ASC4FIRST compared the MMR rate of Scemblix to investigator-selected (IS) standard-of-care (SoC) TKIs (imatinib and 2G TKIs nilotinib, dasatinib, and bosutinib) and to imatinib alone in adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP)[2,3]. The longer-term data showed a progressively larger difference in MMR rates favorable to Scemblix vs. SoC TKIs, vs. imatinib and vs. 2G TKIs[1].

“Because CML patients often need to remain on therapy long term, treatments must combine robust efficacy with a favorable safety and tolerability profile,” said Jorge Cortes, M.D., Chief of Hematology, UAB O’Neal Cancer Center. “These data show asciminib continued to deliver significantly higher response rates versus the comparator TKIs and offers improved response that widens over time, including compared to second-generation TKIs.”

“Drawing on more than 25 years in CML and a Scemblix clinical program of over 10 years, Novartis is focused on addressing treatment challenges for people living with CML,” said Mark Rutstein, M.D., Global Head, Oncology Development, Novartis. “With now nearly 3 years of extended follow-up in ASC4FIRST, we continue to see results that support Scemblix as an important option for newly diagnosed adult CML patients.”

In addition to meeting all primary and key secondary endpoints at weeks 48 and 96, Scemblix continued to extend the treatment benefit for patients vs. SoC TKIs at week 144[1,2,3,4]. At the cutoff, more patients remained on treatment with Scemblix vs. SoC (78.6% vs. 55.9%), imatinib (81.2% vs. 50.0%), and 2G TKIs (76.0% vs. 61.8%)[1]. At week 144, nearly 24% more patients treated with Scemblix achieved MMR vs. all SoC TKIs, and over 32% more patients achieved MMR vs. imatinib alone[1]. The Scemblix MMR rate was 15.2% higher vs. 2G TKIs (75.0% vs. 59.8%; P=0.01*)[1]. Patients treated with Scemblix also achieved deeper molecular responses (MR4 and MR4.5) compared with SoC TKIs[1].

**Unadjusted nominal p-value for descriptive purposes only*

		Overall[a] Scemblix (n=201) vs. IS SoC TKIs (n=204)	Imatinib stratum[b] Scemblix (n=101) vs. imatinib (n=102)	2G TKI stratum[c] Scemblix (n=100) vs. 2G TKIs (n=102)
	MMR rates at week 144	77.1% vs. 53.4%	79.2% vs. 47.1%	75.0% vs. 59.8%
Secondary objectives[d]	MR4 at week 144	55.7% vs. 36.3%	58.4% vs. 33.3%	53.0% vs. 39.2%
	MR4.5 at week 144	42.3% vs. 24.5%	43.6% vs. 19.6%	41.0% vs. 29.4%

[a] All patients receiving Scemblix (n=201) or IS SoC TKIs (n=204). Treatment difference after adjusting for pre-randomization selected TKI and EUTOS long-term survival (ELTS) risk groups at baseline.
[b] The 203 patients within the pre-randomization-selected imatinib stratum were randomized to receive either Scemblix (n=101) or imatinib (n=102). Treatment difference after adjusting for ELTS risk groups at baseline.
[c] The 202 patients within the pre-randomization selected 2G TKIs stratum were randomized to receive either Scemblix (n=100) or 2G TKIs (n=102: nilotinib, 48%; dasatinib, 41%; bosutinib, 11%).
[d] Secondary objectives were not powered for statistical significance.

“For many patients living with CML, managing a lifelong condition means balancing disease control with the real impact of treatment on daily life, and too often side effects can stand in the way of staying on therapy,” said Joannie Clements, CML patient and founder of CML Buster Foundation. “There remains a clear unmet need for treatments that are highly effective and also have a safety and tolerability profile favorable enough to be suitable for long-term use.”

Scemblix demonstrated a safety profile at 144 weeks consistent with the 4-year follow-up of the Phase III ASCEMBL trial, with no new safety concerns observed to date[1,2,5]. Compared with both imatinib and 2G TKIs, Scemblix showed fewer grade ≥3 AEs, fewer dose adjustments to manage adverse events, and more than 50% lower discontinuation due to adverse events[2,4,6]. The most frequent AEs (≥15%) were diarrhea, headache, fatigue, musculoskeletal pain, and rash[4,7].

Week 144	Scemblix n=200	Imatinib n=99	2G TKIs n=102
Grade ≥3 AEs[a]	49%	52%	63%
Discontinuation due to AEs[a]	6%	13%	14%
AEs leading to dose adjustments/interruptions[a]	37%	44%	63%

[a]In patients who experienced ≥1 adverse event.

These data will also be presented as an oral presentation at the European Hematology Association (EHA) 2026 Congress in June.

About the ASC4FIRST Phase III Clinical Trial
ASC4FIRST (NCT04971226) is a Phase III, head-to-head, multi-center, open-label, randomized study of oral Scemblix® 80 mg QD vs. IS first- or second-generation TKIs (imatinib, nilotinib, dasatinib or bosutinib) in 405 adult patients with newly diagnosed Ph+ CML-CP[2,3]. The trial met both primary endpoints with Scemblix demonstrating superior MMR rates at week 48 vs. investigator-selected SoC TKIs (imatinib, nilotinib, dasatinib, and bosutinib) (67.7% vs. 49.0%) and imatinib alone (69.3% vs. 40.2%) as well as the secondary, non-powered endpoint for the 2G TKI stratum of (66% vs. 57.8%)[3]. The study remains ongoing with further efficacy and safety readouts planned.

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)[5,8,9]. Other currently approved CML treatments are TKIs that target the ATP-binding site (ATP-competitive)[9].

In the US, Scemblix was granted accelerated approval to treat newly diagnosed adults with Ph+ CML-CP. Outside the US, Scemblix is approved to treat newly diagnosed adults with Ph+ CML-CP in more than 60 countries, including the EU, China, and Japan. It is also approved in 61 countries, including the US and the EU, for previously treated adults with Ph+ CML-CP, regardless of prior therapy, and in 58 countries, including the US and the EU, for patients with Ph+ CML-CP with the T315I mutation[10].

About Novartis Commitment to CML
Novartis has a long-standing scientific commitment to patients living with CML. For more than 25 years, our bold science has helped transform CML from a life-limiting condition for many patients. Despite these advancements, there's still work to be done. We continue to research ways to target the disease more selectively and to address the challenges of not reaching treatment efficacy goals, experiencing treatment resistance and/or intolerance that many patients face. Our legacy inspires our future innovation.

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," or similar expressions, or by express or implied discussions regarding: potential new products; potential new indications for existing products; potential product launches or potential future revenues from any such products; results of ongoing clinical trials; or potential future, pending or announced transactions; potential future sales or earnings; strategy, plans, expectations or intentions, including discussions regarding our continued investment into new R&D capabilities and manufacturing; or our capital structure. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 could be affected by, among other things, uncertainties concerning: global healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the success of our key products, commercial priorities and strategy; research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; the development or adoption of

new technologies, including artificial intelligence, and new business models; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, 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 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 more than 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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