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MEDIA & INVESTOR RELEASE

Novartis receives positive CHMP opinion for Kymriah® CAR-T cell therapy for adult patients with relapsed or refractory follicular lymphoma in Europe

- *Positive opinion paves way for third indication in Europe for Kymriah, a potentially definitive single infusion CAR-T cell therapy treatment option*
- *CHMP opinion based on Phase II global ELARA trial demonstrating high response rates in heavily pretreated patients; 69% experienced a complete response, with an 86% overall response rate and a remarkable safety profile*[1]
- *If approved, Kymriah may offer an effective, new treatment option to patients with advanced follicular lymphoma to break the cycle of remittent and relapsing diseases*
- *Well-established Kymriah safety profile and post-treatment protocols allow for flexibility to administer in the outpatient setting, reducing the burden of therapy for patients and their healthcare teams across Europe*[1,2]

Basel, March 25, 2022 — Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the European Commission to approve Kymriah® (tisagenlecleucel), a CAR-T cell therapy, for the treatment of adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy.

“Follicular lymphoma patients will often relapse, many having shorter responses to treatment with each subsequent line of therapy,” said Catherine Thieblemont, MD, PhD, Professor of Hematology in the Paris VII- University, France and Head of the Hemato-Oncology Unit of St-Louis Hospital in Paris. “If approved, Kymriah may offer an effective new option with potentially definitive results for these patients with a highly favorable safety profile.”

The CHMP positive opinion is based on results from the global Phase II ELARA trial, in which 94 infused patients were evaluated for efficacy with a median follow-up of approximately 17 months. Among patients treated with Kymriah, 86% had a response, including 69% who experienced a complete response (CR). Prolonged durable response to treatment was demonstrated with an estimated 87% of patients who experienced a CR still in response nine months after initial response[1].

In the ELARA trial, for the 97 patients evaluable for safety, the safety profile of Kymriah was remarkable. Within eight weeks of infusion, 49% of patients experienced cytokine release syndrome (CRS) and there were no reported cases of high-grade (grade 3 or higher) CRS, as

defined by the Lee scale. Grade 3 or 4 neurological events occurred in 3% of patients within eight weeks of infusion[1].

“With today’s positive opinion, we are closer to bringing the life-changing potential of Kymriah to patients with advanced follicular lymphoma in the EU who are in need of a treatment that may provide long-lasting remission,” said Susanne Schaffert, PhD, President, Novartis Oncology. “We are proud to bring our transformative cell therapy innovation to more people around the world who continue to have unmet medical needs.”

If approved, r/r FL would be the third indication for which Kymriah is available to patients in the European Union (EU). Kymriah is currently approved for the treatment of pediatric and young adult patients up to and including 25 years of age with B cell acute lymphoblastic leukemia (ALL) that is refractory, in relapse post transplant or in second or later relapse, and adult patients with r/r diffuse large B cell lymphoma (DLBCL) after two or more lines of systemic therapy.

The European Commission will review the CHMP recommendation and deliver a final decision in approximately two months. The decision will be applicable to all 27 EU member states plus Iceland, Norway and Liechtenstein. Additional regulatory filings are underway with other health authorities worldwide.

About follicular lymphoma
While follicular lymphoma is typically an indolent type of cancer, patients with FL may be exposed to a median of four lines of treatment, with an upper range of 13 lines[3,4]. Although there are multiple systemic therapies available, the efficacy of these regimens drops rapidly in later lines[5].

About Novartis commitment to Oncology Cell Therapy
As part of the unique Novartis Oncology strategy to pursue four cancer treatment platforms – radioligand therapy, targeted therapy, immunotherapy and cell and gene therapy – we strive for cures through cell therapies in order to enable more patients to live cancer-free. We will continue to pioneer the science and invest in our manufacturing and supply chain process to further advance transformative innovation.

Novartis was the first pharmaceutical company to significantly invest in pioneering CAR-T research and initiate global CAR-T trials. Kymriah, the first approved CAR-T cell therapy, developed in collaboration with the Perelman School of Medicine at the University of Pennsylvania, is the foundation of the Novartis commitment to CAR-T cell therapy.

We have made strong progress in broadening our delivery of Kymriah, which is currently available for use in at least one indication in 30 countries and at more than 365 certified treatment centers, with clinical and real-world experience from administration to more than 6,200 patients. We continue to pioneer in cell therapy, leveraging our vast experience to develop next-generation CAR-T cell therapies. These therapies will focus on new targets and utilize our new T-Charge™ platform being evaluated to expand across hematological malignancies and bring the hope for a cure to patients with other cancer types.

Novartis has a comprehensive, integrated global CAR-T manufacturing footprint that strengthens the flexibility, resilience and sustainability of the Novartis manufacturing and supply chain.

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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,” “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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