

MEDIA & INVESTOR RELEASE

FDA approves Novartis Kymriah® CAR-T cell therapy for adult patients with relapsed or refractory follicular lymphoma

- *68% of patients receiving Kymriah in the ELARA trial experienced complete response, with an 86% overall response rate, along with a remarkable safety profile¹*
- *Sustained clinical benefit from Kymriah treatment demonstrated – of patients who achieved a complete response, 85% were still in response at 12 months¹*
- *Kymriah can be administered in the outpatient setting, offering increased flexibility and potentially reducing the burden of therapy for patients and their care teams^{1,2}*
- *Kymriah is now FDA approved in three indications and remains the only CAR-T cell therapy approved in both adult and pediatric settings¹*

Basel, May 28, 2022 — Novartis today announced the US Food and Drug Administration (FDA) has granted accelerated approval for Kymriah® (tisagenlecleucel) for the treatment of adult patients with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy. In accordance with the Accelerated Approval Program, continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Kymriah is now FDA approved in three indications and remains the only CAR-T cell therapy approved in both adult and pediatric settings¹.

"We are proud of today's FDA approval of a third indication for Kymriah. We hope this treatment option that has the potential for long-lasting results may help break the unrelenting cycle of treatment for patients with follicular lymphoma," said Victor Bulto, President, Novartis Innovative Medicines US. "We are on a mission to build on our pioneering work in cell therapy and continue to innovate for patient impact."

The approval is based on data from the Phase II ELARA trial, a single-arm, open-label trial, in which 90 patients were evaluated for efficacy with a median follow-up of approximately 17 months. Eighty-six percent of patients treated with Kymriah achieved a response including 68% who experienced a complete response¹.

Prolonged durable response to treatment was demonstrated with an estimated 85% of patients who achieved a complete response still in response 12 months after initial response¹. Kymriah was shown to be effective in high-risk patients including those who were heavily pretreated or had refractory disease, POD24, bulky disease or those with high Follicular Lymphoma International Prognostic Index (FLIPI) scores¹.

For the 97 patients evaluable for safety at 21 months of median follow-up, the safety profile of Kymriah was remarkable¹. Fifty-three percent of patients experienced any-grade cytokine release syndrome (CRS), as defined by the Lee scale, and there were no reported cases of high-grade (grade 3 or higher) CRS¹. Forty-three percent of patients experienced any-grade neurologic events; grade 3 or higher neurologic events were seen in only 6% of patients¹. Eighteen percent of patients (17 of 97 patients) were infused in an outpatient setting³.

“Patients with follicular lymphoma who relapse or don’t respond to treatment have a poor prognosis and may face a series of treatment options without a meaningful, lasting response,” said Stephen J. Schuster, MD, the Robert and Margarita Louis-Dreyfus Professor in Chronic Lymphocytic Leukemia and Lymphoma in the Division of Hematology Oncology and Director, Lymphoma Program and Translational Research at the University of Pennsylvania’s Abramson Cancer Center, institutional Principal Investigator on the trial. “This new, effective option for patients with follicular lymphoma may offer long-term benefit.”

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^{4,5}. Although there are multiple systemic therapies available, the efficacy of these regimens drops off rapidly in later lines⁶.

“The approval of Kymriah offers patients with relapsed or refractory follicular lymphoma a new treatment option and new hope for improving patient outcomes,” said Meghan Gutierrez, Chief Executive Officer at the Lymphoma Research Foundation. “Having this single infusion treatment option helps to transform the way healthcare providers approach this type of blood cancer and we commend those who have contributed to the acceleration of scientific research for the benefit of patients.”

In early May 2022, the European Commission approved Kymriah for the treatment of adult patients with r/r FL after two or more lines of systemic therapy, the third indication for which Kymriah is available to patients in the European Union.

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 370 certified treatment centers, with clinical and real-world experience from administration to more than 6,900 patients. We continue to pioneer in cell therapy, leveraging our vast experience to develop next-generation CAR-T cell therapies. These therapies will 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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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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Novartis Media Relations

E-mail: media.relations@novartis.com

Amy Wolf
Novartis External Communications
+41 79 576 0723 (mobile)
amy.wolf@novartis.com

Jackie Stahl
Novartis Oncology Communications
+1 862 778 0516
jackie.stahl@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
julie.masow@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Nicole Zinsli-Somm	+4 16 132 43809	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973-876-4912