NOVARTIS AG
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated July 12, 2017

(Commission File No. 1-15024)

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Novartis AG

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes: **No**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis CAR-T cell therapy CTL019 unanimously (10-0) recommended for approval by FDA advisory committee to treat pediatric, young adult r/r B-cell ALL

- *Recommendation based on review of CTL019 r/r B-cell ALL development program, including the pivotal Phase II global ELIANA trial*

- *A Biologics License Application (BLA) for this indication is under FDA priority review; if approved, CTL019 could become first CAR-T cell therapy available*

- *Positive ODAC recommendation is latest milestone for CTL019 program that started through collaboration with the University of Pennsylvania*

Basel, July 12, 2017 – Novartis announced today that the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) unanimously (10-0) recommended approval of CTL019 (tisagenlecleucel), an investigational chimeric antigen receptor T cell (CAR-T) therapy, for the treatment of relapsed or refractory (r/r) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL).

“The panel’s unanimous recommendation in favor of CTL019 moves us closer to potentially delivering the first-ever commercially approved CAR-T cell therapy to patients in need,” said Bruno Strigini, CEO, Novartis Oncology. “We’re very proud to be expanding new frontiers in cancer treatment by advancing immunocellular therapy for children and young adults with r/r B-cell ALL and other critically ill patients who have limited options. We look forward to working with the FDA as they complete their review.”

Acute lymphoblastic leukemia comprises approximately 25% of cancer diagnoses among children under 15 years old and is the most common childhood cancer in the US[1]. Effective treatment options for patients with r/r ALL are limited. In pediatric and young adult patients with B-cell ALL that have relapsed multiple times or become refractory to treatment, the five-year disease-free survival is less than 10-30%[2,3,4].

The ODAC recommendation is based on review of the CTL019 r/r B-cell ALL development program, which includes the Novartis-led ELIANA study (NCT02435849), the first pediatric global CAR-T cell therapy registration trial. Findings from a US multicenter trial and a single site trial examining the safety and efficacy of CTL019 among pediatric and young adult patients with r/r B-cell ALL also supported the recommendation and the Biologics License Application (BLA)[5].

CTL019 was first developed by the University of Pennsylvania (Penn) and uses the 4-1BB costimulatory domain in its chimeric antigen receptor to enhance cellular responses as well as persistence of CTL019 after it is infused into the patient, which may be associated with long-lasting remissions in patients. In 2012, Novartis and Penn entered into a global collaboration to further research, develop and commercialize CAR-T cell therapies, including CTL019, for the investigational treatment of cancers. Children’s Hospital of Philadelphia (CHOP) was the first institution to investigate CTL019 in the treatment of pediatric patients and led the single site trial.

“It is encouraging to see the FDA panel’s recommendation and continued momentum behind this innovative therapy, which has potential to help young patients with relapsed/refractory B-cell ALL,” said the Penn team's leader, Carl June, MD, the Richard W. Vague Professor of Immunotherapy, director of the Center for Cellular Immunotherapies in Penn’s Perelman School of Medicine and director of the Parker Institute for Cancer Immunotherapy at Penn. “We look forward to continuing to work with Novartis to help make a lasting impact on the way this disease is treated.”

“We know firsthand from treating children and young adults with relapsed/refractory B-cell ALL that they desperately need innovative medicines that provide a new approach to managing this aggressive disease,” said Stephan Grupp, MD, PhD, the Yetta Deitch Novotny Professor of Pediatrics at the Perelman School of Medicine at Penn, Director of the Cancer Immunotherapy Frontier Program and Chief of the Section of Cellular Therapy and Transplant at CHOP. “Today’s vote in favor of CTL019 is a positive step and we appreciate Novartis’ commitment to pediatric patients.”

Earlier this year, Novartis submitted a BLA for CTL019 to the FDA, marking the first submission by Novartis for a CAR-T cell therapy. CTL019 previously received FDA Breakthrough Therapy designation and is under Priority Review by the FDA. The FDA will consider the vote as it reviews the BLA, although it is not obligated to follow the recommendation. Novartis continues to invest in the necessary infrastructure for the potential commercialization of CTL019, including manufacturing and the establishment of a network of certified treatment centers.

Novartis plans additional filings for CTL019 in the US and EU later this year, including applications with the FDA and European Medicines Agency (EMA) for the treatment of adults with r/r diffuse large B-cell lymphoma (DLBCL).

About CAR-T and CTL019

CAR-T is different from typical small molecule or biologic therapies because it is manufactured for each individual patient using their own cells. During the treatment process, T cells are drawn from a patient's blood and reprogrammed in the manufacturing facility to create T cells that are genetically coded to express a chimeric antigen receptor to recognize and fight cancer cells and other B-cells expressing a specific antigen.

ELIANA (NCT02435849) is the first pediatric global CAR-T cell therapy registration trial, with study enrollment having occurred across 25 centers in the US, Canada, EU, Australia and Japan.

Because CTL019 is an investigational therapy, the safety and efficacy profile has not yet been established. Access to investigational therapies is available only through carefully controlled and monitored clinical trials. These trials are

designed to better understand the potential benefits and risks of the therapy. Because of the uncertainty of clinical trials, there is no guarantee that CTL019 will ever be commercially available anywhere in the world.

About CTL019 Manufacturing

The Novartis leukapheresis process using cryopreservation allowed for manufacturing and treatment of patients from around the world. Cryopreserved leukapheresis involves removing white blood cells from a patient's blood and preserving them at very low temperatures. Cryopreserved leukapheresis gives physicians the flexibility to schedule apheresis at a time that is in the best interest of their patients. Novartis commercial manufacturing for CTL019 continues to build on its experience in its Morris Plains, New Jersey facility, which has already manufactured CTL019 for hundreds of patients in global clinical trials. Novartis believes that experience is important in cell therapy manufacturing, and the experience gained at the Morris Plains, New Jersey facility will be a foundation for commercial manufacturing of CAR-T therapies. Novartis has made and continues to make investments in manufacturing.

Disclaimer

This press release contains forward-looking statements, including "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," "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 CTL019 and the other investigational 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 CTL019 or the other investigational 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. Neither can there be any guarantee that Novartis will successfully implement and maintain commercial manufacturing for CTL019 or the other investigational products described in this press release, or successfully build a network of treatment centers to offer CTL019 or the other investigational products described in this press release. 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; our ability to successfully implement and maintain commercial manufacturing and build a network of treatment centers; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues, 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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5. Novartis CTL019 ODAC Briefing Document.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: July 12, 2017 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
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Accounting