NOVARTIS AG
Form 6-K
June 29, 2018

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 June 29, 2018

(Commission File No. 1-15024)

_____

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

_____

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

Form 20-F: Form 40-F:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: **No**:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: **No**:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: **No**:

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives positive CHMP opinion for Kymriah® for treating two aggressive blood cancers, marking important medical advance for patients in Europe

- *First CHMP opinion for a CAR-T cell therapy in two distinct indications – DLBCL in adults and B-cell ALL in children*
- *Marketing Authorization Application (MAA) based on landmark global CAR-T clinical trials ELIANA and JULIET, the only CAR-T registrational trials to include European patients*
- *Novartis has demonstrated strong and durable response rates, and a consistent safety profile for Kymriah*
- *Recommendation brings Novartis closer to making Kymriah available in the EU to patients who are in critical need of new treatment options*

Basel, June 29, 2018 – Novartis today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of Kymriah® (tisagenlecleucel, formerly CTL019) – a novel one-time treatment that uses a patient's own T cells to fight cancer. The positive opinion includes two B-cell malignancies: B-cell acute lymphoblastic leukemia (ALL) that is refractory, in relapse post-transplant or in second or later relapse in patients up to 25 years of age; and diffuse large B-cell lymphoma (DLBCL) that is relapsed or refractory (r/r) after two or more lines of systemic therapy in adults.

“The positive CHMP opinion for Kymriah is a watershed moment for pediatric and adult patients in Europe with aggressive blood cancers,” said Liz Barrett, CEO, Novartis Oncology. “This truly transformative therapy helps address a

profound unmet need, and Novartis is proud that our leadership in CAR-T innovation will make a meaningful difference to patients in the EU."

If approved by the European Commission, Kymriah will be the first CAR-T cell therapy available in the European Union (EU) for both DLBCL and B-cell ALL.

Both B-cell ALL and DLBCL are aggressive malignancies with significant treatment gaps for patients. In Europe, ALL accounts for approximately 80% of leukemia cases among children[1], and for those patients who relapse, the outlook is poor[2]. This low survival rate is in spite of patients having to undergo multiple treatments, including chemotherapy, radiation, targeted therapy or stem cell transplant, and further highlights the need for new treatment options. DLBCL is the most common form of non-Hodgkin lymphoma, accounting for up to 40% of all cases globally[3]. For patients who relapse or don't respond to initial therapy, there are limited treatment options that provide durable responses, and survival rates are low for the majority of patients due to ineligibility for autologous stem cell transplant (ASCT) or because salvage chemotherapy or ASCT have failed[4].

The positive CHMP opinion is based on two pivotal Novartis-sponsored global, multi-center, Phase II trials, ELIANA and JULIET, which included patients from Europe, the US, Australia, Canada and Japan.

The collaboration of Novartis and the University of Pennsylvania has led to historic milestones in CAR-T cell therapy since 2012, including the initiation of the first global CAR-T trials, the PRIME designation granted by the EMA for Kymriah in pediatric patients with r/r B-cell ALL, and the approval of Kymriah in two distinct indications by the US Food and Drug Administration (FDA).

“Kymriah is already transforming the way we treat certain types of leukemia and lymphoma in the United States, and showing us that personalized cell therapies are an incredibly powerful tool in the fight against cancer,” said Carl June, MD, the Richard W. Vague Professor in Immunotherapy in the department of Pathology and Laboratory Medicine and director of the Center for Cellular Immunotherapies in the Abramson Cancer Center. “We are excited to see that through our collaboration with Novartis, physicians in more countries around the world may be able to use this novel and innovative CAR-T cell therapy to improve the treatment outcomes for their patients.”

ELIANA is the first pediatric global CAR-T cell therapy registration trial, treating patients in 25 centers in the US, Canada, Australia, Japan and the EU, including: Austria, Belgium, France, Germany, Italy, Norway and Spain. JULIET is the first multi-center global registration study for Kymriah in adult patients with r/r DLBCL.

JULIET is also the largest global study evaluating a CAR-T cell therapy in patients with DLBCL, enrolling patients from 27 sites in 10 countries across the US, Canada, Australia, Japan and the EU, including: Austria, France, Germany, Italy, Norway and the Netherlands.

The Novartis CAR-T cell manufacturing platform includes cryopreservation, the process of freezing patients’ harvested cells in order to preserve them, which provides physicians with the flexibility to decide when to initiate both the harvesting of patients’ cells and the infusion of Kymriah, based on each patient’s condition, and allows for this individualized treatment approach on a global scale.

“Today’s positive opinion from the CHMP marks a truly extraordinary moment for those who have been impacted by these types of advanced and aggressive B-cell malignancies,” said Dr. Ulrich Jäger, Professor of Hematology at the Medical University of Vienna and Head of Hematology at the General Hospital of the City of Vienna. “European patients and doctors have been anxiously awaiting the introduction of Kymriah, which will bring a significant advancement in the treatment landscape for these patients who face a poor prognosis.”

The European Commission will now review the CHMP recommendation to deliver its final decision, applicable to all 28 EU member states, plus Iceland, Liechtenstein and Norway.

“This CHMP decision brings an innovative option closer to European patients who have exhausted most alternative treatments,” said Zack Pemberton-Whiteley, Chair of the Global Acute Leukemia Advocates Network and Campaigns and Advocacy Director at Leukaemia Care. “It’s important to note that CAR-T therapy may be suitable for a limited group of patients. Working with healthcare professionals to ensure safe and timely access for those who need it will be of paramount importance.”

Additional regulatory filings are under review for Kymriah in Canada, Switzerland, Australia and Japan.

About CAR-T

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 laboratory to create T cells

that are genetically coded to recognize and fight the patient's cancer cells and other B cells expressing a particular antigen.

Novartis Leadership in Immuno-Oncology

Novartis is at the forefront of investigational immunocellular therapy as the first pharmaceutical company to initiate global CAR-T trials, and has significantly invested in CAR- T research and worked with pioneers in the field. Kymriah, the first approved CAR-T cell therapy, is the cornerstone of this strategy. Active research programs are underway targeting other hematologic malignancies and solid tumors, and include efforts focused on next generation CAR-Ts with evolved manufacturing schemes and gene edited cells.

Kymriah® (tisagenlecleucel, formerly CTL019) Important Safety Information from the US Prescribing Information

Kymriah is currently only approved in the United States.

Kymriah is made from your own white blood cells and is a prescription cancer treatment used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that is either relapsing (went into remission, then came back) or refractory (did not go into remission after receiving other leukemia treatments). It is also used in patients with certain forms of large B- cell lymphoma that have relapsed or are refractory after having at least two other kinds of treatment.

Kymriah may cause side effects that are severe or life threatening, such as Cytokine Release Syndrome (CRS) or Neurological Toxicities. Patients with CRS may experience symptoms including difficulty breathing, fever (100.4F/38C or higher), chills/shaking chills, severe nausea, vomiting and diarrhea, severe muscle or joint pain, very low blood pressure, or dizziness/lightheadedness. Patients may be admitted to the hospital for CRS and treated with other medications.

Patients with neurological toxicities may experience symptoms such as altered or decreased consciousness, headaches, delirium, confusion, agitation, anxiety, seizures, difficulty speaking and understanding, or loss of balance. Patients should be advised to call their healthcare provider or get emergency help right away if they experience any of these signs and symptoms of CRS or neurological toxicities.

Because of the risk of CRS and neurological toxicities, Kymriah is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called Kymriah REMS.

Serious allergic reactions, including anaphylaxis, may occur after Kymriah infusion. Kymriah can increase the risk of life-threatening infections that may lead to death. Patients should be advised to tell their healthcare provider right away if they develop fever, chills, or any signs or symptoms of an infection.

Patients may experience prolonged low blood cell counts (cytopenia), where one or more types of blood cells (red blood cells, white blood cells, or platelets) are decreased. The patient's healthcare provider will do blood tests to check all of their blood cell counts after treatment with Kymriah. Patients should be advised to tell their healthcare provider right away if they get a fever, are feeling tired, or have bruising or bleeding.

Patients may experience hypogammaglobulinemia, a condition in which the level of immunoglobulins (antibodies) in the blood is low and the risk of infection is increased. It is expected that patients may develop hypogammaglobulinemia with Kymriah, and may need to receive immunoglobulin replacement for an indefinite amount of time following treatment with Kymriah. Patients should tell their healthcare provider about their treatment with Kymriah before receiving a live virus vaccine.

After treatment with Kymriah, patients will be monitored lifelong by their healthcare provider, as they may develop secondary cancers or recurrence of their cancer.

Patients should not drive, operate heavy machinery, or do other dangerous activities for eight weeks after receiving Kymriah because the treatment can cause temporary memory and coordination problems, including sleepiness, confusion, weakness, dizziness, and seizures.

Some of the most common side effects of Kymriah are difficulty breathing, fever (100.4°F/38°C or higher), chills/shaking chills, confusion, severe nausea, vomiting and diarrhea, severe muscle or joint pain, very low blood pressure, dizziness/lightheadedness, and headache. However, these are not all of the possible side effects of Kymriah. Patients should talk to their healthcare provider for medical advice about side effects.

Prior to a female patient starting treatment with Kymriah, their healthcare provider may do a pregnancy test. There is no information available for Kymriah use in pregnant or breast- feeding women. Therefore, Kymriah is not recommended for women who are pregnant or breast feeding. Patients should talk to their healthcare provider about birth control and pregnancy.

Patients should tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

After receiving Kymriah, patients should be advised that some commercial HIV tests may cause a false-positive test result. Patients should also be advised not to donate blood, organs, or tissues and cells for transplantation after receiving Kymriah.

Please see the full Prescribing Information for Kymriah, including Boxed WARNING, and Medication Guide at www.Kymriah.com

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,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” “strategy,” “underway,” “next-generation,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Kymriah and the other investigational or approved products

described in this press release, regarding our ability to scale and sustain commercial manufacturing for Kymriah and such other products, or regarding potential future revenues from Kymriah and such other 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 Kymriah or the other 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. Neither can there be any guarantee that Novartis will successfully scale and sustain commercial manufacturing for Kymriah or the other products described in this press release, or successfully sustain a network of treatment centers to offer Kymriah or such other products. Nor can there be any guarantee that Kymriah or such other products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, our ability to successfully scale and sustain commercial manufacturing and sustain a network of treatment centers; 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, payer and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing

preferences of physicians and patients; general political and economic conditions; safety, quality 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 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 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 124,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis

For Novartis multimedia content, please visit www.novartis.com/news/media-library

For questions about the site or required registration, please contact media.relations@novartis.com

References

1. World Health Organization and European Environment and Health Information System, "Incidence of Childhood Leukaemia." December 2009. Available at: http://www.euro.who.int/ data/assets/pdf_file/0005/97016/4.1.-Incidence-of-childhood-leukaemia-EDITED_layouted.pdf. Accessed June 2018.
2. Ronson, A., Tvito, A., Rowe, JM., "Treatment of Relapsed/Refractory Acute Lymphoblastic Leukemia in Adults." *Current Oncology Reports*, 2016 Jun;18(6):39. https://www.ncbi.nlm.nih.gov/pubmed/27207612. Accessed June 2018.
3. World Health Organization. Diffuse large B-cell lymphoma. Review of cancer medicines on the WHO list of essential medicines. Available at: http://www.who.int/selection_medicines/committees/expert/20/applications/DiffuseLargeBCellLymphoma.pdf. Accessed June 2018.
4. Crump M, Neelapu S, Farooq U, Van Den Neste E, Kuruvilla J et al. (2017) Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. Blood. E-pub ahead of print August 03. doi: https://doi.org/10.1182/blood-2017-03-769620. Accessed June 2018.

# # #

Novartis Media Relations

Central media line: +41 61 324 2200

E-mail: media.relations@novartis.com

Eric Althoff	Fiona Phillips
Novartis Global Media Relations	Novartis Oncology Communications
+41 61 324 7999 (direct)	+1 862-778-7705 (direct)
+41 79 593 4202 (mobile)	+1 862-217-9396 (mobile)
eric.althoff@novartis.com	fiona.phillips@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	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		

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: June 29, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting