Novartis wins esteemed Prix Galien Foundation Best Biotechnology Product Award for CAR-T cell therapy, Kymriah®

Oct 29, 2018

- -- Kymriah was the first CAR-T cell therapy to ever be approved by a regulatory authority
- -- Since 1970, more than 40 Novartis innovative therapies have been recognized by the Prix Galien Foundation

EAST HANOVER, N.J., Oct. 29, 2018 /PRNewswire/ -- Novartis was awarded the 2018 Prix Galien USA Award for Best Biotechnology Product for Kymriah® (tisagenlecleucel) following its first-in-class approval by the US Food and Drug Administration (FDA) for the treatment of children and young adults with relapsed or refractory (r/r) B-cell precursor acute lymphoblastic leukemia (ALL). Kymriah is a ground-breaking one-time treatment that uses a patient's own T cells to fight cancer, and the only chimeric antigen receptor T cell (CAR-T) therapy approved for two distinct B-cell malignancies[1]. The award, which recognizes excellence in scientific innovation that improves the state of human health, was presented at a ceremony in New York City.

"It is a great honor to receive this prestigious award for Kymriah," said Liz Barrett, CEO, Novartis Oncology. "The impact for patients with aggressive blood cancers who previously had limited treatment options is our greatest reward and drives us to continue pioneering efforts to reimagine the way cancer is treated."

The historic approval of Kymriah was a result of collaboration with researchers at University of Pennsylvania (Penn) who demonstrated the first successful use of gene transfer therapy to use the body's immune cells to fight cancer. Novartis further researched this emerging class of drug, initiating the first global CAR-T trials and in August 2017, became the first company to gain a regulatory approval of a CAR-T cell therapy. This year, Kymriah has also been approved in the United States for the treatment of adult patients with r/r diffuse large B-cell lymphoma (DLBCL); and for the treatment of pediatric and young adult patients with r/r ALL and adults with r/r DLBCL in the European Union, Canada and Switzerland. Of note, Kymriah is not approved for the treatment of patients with primary central nervous system lymphoma[1].

Both B-cell ALL and DLBCL are aggressive malignancies, and for patients who relapse or don't respond to therapy, there are limited treatment options[2,3].

Novartis Prix Galien Awards
Considered "the pharmaceutical industry's Nobel Prize," the Prix Galien recognizes excellence in scientific innovation that improves the state of human health, and acknowledges the technical, scientific and clinical research skills necessary to develop such innovative medicines. As a true testament to the company's commitment to reimagine medicine, since 1970, Novartis has received more than 40 national Prix Galien awards in 15 countries for innovative therapies including Gleevec® (imatinib mesylate), Kymriah® (tisagenlecleucel), Parlodel® (bromocriptine mesylate), Rimactane® (rifampin), Sandimmune® (cyclosporine), Sandostatin® (octreotide acetate), Simulect® (basiliximab) and Visudyne® (verteporfin)[4].

About Kymriah® (tisagenlecleucel)

Kymriah is an innovative immunocellular therapy, manufactured individually for each patient by reprogramming the patient's own immune system cells. Kymriah is the only approved CAR-T cell therapy manufactured using the 4-1BB costimulatory domain, which is critical for full activation of the therapy, enhancement of cellular expansion and durable persistence of the cancer-fighting cells. In 2012, Novartis and Penn entered into a global collaboration to further research, develop and commercialize CAR-T cell therapies, including Kymriah, for the investigational treatment of cancers.

Kymriah® (tisagenlecleucel) US Important Safety information
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 (100.4°F/38°C 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

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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 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125 000 people of more than 140 nationalities work at Novartis around the world. Novartis Pharmaceuticals Corporation, a US affiliate of Novartis, is located in East Hanover, NJ. For more information, please visit http://www.novartis.com.

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