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MEDIA UPDATE

Novartis receives European Commission approval for Jakavi® to be the first post-steroid treatment for acute and chronic graft-versus-host disease

- *Jakavi is the first JAK1/2 inhibitor available for patients in Europe who previously had no approved therapies for the treatment of steroid-refractory graft-versus-host disease (GvHD)*[1,2]

- *In clinical trials, Jakavi demonstrated superiority versus best available therapy in patients with steroid-refractory/dependent acute and chronic GvHD, with overall response rates of 62% vs. 39%, and 50% vs. 26% respectively*[2,3]

- *GvHD is a common and potentially life-threatening complication that arises in approximately half of patients following allogeneic stem cell transplants*[4]

Basel, May 5, 2022 — Novartis today announced the European Commission (EC) has approved Jakavi (ruxolitinib) for the treatment of patients aged 12 years and older with acute or chronic GvHD who have inadequate response to corticosteroids or other systemic therapies.

“Today, 30-60% of patients with GvHD do not respond to first-line steroid treatment, underscoring the need for new approaches to ensure long-term treatment goals are met,” said Dr. Robert Zeiser, University Hospital Freiburg, Department of Haematology, Oncology and Stem Cell Transplantation, Freiburg, Germany. “The approval of Jakavi offers healthcare providers and patients with GvHD who remain dependent on or refractory to steroids a new way to manage this debilitating and life-threatening condition.”

The approval of Jakavi follows the **positive opinion** granted in March by the Committee for Medicinal Products for Human Use of the European Medicines Agency, based on the Phase III REACH2 and REACH3 trials in which Jakavi demonstrated superiority in overall response rate (ORR) compared to best available therapy (BAT). Results of **REACH2** showed 62% ORR with Jakavi at Day 28, compared to 39% for BAT; and **REACH3** demonstrated a significantly improved ORR at week 24 (50% vs. 26%) with a higher best ORR (76% vs. 60%) vs. BAT, among steroid-refractory/dependent chronic GvHD patients[2,3].

“Five out of ten patients who receive allogeneic stem cell transplants experience the serious and sometimes fatal symptoms of graft-versus-host disease,” says Marie-France Tschudin, Novartis President of Innovative Medicines International and Chief Commercial Officer. “Jakavi, with this new indication in GvHD, will help to redefine treatment for patients who do not respond to first-line care.”

GvHD occurs when donor cells see the recipient's healthy cells as foreign and attack them. Symptoms of GvHD can appear in the skin, gastrointestinal tract, liver, mouth, eyes, genitals, lungs and joints. Approximately 50% of allogeneic stem cell transplant recipients will develop either acute or chronic GvHD. Both acute and chronic GvHD can be fatal and until now both have lacked an established standard of care for patients who do not adequately respond to first-line steroid treatment[1,4-9]. Currently, there are no other approved therapies for the treatment of GvHD after steroid failures[1,2].

About Jakavi® (ruxolitinib)
Jakavi® (ruxolitinib) is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. Jakavi is approved by the European Commission for the treatment of adult patients with polycythemia vera (PV) who are resistant to or intolerant of hydroxyurea and for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (MF) (also known as chronic idiopathic MF), post-polycythemia vera MF or post-essential thrombocythemia MF, and also for patients aged 12 years and older with acute or chronic GvHD who have inadequate response to corticosteroids or other systemic therapies. Jakavi is approved in over 100 countries for patients with MF, including EU countries, Switzerland, Canada, Japan and in more than 85 countries for patients with PV, including EU countries, Switzerland, Japan and Canada. The exact indication for Jakavi varies by country. Additional worldwide regulatory filings are underway in MF and PV.

Novartis licensed ruxolitinib from Incyte for development and commercialization outside the United States. Ruxolitinib is marketed in the United States by Incyte as Jakafi® for adults with PV who have had an inadequate response to or are intolerant of hydroxyurea, for adults with intermediate or high-risk MF, for adult and pediatric patients 12 years and older with steroid-refractory acute GvHD, and adult and pediatric patients 12 years and older with chronic GvHD after failure of one or two lines of corticosteroids or other systemic therapy.

Jakavi is a registered trademark of Novartis AG in countries outside the United States. Jakafi is a registered trademark of Incyte. The safety and efficacy profile of Jakavi has not yet been established outside of its approved indications.

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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 media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update 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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References

1. Jaglowski SM, et al. Graft-versus-Host Disease: Why Haven't We Made More Progress? Curr Opin Hematol. 2014;21(2):141-147
2. Zeiser R, et al. Ruxolitinib for Glucocorticoid-Refractory Chronic Graft-versus-Host Disease (REACH3). New England Journal of Medicine; July 2021.
3. Zeiser, R, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease (REACH2). New England Journal of Medicine. April 2020.
4. Leukemia and Lymphoma Society. Graft-Versus-Host Disease Overview. 2021. Available at: https://www.lls.org/treatment/types-treatment/stem-cell-transplantation/graft-versus-host-disease
5. Jakavi (ruxolitinib) Summary of Product Characteristics. Novartis Pharma AG; 2022.
6. Ferrara JL., et al. Graft-versus-host disease. Lancet. 2009;373(9674):1550-1561.
7. Zeiser R., et al. Pathophysiology of Chronic Graft-versus-Host Disease and Therapeutic Targets. N Engl J Med. 2017 Dec 28;377(26):2565-2579
8. Jagasia MH, et al. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: I. The 2014 Diagnosis and Staging Working Group report. Biol Blood Marrow Transplant. 2015.
9. Martin PJ, Rizzo JD, Wingard JR, et al. First- and second-line systemic treatment of acute graft-versus-host disease: recommendations of the American Society of Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2012;18(8):1150-1163.

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