Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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MEDIA UPDATE

Novartis announces Phase III study of Jakavi® in chronic graft-versus-host disease met primary and key secondary endpoints

- *Jakavi® demonstrated superior overall response rate in patients with chronic graft-versus-host disease (GvHD) compared to best available therapy, building on previous positive findings in acute GvHD[1]*

- *Study also met key secondary endpoints, significantly improving failure-free survival and patient-reported symptoms[1]*

- *GvHD is a serious and common complication of stem cell transplants with no widely approved treatment options for patients who do not respond to steroids[2,3]*

Basel, July 23, 2020 — Novartis today announced that the Phase III REACH3 study evaluating Jakavi® (ruxolitinib) in patients with steroid-refractory or steroid-dependent chronic graft-versus-host disease (GvHD) met its primary endpoint of superior overall response rate (ORR) at Week 24 versus best available therapy (BAT)[1]. The study also met key secondary endpoints, significantly improving failure-free survival and patient-reported symptoms assessed by a validated chronic GvHD-specific score[1]. These topline results build on positive data from the previously reported REACH2 trial, which demonstrated that Jakavi improved outcomes across a range of efficacy measures in patients with steroid-refractory or steroid-dependent acute GvHD[2].

“These positive topline results of the pivotal Phase III trial in chronic GvHD show that treatment with Jakavi results in superior overall response and failure-free survival compared to alternative treatment options and will help to inform treatment decisions among patients refractory to steroids following bone marrow transplantation,” said David Feltquate, Head Hematology Development Unit, Novartis. “We look forward to sharing further details of the data, which complement the previous findings for Jakavi in the acute form of the disease, and plan to initiate regulatory filings for steroid-refractory GvHD in Europe and other ex-US countries.”

REACH3 (NCT03112603) is a Phase III, randomized, open-label, global multicenter study to evaluate Jakavi compared to BAT in patients with steroid-refractory or steroid-dependent chronic GvHD following allogeneic stem cell transplant[4]. Data from this study are expected to be presented at an upcoming major medical congress.

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. 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 Corporation for development and commercialization outside the United States. Ruxolitinib is marketed in the United States by Incyte Corporation as Jakafi® for patients with PV who have had an inadequate response to or are intolerant of hydroxyurea, for patients with intermediate or high-risk MF, and steroid-refractory acute GvHD in adult and pediatric patients 12 years and older[5].

The recommended starting dose of Jakavi in PV is 10 mg given orally twice daily. The recommended starting dose of Jakavi in MF is 15 mg given orally twice daily for patients with a platelet count between 100,000 cubic millimeters (mm) and 200,000 mm, and 20 mg twice daily for patients with a platelet count of >200,000 mm. Doses may be titrated based on safety and efficacy. There is limited information to recommend a starting dose for MF and PV patients with platelet counts between 50,000/mm and <100,000/mm. The maximum recommended starting dose in these patients is 5 mg twice daily, and patients should be titrated cautiously[5].

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

Important Safety Information
Jakavi can cause serious side effects, including a decrease in blood cell count and infections. Complete blood count monitoring is recommended. Dose reduction or interruption may be required in patients with any hepatic impairment or severe renal impairment or in patients developing hematologic adverse reactions such as thrombocytopenia, anemia and neutropenia. Dose reductions are also recommended when Jakavi is co-administered with strong CYP3A4 inhibitors or fluconazole. Use of Jakavi during pregnancy is not recommended, and women should avoid becoming pregnant during Jakavi therapy. Women taking Jakavi should not breast feed. Progressive multifocal leukoencephalopathy (PML) has been reported. Physicians should be alert for neuropsychiatric symptoms suggestive of PML.

Hepatitis B viral load (HBV-DNA titer) increases have been reported in patients with chronic HBV infections. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. Non-melanoma skin cancer (NMSC) has been reported in Jakavi treated patients. Periodic skin examination is recommended. Very common adverse reactions in MF (>10%) include urinary tract infections, anemia, thrombocytopenia, neutropenia, hypercholesterolemia, dizziness, headache, alanine aminotransferase increased, aspartate aminotransferase increased, bruising and weight gain. Common adverse reactions in MF (1 to 10%) include herpes zoster and flatulence. Uncommon adverse reactions in MF include tuberculosis. Very common adverse reactions in PV (>10%) include anemia, thrombocytopenia, hypercholesterolemia, hypertriglyceridemia, dizziness, alanine aminotransferase increased and aspartate aminotransferase increased. Common adverse reactions in PV (1 to 10%) include urinary tract infections, herpes zoster, weight gain, constipation and hypertension.

Please see full Prescribing Information available at **www.jakavi.com**.

Disclaimer

This media update 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,” “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 media update, 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 media update 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 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 110,000 people of more than 145 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

Anja von Treskow
Novartis Global Media Relations
+41 61 324 2279 (direct)
+41 79 392 8697 (mobile)
anja.von_treskow@novartis.com

Michael Billings
Novartis Hematology Communications
+1 862 778 8656 (direct)
+1 201 400 1854 (mobile)
michael.billings@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@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	+1 862 778 5052
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		