

MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE**Novartis announces plan to initiate clinical study of Jakavi® in severe COVID-19 patients and establish international compassionate use program**

- *New clinical trial to evaluate Jakavi® (ruxolitinib) in patients with COVID-19 associated cytokine storm*
- *Cytokine storm is a type of severe immune overreaction that can result from coronavirus infection and may contribute to respiratory compromise in patients with COVID-19¹⁻³*
- *Pre-clinical and preliminary clinical evidence suggests Jakavi, a well-established JAK inhibitor, could reduce the number of patients requiring intensive care and mechanical ventilation*
- *Novartis to establish compassionate use program for COVID-19 patient access and undertake steps to ensure uninterrupted supply of Jakavi for currently licensed indications*

Basel, April 2, 2020 — Novartis today announced plans to initiate a Phase III clinical trial in collaboration with Incyte to evaluate the use of Jakavi® (ruxolitinib) for treatment of a type of severe immune overreaction called cytokine storm that can lead to life-threatening respiratory complications in patients with COVID-19¹⁻³.

The decision is based on pre-clinical evidence and preliminary reports from independent studies, and is supported by extensive data on the safety and efficacy of Jakavi in conditions like acute graft versus host disease and myeloproliferative neoplasms. The proposed trial will assess Jakavi in combination with standard of care (SoC) therapy, compared to SoC therapy alone, in patients with severe COVID-19 pneumonia as a result of SARS-CoV-2 infection.

“Novartis is taking a number of steps to address the urgent needs arising from the COVID-19 pandemic, including the evaluation of our existing therapies to assess if any can be utilized beyond their approved indications,” said John Tsai, Head Global Drug Development and Chief Medical Officer, Novartis. “The potential that Jakavi could lead to faster recovery times for COVID-19 patients with fewer requiring intensive care and mechanical ventilation is encouraging and absolutely merits further investigation. We now are moving rapidly to finalize the study plan and then to enroll eligible patients, as well as put in place a process to provide access for patients unable to participate in the trial.”

Given the rapid spread of the pandemic, and as plans for the study are finalized, Novartis also has set up an international compassionate use program for eligible patients, subject to local regulations. In addition, we are taking steps to manage the anticipated increase in COVID-19 related requests for Jakavi without interrupting access for patients taking the drug for its licensed indications. In the US, ruxolitinib access requests are coordinated by Incyte.

Novartis commitment and response to COVID-19

Novartis is deeply dedicated to the global effort to combat COVID-19 and doing our part to support the stability of global healthcare systems. We announced a broad set of measures including the creation of a global fund of USD 20 million to support communities around the world impacted by the COVID-19 pandemic. Novartis also has committed 130 million doses of hydroxychloroquine to support pandemic response. In addition, Novartis joined two key cross-industry research initiatives, the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative (IMI). Novartis is separately supporting COVID-19 related clinical investigations of several Novartis medicines. To support access, the Novartis generics and biosimilars division Sandoz became the first company to commit to keeping stable prices for a basket of essential medicines that may help in the treatment of COVID-19. More information about the Novartis response to COVID-19 is available on [Novartis.com/coronavirus](https://www.novartis.com/coronavirus).

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 101 countries for patients with MF, including EU countries, Switzerland, Canada, Japan and in more than 75 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 in selected indications 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 older⁴.

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 cautiously⁴.

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.

Jakavi Important Safety Information for Treatment of Myelofibrosis (MF) and Polycythemia Vera (PV)

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 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,” “may,” “could,” “would,” “expect,” “anticipate,” “seek,” “look forward,” “believe,” “committed,” “suggests,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for Jakavi, regarding potential future revenues from such products, regarding our plans to initiate a clinical trial to evaluate the use of Jakavi in severe COVID-19 patients, or regarding the international compassionate use program for eligible patients. 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 Jakavi 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 we will initiate the planned clinical trial in the expected time frame, or at all. Nor can there be any guarantee that Jakavi will meet the primary or any secondary endpoints of the planned trial. Neither can there be any guarantee that Jakavi will be commercially successful in the future. In particular, our expectations regarding such products and the international compassionate use program 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 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 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 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <https://twitter.com/novartisnews>
For Novartis multimedia content, please visit <https://www.novartis.com/news/media-library>
For questions about the site or required registration, please contact media.relations@novartis.com.

References

1. "NCI Dictionary of Cancer Terms: cytokine release syndrome." National Cancer Institute, www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome. Accessed 28 March, 2020.
2. Mehta, Puja, *et al.* "COVID-19: Consider Cytokine Storm Syndromes and Immunosuppression." *The Lancet*, vol. 395, no. 10229, 28 Mar. 2020, pp. 1033–1034., doi:10.1016/s0140-6736(20)30628-0.
3. Shimabukuro-Vornhagen, Alexander, *et al.* "Cytokine Release Syndrome." *Journal for ImmunoTherapy of Cancer*, vol. 6, no. 56, 15 June 2018, doi:10.1186/s40425-018-0343-9.
4. Jakavi® (ruxolitinib) tablets: EU Summary of Product Characteristics. Novartis; Mar 2015.

###

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
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Sloan Simpson +1 862 778 5052
Cory Twining +1 862 778 3258