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MEDIA & INVESTOR RELEASE

Novartis provides update on RUXCOVID study of ruxolitinib for hospitalized patients with COVID-19

- *Phase III study did not meet its primary endpoint of reducing the number of hospitalized COVID-19 patients who experienced severe complications (death, mechanical ventilation or ICU care)*[1]

- *Detailed results will be submitted for publication to support scientific understanding of JAK inhibition in COVID-19 and inform ongoing research*

- *Novartis commitment to address COVID-19 pandemic remains strong with multiple research collaboration initiatives ongoing*

Basel, December 14, 2020 — Novartis today announced that the Phase III RUXCOVID study evaluating ruxolitinib on top of standard of care (SoC) therapy compared to SoC treatment alone in patients with COVID-19 did not meet its primary endpoint[1]. Initial data show there was no statistically significant reduction in the proportion of patients on ruxolitinib plus SoC therapy who experienced severe complications, including death, respiratory failure requiring mechanical ventilation or admission to the intensive care unit (ICU) by Day 29, compared to SoC alone[1]. The trial also did not show clinically relevant benefit among secondary and exploratory endpoints including mortality rate by Day 29, and time to recovery (no longer infected, or ambulatory with no or minimal limitations)[1].

“While the RUXCOVID trial did not give us the results we hoped for, we will continue working with the medical community to analyze its findings to better understand COVID-19 and the role of JAK inhibition,” said John Tsai, Head Global Drug Development and Chief Medical Officer, Novartis. “We would like to thank the front-line clinical teams and staff at each of the trial sites and the hundreds of patients who volunteered to participate and their loved ones. We are deeply grateful to them and will continue our dedicated scientific research into the ongoing global pandemic.”

In the trial, the proportion of patients who died, or required mechanical ventilation due to respiratory failure or ICU care by Day 29, the primary endpoint, was 12.0% for ruxolitinib plus SoC vs. 11.8% for placebo plus SoC (OR: 0.91 [95% CI: 0.48-1.73]; p=0.769)[1]. Ruxolitinib was generally well-tolerated, and a comprehensive analysis including safety data is ongoing[1]. The results of RUXCOVID do not affect any ongoing trials for ruxolitinib in non-COVID-19 diseases.

About RUXCOVID
RUXCOVID (NCT04362137) is a Phase III multicenter, randomized, double-blind, placebo-controlled, 29-day study to evaluate the efficacy and safety of ruxolitinib plus standard of care (SoC) therapy compared to placebo plus SoC therapy in patients aged ≥12 years hospitalized for COVID-19 and not intubated or receiving ICU care prior to randomization. The study has enrolled 432 patients globally[2].

The composite primary endpoint is the proportion of patients who die, develop respiratory failure (require mechanical ventilation), or require admission to ICU by Day 29. Secondary endpoints include various efficacy assessments including evaluation of clinical status using a 9-point ordinal scale; in-hospital outcomes (mortality rate; proportion of patients requiring mechanical ventilation; duration of hospitalization, ICU stay, supplemental oxygen, invasive mechanical ventilation); change in the National Early Warning Score (NEWS2); change in SpO2/FiO2 ratio; proportion of patients with no oxygen therapy (oxygen saturation of ≥94% on room air); and safety. The exploratory endpoint of time to recovery (no longer infected, or ambulatory with no or minimal limitations) was also evaluated[2].

Eligible patients were randomized 2:1 to receive oral ruxolitinib 5mg twice daily (BID) or oral-matching placebo for a total of 14 days. Study treatment is given in combination with SoC therapy according to the investigator's clinical judgement. After 14 days of therapy, should clinical signs or symptoms not improve or worsen, and the potential benefit outweighs the potential risks, patients may receive an additional 14 days of study therapy. In total, patients are followed on study for 29 days post-randomization[2].

RUXCOVID is sponsored by Novartis outside of the US and by Incyte in the US.

About ruxolitinib
Ruxolitinib is an oral inhibitor of the JAK 1 and JAK 2 tyrosine kinases. It is approved under the trade name Jakavi® in Europe and other regions and countries 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. Approved indications vary by country[3]. The safety and efficacy profile of Jakavi has not yet been established outside of its approved indications.

Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the US. Ruxolitinib is marketed outside the US by Novartis as Jakavi®, and in the US 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[3]. Jakavi is a registered trademark of Novartis AG in countries outside the US. Jakafi is a registered trademark of Incyte Corporation.

Novartis response to COVID-19 pandemic
Novartis is making multiple contributions to the global effort to combat the COVID-19 pandemic and support the stability of global healthcare systems. The company has committed to donating USD 40 million to support communities around the world impacted by the pandemic. In addition, Novartis is active in several 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 supported by the Innovative Medicines Initiative (IMI)[4]. Novartis has also announced a collaboration with Molecular Partners to develop two DARPin® therapies designed for potential use against COVID-19[5], and the company is separately supporting COVID-19-related clinical investigations of several Novartis medicines. Two medicines in early stage development are also being investigated focusing on stopping or slowing the body's overactive immune response to COVID-19[6,7]. In our labs, we have started a collaborative, longer-term drug discovery effort to develop an antiviral molecule to potentially treat all coronaviruses. To sustain 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 and entered into a partnership with US-based Civica Rx to support stable supply of essential generic hospital medicines. We are making 15 drugs that treat key symptoms of COVID-19 available to low-and lower-middle income countries at zero profit until a vaccine or curative treatment is found. This includes dexamethasone, which is the only medicine shown to decrease mortality so far in severe hospitalized COVID pneumonia[4].

Furthermore, Novartis Gene Therapies entered into a manufacturing agreement with Massachusetts Eye and Ear and Massachusetts General Hospital to produce its novel genetic COVID-19 vaccine candidate called AAVCOVID[8]. More information about the Novartis response to COVID-19 is available at www.novartis.com/coronavirus.

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,” “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 press release, 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 press release 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 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 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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