Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
https://twitter.com/novartisnews

MEDIA & INVESTOR RELEASE

Novartis expands Oncology pipeline with in-licensing of tislelizumab from BeiGene

- *Agreement expands Novartis Oncology portfolio, adding late-stage PD-1 for monotherapy and potential proprietary PD-1 combinations, driving mid- and long-term growth*

- *Novartis secures development and commercialization rights in North America, Europe, and Japan*

- *Accelerates Novartis immuno-oncology combination strategy with multiple potential tislelizumab plus Novartis therapy combinations*

- *Tislelizumab already approved for patients with classical Hodgkin's lymphoma and metastatic urothelial carcinoma in China; 15 registration-enabling clinical trials under way in non-small cell lung cancer (NSCLC) and other solid tumors*

Basel, January 11, 2021 — Novartis has signed a strategic collaboration agreement to in-license tislelizumab from BeiGene, Ltd. in major markets outside of China, accelerating the potential for Novartis to enter the large and growing checkpoint inhibitor field. Tislelizumab is an anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Under the terms of the agreement, Novartis will obtain the development and commercialization rights to tislelizumab in the United States, Canada, Mexico, the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan in exchange for an upfront payment of USD 650 million plus royalties and milestone payments. BeiGene will retain the rights to tislelizumab in China and other countries. The transaction has been approved by the Boards of Directors of both companies.

More than 7,700 patients have been enrolled in 15 potentially registration-enabling clinical trials with tislelizumab in a dozen indications, including non-small cell lung cancer (NSCLC), hepatocellular carcinoma (HCC), esophageal squamous cell carcinoma, gastric cancer and nasopharyngeal carcinoma. The first ex-China regulatory filing is expected in 2021. In addition, Novartis and BeiGene have identified multiple tislelizumab plus Novartis therapy combination clinical trial opportunities in solid tumors.

"Novartis has a bold ambition to reimagine medicine and find new cures for cancer and blood disorders. This agreement expands on our strategy as the only company pursuing four different approaches to treating cancer: targeted therapy, radioligand therapy, cell and gene therapy, and immunotherapy. No other company has this range of therapeutic approaches, and the opportunity to combine them to offer the best outcomes for each patient," said

Susanne Schaffert, PhD, President, Novartis Oncology. “We are excited about collaborating with BeiGene, a leading global biotechnology company with roots in China, to bring tislelizumab to patients around the world, and pair it with our extensive portfolio and pipeline to develop transformative combination therapies for patients.”

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for certain patients with classical Hodgkin’s lymphoma and metastatic urothelial carcinoma. In addition, BeiGene has filed three supplemental new drug applications for tislelizumab in China for first-line treatment of patients with advanced squamous NSCLC in combination with chemotherapy, first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and previously treated unresectable HCC.

Closing of the transaction is subject to expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

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,” “to develop,” “development,” “ambition,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for tislelizumab, or regarding potential future revenues from tislelizumab; or regarding the agreement to in-license tislelizumab from BeiGene in major markets outside of China. 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 transaction described in this press release will be completed in the expected time frame, or at all. Neither is there any guarantee that the expected benefits and synergies from such transaction will be achieved in the expected timeframe, or at all. Nor can there be any guarantee that tislelizumab will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that tislelizumab will be commercially successful in the future. In particular, our expectations regarding the transaction described in this press release and tislelizumab could be affected by, among other things, the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act; 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.

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

# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Anja von Treskow
Novartis External Communications
+41 79 392 86 97 (mobile)
anja.von_treskow@novartis.com

Julie Masow
Novartis Oncology Communications
+1 862 579 8456 (mobile)
julie.masow@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		