Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

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MEDIA & INVESTOR RELEASE

Novartis strengthens immunotherapy pipeline with option, collaboration and license agreement with BeiGene for TIGIT inhibitor ociperlimab

- *Ociperlimab adds innovative and complementary late-stage TIGIT inhibitor to an Oncology portfolio poised for growth*
- *Two Phase III trials underway in non-small cell lung cancer and additional studies ongoing in a wide range of solid tumors*
- *Strategic partnership expands opportunities for development with the PD-1 inhibitor tislelizumab, a potential bridge to synergistic combinations in the Novartis immunotherapy program*
- *Innovative market development collaboration also signed, expanding availability of select Novartis Oncology products in regions across China currently not covered by Novartis*

Basel, December 20, 2021 — Novartis announced today the signing of an option, collaboration and license agreement with BeiGene, Ltd. for ociperlimab (BGB-A1217), expanding the company's research and development activities in immuno-oncology. Ociperlimab is a late-stage TIGIT inhibitor, a novel class of anti-cancer therapies that blocks the TIGIT protein receptor. Ociperlimab is currently being evaluated in two Phase III lung cancer trials and additional studies are ongoing in a wide range of solid tumors.

Under terms of the agreement, Novartis will make an upfront payment to BeiGene of USD 300 million. A fee of up to USD 700 million would be paid to BeiGene if the option is exercised before late 2023. Upon exercise of the option, Novartis would obtain the development and commercialization rights to ociperlimab in the United States, Canada, Mexico, the European Union, United Kingdom, Norway, Iceland, Liechtenstein, Switzerland, Russia and Japan. BeiGene agrees to provide 50 percent of the co-detailing efforts in the United States following approval and will retain the rights to ociperlimab in China and all other countries.

"This agreement adds a potentially transformative new therapy to our expanding immunotherapy platform and is part of the broad Novartis Oncology effort to drive the next wave of innovation in cancer treatments," said Susanne Schaffert, PhD, President, Novartis Oncology. "Ociperlimab is a promising late-stage compound in non-small cell lung cancer, with potential in a wide range of solid tumors. We believe it is a strong candidate for potentially synergistic combination with the PD-1 inhibitor tislelizumab. We're proud of the strong and innovative partnership we've established with BeiGene, as it builds on our previous collaboration with tislelizumab and will continue to help us reimagine medicine for people living with cancer."

Ociperlimab is currently being studied in Phase III trials for advanced non-small cell lung cancer, and its development is complementary to the Novartis development plan for the PD-1

inhibitor tislelizumab. Early research suggests TIGIT inhibitors may be active against a broad range of tumors including lung, esophageal, gastric, breast cancer and melanoma.

During the option period, Novartis and BeiGene will collaborate on the clinical development of ociperlimab in combination with tislelizumab, with Novartis designing, sponsoring, conducting, and funding global combination clinical trials.

Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote a select number of Novartis Oncology products in the China broad market, leveraging the operational resources and expertise of the BeiGene team in specific regions that are not currently covered by Novartis. Novartis will continue to market the same selected products and its broad portfolio in areas where it currently has a commercial presence. This market development partnership is expected to grow Novartis Oncology's presence in China, where the company is committed to bringing novel treatments to patients.

About ociperlimab and TGIT inhibition
An immune checkpoint molecule, ociperlimab is an investigational potent TIGIT inhibitor with intact Fc function, believed to be critical for the anti-tumor activities of TIGIT antibodies. Targeting TIGIT provides a potential mechanism to rescue immune cells (e.g., T cells, NK cells, and dendritic cells) from the immunosuppressive tumor microenvironment, to induce an efficient antitumor immune response. The TIGIT pathway has been understood to cooperate with PD-1 to maximize the suppression of effector tumor infiltrating immune cells as well as to promote resistance to anti-PD-1 therapy. TIGIT represents a promising target with the potential to significantly improve and/or extend the therapeutic benefit of anti-PD-1 therapy to a greater number of patients.

Ociperlimab is currently being investigated in two global Phase III clinical trials, the AdvanTIG-301 and AdvanTIG-302 trials, in combination with tislelizumab in non-small cell lung cancer. To date, approximately 600 patients have been enrolled across the ociperlimab development program, which includes six global trials in patients with lung cancers, esophageal squamous cell carcinoma, and cervical cancer.

Ociperlimab collabortion expands existing Novartis partnership with BeiGene
In an agreement signed earlier this year, BeiGene granted Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan through a collaboration and license agreement. Tislelizumab is a humanized 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. The clinical impact of these features is not yet known.

Novartis is advancing tislelizumab as a potential bridge to enable synergistic combinations, with the goal of extending survival for more patients through novel combinations across tumors and lines of therapy. Novartis has the rights to develop, manufacture and commercialize tislelizumab in North America, Europe and Japan through its collaboration and license agreement with BeiGene.

Novartis and lung cancer
Novartis is committed to working with the scientific and medical communities to reimagine the treatment of lung cancer and pursue advances in medicine that could extend the survival of people with the disease. The company is developing experimental therapies that block cancer growth; learning more about ways to activate the body's immune system; increasing understanding of the relationship between chronic inflammation and tumor growth and progression; and exploring the potential for advanced nuclear medicine to fight the disease.

Lung cancer is one of the most common cancers worldwide, accounting for more than 2 million new cases diagnosed each year. More people die of lung cancer every year than any other cancer.

Disclaimer

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

Anja von Treskow
Novartis External Communications
+41 79 392 8697
anja.von_treskow@novartis.com

Mary Curtin Creaser
Novartis Oncology
+1 862 345 4102 (mobile)
mary.curtin_creaser@novartis.com

Julie Masow
Novartis US External Communications
+1 862 579 8456
Julie.masow@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	+1 862 345 4440
Thomas Hungerbuehler	+41 61 324 8425	Alina Levchuk	+1 862 778 3372
Isabella Zinck	+41 61 324 7188	Parag Mahanti	+1 973-876-4912