Molecular Partners announces collaboration with Novartis to develop two DARPin® therapies designed for potential use against COVID-19

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- **Novartis has been granted an option to in-license global rights of MP0420 and MP0423 – multi-targeted direct-acting antiviral therapeutic candidates demonstrating potential efficacy against COVID-19**
- **MP0420 and MP0423 are potential medicines with a unique approach for both the prevention and treatment of COVID-19, with the possibility to manufacture at scale, easy administration and with the potential to bypass cold storage**
- **Molecular Partners, a global leader in the development of DARPin® therapeutics, will be responsible for the conduct of phase 1 & 2 trials that may lead to emergency use approval; Novartis will be responsible for further development, manufacturing, distribution and commercialization**
- **This collaboration strengthens Novartis' ongoing commitment to research and partner with other companies to find and develop treatment options for COVID-19 and make them available around the world as fast as possible**

Zurich-Schlieren, Switzerland, October 28, 2020. Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of custom-built protein drugs known as DARPin® therapeutics, and Novartis (SIX: NOVN) today announced a collaboration in the form of an option and license agreement to develop, manufacture and commercialize Molecular Partners' anti-COVID-19 DARPin® program, consisting of two therapeutic candidates, MP0420 and MP0423. The collaboration aims to leverage Molecular Partners' proprietary DARPin® technologies and Novartis' broad expertise in global drug development, regulatory affairs, manufacturing and commercialization to rapidly advance the program in keeping with the unprecedented global urgency created by the pandemic.

Novartis is making multiple contributions to the global efforts to combat the COVID-19 pandemic. As part of those efforts, it has become increasingly clear that to tackle the pandemic at a global level the development of medicines that can prevent and treat the virus, in addition to the development of vaccines, will be crucial. Multiple treatment options increase the likelihood of reaching and treating patients around the world and, in addition, may be especially important for certain populations at greater risk who may benefit from a prophylactic treatment. MP0420 and MP0423 are potential medicines for the prevention and treatment of COVID-19, with the possibility of being manufactured at scale and potentially bypassing cold storage.

"Novartis remains unwavering in its support for tackling COVID-19 and it is clear that this pandemic calls for not just scientific solutions, but also for collaboration between companies to provide treatments in an area of high unmet need. This Swiss led partnership, which could deliver both prophylactic and treatment options at scale for COVID-19 patients across the globe, is another demonstration of our sustained commitment to addressing one of the greatest health challenges of our time," said Vas Narasimhan, Chief Executive Officer of Novartis.

Under the agreement, during the option period, Molecular Partners will conduct Phase 1 clinical trials for MP0420, expected to begin in November 2020, and perform all remaining preclinical work for MP0423 and Novartis will conduct Phase 2 and Phase 3 clinical trials, with Molecular Partners as sponsor of these trials. Upon option exercise, Novartis would be responsible for all further development and commercialization activities. During the clinical development stage, Molecular Partners will provide clinical supply. The companies will work together to scale-up manufacturing capacity, in collaboration with Sandoz, the generics and biosimilar Novartis division, to provide worldwide supply.

Several characteristics of DARPin® therapeutics make them ideally suited for antiviral therapy including multi-specific target binding with the potential to prevent viral escape via mutations, the possibility for subcutaneous administration, long half-life for sustained activity, the potential to bypass cold storage and typically high-yield, highly scalable production in bacterial fermenters. These factors provide the possibility of developing and manufacturing this innovation at scale. This supports the commitment of both companies to leverage their respective strengths and expertise to urgently develop these two potential treatments and if the data are positive, facilitate access to these medicines for patients around the world as quickly as possible.

"Our team rapidly mobilized to deliver a unique DARPin®-based approach to address the overwhelming need for effective therapeutics against COVID-19. As a class, DARPin® therapeutics have demonstrated over years of clinical research a number of characteristics that enhance their profile as antiviral therapeutics for a global pandemic. We have built on this long-term research with these two candidates, which have demonstrated extremely potent neutralization of the virus through inhibiting multiple viral mechanisms," said Patrick Amstutz, Chief Executive Officer of Molecular Partners. "We are thrilled to partner with Novartis, who has shown great commitment to combatting this pandemic and bringing innovative solutions to people around the world."

Collaboration Terms and Share Subscription

Under the terms of the agreement, Molecular Partners will receive a cash payment of CHF 20 million (~$22 million USD). As part of the transaction, Novartis also agreed to acquire CHF 40 million (~$44 million USD) worth of ordinary shares with immediate effect, at a price of CHF 23 (~$25 USD) per share. As a result, Novartis will hold approximately 6% of the outstanding shares of Molecular Partners.

Molecular Partners is eligible to receive a future milestone payment of CHF 150 million (~$165 million USD), upon Novartis exercising the option to both therapeutic candidates, and 22% royalty on sales. Molecular Partners has agreed to forgo royalties in lower income countries, and is aligned with Novartis' plans to ensure affordability based on countries' needs and capabilities.

About Molecular Partners' anti-COVID-19 program

Molecular Partners has developed a series of tri-specific antiviral DARPin® candidates with strong binding and neutralizing potency targeting multiple epitopes on the SARS-CoV-2 spike protein that are crucial for infection. The source of these constructs is a pool of hundreds of mono-DARPin® binders which individually bind and inhibit the virus with high potency. The construction of multi-specific candidates from monospecific proteins is the foundation of Molecular Partners' drug discovery engine and has yielded multiple clinical candidates in other indications.

These building blocks are designed to target different sites on the virus for multiple concurrent effects. These include blocking viral binding to the human ACE2 receptor (Receptor Binder Domain or RBD), the primary docking mechanism to host cells, as well as allosteric inhibition or "molecular handcuffing", of the spike protein, preventing the conformational change it undergoes prior to injection of viral RNA into the human cell.

The formatting as tri-specific candidates is designed for cooperative binding, extremely high potencies and prevention of viral escape via mutations. The candidates are formatted with a half-life enhanced DARPin® domain that binds to human serum albumin (HSA) to support long-acting activity. All DARPin® candidates are constructed to benefit from high-yield and low-cost microbial manufacturing. Molecular Partners is investigating whether the high thermal stability of DARPin® molecules can be used to overcome cold-chain requirements.

The ability of DARPin® products to be produced in *E.coli*-based biofermentation is a major advantage over antibodies, which often require substantial manufacturing process optimization and protein modification, significantly increasing cost and complexity. By contrast, DARPin® molecules are much smaller molecules that do not require glycosylation or extensive post-translational modification by producer cells, making simple, highly scalable bacterial fermentation feasible.

Molecular Partners is collaborating with AGC Biologics and Baccinex to support development of its anti-COVID-19 program, and has reached an agreement with the Swiss Government regarding rights to purchase up to 3.2 million doses of MP0420, if it is approved in Switzerland.

About DARPin® therapeutics

DARPin® therapeutics are a new class of custom-built protein therapeutics based on natural binding proteins that open a new dimension of multi-functionality and multi-target specificity in drug design. A single DARPin® candidate can engage more than five targets, and its flexible architecture and small size offer benefits over conventional monoclonal antibodies or other currently available protein therapeutics. DARPin® therapeutics have been clinically validated through to the registrational stage. The DARPin® platform is a fast and cost-effective drug discovery engine, producing drug candidates with optimized properties for development and very high production yields. DARPin® is a registered trademark owned by Molecular Partners AG.

About Molecular Partners AG

Molecular Partners AG is a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin® therapeutics, designed to address challenges current modalities cannot. The company has compounds in various stages of clinical and preclinical development with a focus on oncology. Molecular Partners has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics across multiple therapeutic areas. For more information regarding Molecular Partners AG visit www.molecularpartners.com or follow the company on Twitter @MolecularPrtnrs.

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 medicines 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 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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