# Molecular Partners to Collaborate with AGC Biologics for Manufacturing of Anti-COVID-19 DARPin® Program

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- **Partnership secures initial clinical and commercial-scale microbial manufacturing capacity**
- **The only tri-specific antiviral protein in development, with potential best-in-class potency**
- **Clinical studies planned for Q4 2020**

**Zurich-Schlieren, Switzerland, July 9, 2020.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of custom-built proteins known as DARPin® therapeutics, today announced a collaboration with AGC Biologics, a global biopharmaceutical contract development and manufacturing organization (CDMO), to support development of the company's tri-specific DARPin® anti-COVID-19 program. The company plans to initiate clinical studies for this program in the fourth quarter of 2020.

The parties will work together to deliver clinical and commercial-scale GMP manufacturing solutions at initial capacities of 100 liters and 1000 liters, a scale which Molecular Partners estimates is suitable for development and initial global supply of patients in need. This projection is based on established manufacturing properties of clinical-stage DARPin candidates, and the potency data produced to-date from the anti-COVID-19 program.

Preclinical testing supports a highly favorable target product profile, including a long half-life, high solubility, high temperature stability and ease of manufacturability via validated bacterial fermentation. This manufacturing approach is scalable and may bring a significant speed and cost advantage as other protein-based antiviral approaches, such as monoclonal antibodies, often require expensive, extensive manufacturing process development and optimization.

Molecular Partners' DARPin platform constructs its protein therapeutics through the assembly of single, monospecific DARPin proteins into a multi-functional chain that can bind to several targets at once: a 'multi-specific' DARPin. In the case of its anti-COVID-19 program, Molecular Partners is focused on unique tri-specific modalities that can bind to three parts of the novel coronavirus simultaneously.

"Securing manufacturing capacity is a critical step in advancing our novel antiviral DARPin program to clinical readiness. We are moving this program quickly to patients, building upon our strong preclinical data that shows potential best in class potency in neutralizing live virus, and the wealth of our previous clinical experience with DARPin candidates," said Patrick Amstutz, Chief Executive Officer of Molecular Partners. "We are greatly encouraged by the recent data supporting the potential of our unique tri-specific approach to target SARS-CoV-2, as we believe novel therapeutics will be an essential tool for addressing the global COVID-19 pandemic."

"AGC Biologics is pleased to be working with Molecular Partners on such an essential and innovative program," says AGC Biologics CBO Mark Womack. "We are very proud to work alongside Molecular Partners in the fight against COVID-19."

Molecular Partners has selected a lead candidate (MP0420) and a variant molecule for preclinical development. Both are tri-specific multi-DARPin candidates that inhibit the virus in several assays to the lowest picomolar potency or the assay sensitivity limit. These data, in combination with the anticipated half-life, suggests that subcutaneous administration could potentially function as both a therapeutic for existing viral infection and a prophylactic.

**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. These building blocks target different sites on the virus, including blocking binding to the human ACE2 receptor (Receptor Binder Domain or RBD), the virus's primary docking mechanism to host cells and allosteric inhibition, or "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 allows for cooperative binding and with that unrivaled 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 candidates will profit from high-yield and low-cost microbial manufacturing. It will be investigated if the high thermal stability can be used to overcome cold-chain requirements.

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.

**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 AGC Biologics**

AGC Biologics is a leading global Contract Development and Manufacturing Organization (CDMO) with a strong commitment to deliver the highest standard of service to clients and partners. The company currently employs more than 1,000 employees worldwide. AGC Biologics' global network spans three continents, with cGMP-compliant facilities in Seattle, Washington; Boulder, Colorado; Copenhagen, Denmark; Heidelberg, Germany; and Chiba, Japan.

AGC Biologics offers deep industry expertise and unique customized services for the scale-up and cGMP manufacture of protein-based therapeutics, from pre-clinical to commercial mammalian and microbial production. Integrated service offerings include plasmid (GMP pDNA) manufacturing, cell line development, bioprocess development, formulation, analytical testing, antibody drug development and conjugation, cell banking and storage and protein expression, including the proprietary CHEF1® Expression System for mammalian production.

Learn more at www.agcbio.com .

**About Molecular Partners AG**

Molecular Partners is a clinical-stage biotech company developing a new class of custom-built protein therapeutics 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, go to: www.molecularpartners.com.

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