
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE
ACT OF 1934**

January 2022

Commission File Number: **001-40488**

Molecular Partners AG

(Translation of registrant's name into English)

**Wagistrasse 14
8952 Zurich-Schlieren
Switzerland**

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

EXPLANATORY NOTE

On January 10, 2022, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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<u>99.1</u>	<u>Press Release dated January 10, 2022</u>
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<u>99.2</u>	<u>Presentation of the Company, dated January 10, 2022</u>
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Molecular Partners AG
(Registrant)

Date: January 10, 2022

/s/ PATRICK AMSTUTZ
Patrick Amstutz
Chief Executive Officer

Molecular Partners and Novartis Report Positive Topline Data from Phase 2 Study for Ensovibep (MP0420), a DARPin Antiviral Therapeutic for COVID-19

- *Topline results from the randomized, placebo-controlled EMPATHY Part A study in acute COVID-19 ambulatory patients comparing single intravenous doses of ensovibep, a DARPin antiviral therapeutic candidate vs. placebo, met the primary endpoint of viral load reduction over eight days*
- *The secondary endpoint of hospitalization and/or ER visits related to COVID-19, or death showed an overall 78% reduction in risk of events across ensovibep arms compared to placebo; No deaths were observed in the ensovibep treatment arms*
- *A total of 407 patients were recruited in the Phase 2 study and ensovibep was safe and well-tolerated at all doses (75mg, 225mg and 600mg) – with 75mg the planned dose for further development*
- *Ensovibep continues to maintain potent in vitro pan-variant activity against all variants of concern identified so far, including Omicron*
- *Ensovibep is a multi-specific DARPin (Designed Ankyrin Repeat Protein), specifically designed to block the receptor binding domains of SARS-CoV-2 spike protein through highly potent and cooperative binding, making it challenging for escape mutants*
- *Novartis confirms it will exercise its option to in-license ensovibep from Molecular Partners, accelerate manufacturing scale-up, and plans to seek expedited regulatory authorizations globally – first via the U.S. Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA)*
- *Upon completion of in-licensing, Molecular Partners will receive a milestone payment of 150M CHF and be entitled to a 22% royalty on sales of ensovibep in commercial territories*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Jan. 10, 2022 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR:**

Molecular Partners AG (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin therapeutics, and Novartis today announced that Part A of the EMPATHY clinical trial¹, that compared single intravenous doses of ensovibep, a DARPin antiviral therapeutic candidate vs. placebo to treat COVID-19, met the primary endpoint of viral load reduction over eight days. The two secondary endpoints also showed clinically meaningful benefit over placebo – (1) composite endpoint of hospitalization and/or Emergency Room (ER) visits or death, and (2) time to sustained clinical recovery. Novartis confirms it will now exercise its option to in-license ensovibep from Molecular Partners and, following exercise of the option, will seek expedited access globally, first via the FDA’s EUA process.

The global EMPATHY clinical trial, which is being conducted by Novartis, with Molecular Partners as sponsor, is a randomized, double-blind, placebo controlled study in ambulatory (non-hospitalized) adult patients with COVID-19. EMPATHY Part A enrolled 407 patients to identify a dose of ensovibep with optimal safety and efficacy and recruited patients in the USA, South Africa, India, the Netherlands, and Hungary to explore three doses: 75mg, 225mg and 600mg.

Results from the study showed that the primary endpoint was met with a statistically significant reduction in viral load over eight days, compared to placebo, for all three dosing arms. The secondary endpoint of hospitalization and/or ER visits related to COVID-19, or death showed an overall 78% reduction in risk of events across ensovibep arms compared to placebo. Treatment arms were generally balanced in terms of demographic, baseline and disease characteristics. The placebo arm with 99 patients had a total of six events (event rate of 6%); five patients were hospitalized, two of whom died due to worsening of COVID-19 and one patient had an ER visit only. In the 301 patients treated with ensovibep, there were four events; hospitalizations occurred in two patients and two needed to visit ER (event rate of 1.3%). No deaths occurred in any of the patients treated with ensovibep. All doses were well-tolerated and no unexpected safety issues were identified for any of the doses². The lowest dose of 75mg is the planned dose for further development. The data will now undergo further review so that Novartis and Molecular Partners can determine the appropriate next steps for the program.

“These encouraging results come at a time when the need for therapies with pan-variant activity, such as ensovibep, has never been greater. We are incredibly excited about the opportunity to provide a potential therapeutic option for patients around the world who require access to effective COVID-19 treatments,” said Patrick Amstutz, Ph.D., CEO of Molecular Partners. “Today’s data are a culmination of a persistent team effort, between ourselves and Novartis, to deliver a tailored antiviral with demonstrated safety and efficacy in global clinical trials. As pioneers of DARPin therapeutics, our team has the unique ability to rapidly generate and develop multi-specific DARPin therapeutics. We look forward to continue to demonstrate our capabilities and the potential of our pipeline in oncology and virology for patients in need.”

As the SARS-CoV-2 virus evolves, a multi-solution strategy is needed to combat the pandemic and there will be a need for antiviral treatments to complement the global vaccination efforts. Despite availability of vaccinations, there continues to be disease transmission, either through pockets of unvaccinated populations, in patients with compromised immune systems and co-morbidities or through emerging variants, and breakthrough infections are likely to continue. A recent in vitro analysis³ also showed that ensovibep maintains full neutralization of the pseudoviruses containing the mutations identical to the Omicron variant of concern.

“We are pleased that the results from the EMPATHY trial demonstrate the positive therapeutic effect of ensovibep, with the potential to be an important new treatment option to combat the rapidly evolving SARS-CoV-2 pandemic,” said Vas Narasimhan, CEO of Novartis. “As COVID-19 continues to burden healthcare systems across the globe, a range of treatments will be needed, and Novartis is proud to continue our collaboration with Molecular Partners on this unique treatment for COVID-19 and contribute ensovibep to this suite of options.”

Given the pressing public health emergency and the rapid spread of the Omicron variant across the world, Novartis and Molecular Partners are in close liaison with regulatory bodies to seek expedited review and approval of ensovibep as soon as possible. If approved, ensovibep will be the first multi-specific antiviral molecule for the treatment of COVID-19.

Novartis has informed Molecular Partners of its intent to option its exclusive license to global rights of ensovibep, which will lead to a milestone payment of CHF 150m. In addition, Molecular Partners will be eligible to receive 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. With the decision made to exercise the option, Novartis will become responsible for development, manufacturing, distribution and commercialization activities of ensovibep. Novartis has already initiated scale-up activities in its large-scale biologics production facilities.

Financial guidance update

The Company expects approximately CHF 133 million cash and cash equivalents as per December 31, 2021. Upon receipt of the CHF 150 million option exercise milestone from Novartis, Molecular Partners now estimates its cash runway to extend well into 2025, excluding any potential royalty income as well as excluding potential further cash flows to or from R&D partners.

Conference call and audio webcast

Molecular Partners will hold a conference call and audio webcast on Monday, January 10, 2022, at 7am ET.

To register for the conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland / Europe	0800836508
USA	(844) 865-3856
Conference ID	5090778

Participants in the conference call will have the opportunity to ask questions after a statement from management.

Audio webcast

The call will be webcast live and will be made [available](#) on the Company's website under the investor section. The replay will be available for 90 days following the presentation. Webcast participants will have the opportunity to ask questions via chat.

About ensovibep

Ensovibep is a DARPin therapeutic candidate, designed specifically to inactivate SARS-CoV-2, the virus that causes COVID-19. DARPins (Designed Ankyrin Repeat Proteins) are mono- or multi-specific protein-based therapies, designed to specifically engage their targets for various effects. Ensovibep was designed to include three individual DARPin domains, each highly neutralizing to SARS-CoV-2. With these domains constructed into a single molecule, ensovibep can block the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein through highly potent and cooperative binding. This design ensures strong neutralization, even in the presence of mutations of the spike protein and limits the development of escape mutants. Several characteristics of DARPin therapeutics make them suitable for COVID-19 treatment, including multi-specific binding, the rapid onset of action, and scalable bacterial production.

In vitro testing has shown high neutralization activity of ensovibep against all known SARS-CoV-2 variants, including the variants of concern: Alpha, Beta, Gamma, Delta and Omicron.³

About the EMPATHY clinical trial program²

Following promising Phase 1 clinical data for ensovibep the global EMPATHY clinical trial was initiated by Novartis, with Molecular Partners as sponsor, in May 2021. EMPATHY is a Phase 2 and 3 study looking at the safety and efficacy of ensovibep in symptomatic COVID-19 patients in the ambulatory (non-hospitalized) setting. Ensovibep is administered via a single dose IV infusion.

The EMPATHY clinical trial plans to enroll 2,100 patients. 407 patients were randomized into four arms of Part A of the study to identify a dose with optimal safety and efficacy. The clinical efficacy and safety of this dose vs. placebo will be further evaluated in Part B, the Phase 3 component of the EMPATHY study which will enroll an additional 1,700 patients globally.

The EMPATHY clinical trial enrolled both vaccinated and unvaccinated adult patients who have experienced at least two mild/ moderate symptoms of COVID-19 within seven days of onset and had a positive rapid antigen test on the day of dosing, confirmed by a PCR test at baseline. The COVID-19 symptoms include fever, cough, sore throat, low energy, tiredness, headache, muscle or body aches, chills and/ or shortness of breath.

About Molecular Partners AG

Molecular Partners AG is a clinical-stage biotech company developing DARPin therapeutics, a new class of custom-built protein drugs designed to address challenges current modalities cannot. The Company has formed partnerships with leading pharmaceutical companies to advance DARPin therapeutics in the areas of oncology, infectious disease, and ophthalmology, and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. www.molecularpartners.com; Find us on Twitter - @MolecularPrtnrs

References

1. <https://clinicaltrials.gov/ct2/show/NCT04828161?term=ensovibep&draw=2&rank=2>
2. Data on file, Molecular Partners, 2021.
3. <https://www.biorxiv.org/content/10.1101/2021.02.03.429164v3>

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the clinical development of Molecular Partners' current or future product candidates, including expectations regarding timing of clinical trials or the potential therapeutic and clinical benefits of Molecular Partners' product candidates. These statements may be identified

by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, “would” and similar expressions, and are based on Molecular Partners AG’s current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Some of the key factors that could cause actual results to differ from our expectations include our reliance on third party partners and collaborators over which we may not always have full control; our plans to develop and potentially commercialize our product candidates; our ongoing and planned clinical trials and preclinical studies for our product candidates, including the timing of such trials and studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our ability to identify and in-license additional product candidates; the extent of clinical trials potentially required for our product candidates; the clinical utility and ability to achieve market acceptance of our product candidates; our intellectual property position; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners’ Registration Statement on Form F-1 filed with Securities and Exchange Commission (SEC) on June 14, 2021 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners’ website at <http://www.molecularpartners.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to Molecular Partners as of the date of this release, and Molecular Partners assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Ensovibep Clinical Results Call

EMPATHY Part A

January 2022

Molecular Partners AG, Switzerland
(SIX: MOLN, NASDAQ: MOLN)



Disclaimer

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Any forward-looking statements speak only as of the date of this press release and are based on information available to Molecular Partners as of the date of this release, and Molecular Partners assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

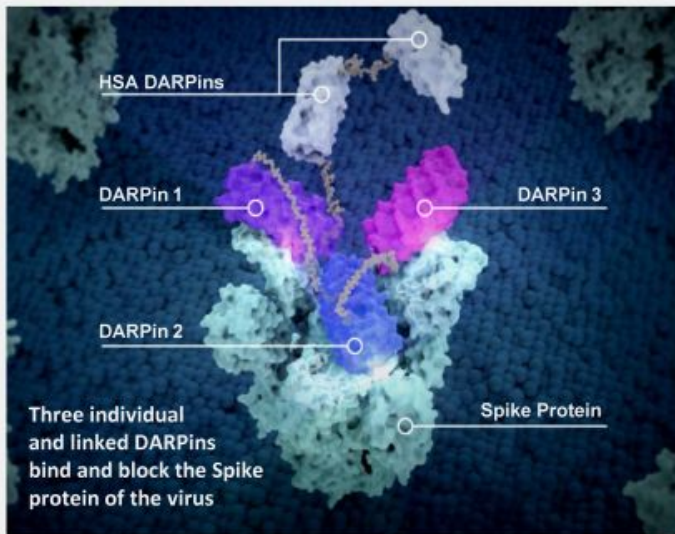


Ensovibep:

**Advancement of COVID-19
Clinical Program**

Structure and Features of Ensovibep Neutralizing the SARS-CoV-2 Spike Protein

3D model of a DARPin molecule



Characteristics

- High potency: high binding affinity and avidity leads to one of the highest anti-viral potencies reported to date
- Pan-variant activity: cooperative binding of different sites allows blocking of all described variants of concern, so far
- Simple administration: long-half life, high solubility and low dose efficacy can allow for single administration via i.v., i.v. bolus, or s.c. injection
- Supply: microbial manufacturing in *E.coli*

Ensovibep: Clinical Development Overview

- **Empathy study (top-line analysis):**

- **Randomized 407 pts in Part A**

- Mild or moderate symptoms
- Rapid antigen test positive
- Un-vaccinated and vaccinated patients

- **Met primary endpoint:**

- Significant reduction in viral load ✓

- Clinically relevant secondary endpoints include:

- Reduction in risk of hospitalization and/or ER visits due to COVID-19, or deaths ✓
- Reduction in time to sustained clinical recovery ✓
- Safe and well-tolerated ✓

- **Novartis option exercise underway**

- **Phase 1 results / status (48 healthy subjects):**

- Healthy volunteer safety trial
- Half-life established: 2-3 weeks
- i.v. infusion, i.v. bolus, s.c. injection

- **Phase 2 single-arm results (12 pts):**

- Patients, confirmed COVID positive, with symptoms
- Validation of methods and approach

- **ACTIV-3 Phase 3 interim results**

- Hospitalized patients with confirmed COVID
- High dose of 600 mg tested in ~250 patients, stopped at futility analysis for lack of efficacy
- **Safe and well-tolerated (included in ensovibep safety database)**

EMPATHY Phase Part A (Phase 2) Clinical Design and Endpoints

Objective	Demonstrate superiority of ensovibep, compared to placebo, in reducing SARS-CoV-2 viral load through Day 8 and select a dose for Phase 3 (PoC & DRF)
Population	<ul style="list-style-type: none"> Ambulatory symptomatic adult patients diagnosed with COVID-19 with onset of symptoms within 7 days prior to dosing and with a positive pre-dose Rapid Antigen Test on the day of dosing

Primary Endpoint	<ul style="list-style-type: none"> Time-weighted change from baseline (measured at Day 3, Day 5, and Day 8) in \log_{10} SARS-CoV-2 viral load in nasopharyngeal swabs through Day 8
Key Secondary Endpoints	<ul style="list-style-type: none"> Proportion of patients with hospitalizations (≥ 24 hours of acute care) and/or ER visits related to COVID-19 or death from any cause up to Day 29 Time to sustained clinical recovery based on resolution or improvement in clinical symptoms with no worsening up to Day 29

ensovibep 600mg i.v.	~ 100 pts
ensovibep 225mg i.v.	~ 100 pts
ensovibep 75mg i.v.	~ 100 pts
placebo i.v.	~ 100 pts

EUA Submission Supported by Secondary End Point in Reductions in Hospitalization and or ER Visit or Death

Patients with hospitalization and/or ER visit related to COVID-19 or death

Percent of patients with events



Numbers indicate absolute number of patients

Note:

In the hierarchy of ER-visit/ hospitalization/ death- patients are counted in the highest category

- ER visits exclude those resulting in hospitalization/ death
- Hospitalizations exclude those that resulted in death

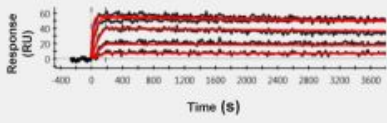
Topline Results Show Significant Reductions in Viral Load, Risk of Hospitalization and Death, and Faster Time to Recovery

- Statistically significant reduction of viral load from baseline, through Day 8 over placebo for all doses (primary endpoint)
- Fewer hospitalization and/or ER visits related to COVID-19 and no deaths for ensovibep treated patients vs. those on placebo (secondary endpoint)
 - **4/301** patients with hospitalizations and/or ER visits related to COVID-19 or death across all treatment arms
 - **6/99** patients in the Placebo arm
 - Relative risk reduction of **78% for all events; hospitalization, ER visits and/or death**
 - Relative risk reduction of **87% for hospitalization and/or death***
 - **No deaths** in any treatment groups, whereas **two deaths** occurred in placebo treated patients
- Clinically meaningful benefit for patients treated with ensovibep (secondary endpoint)
 - **Median time to clinical recovery was faster** for ensovibep treated patients vs. placebo
 - **More patients demonstrated clinical recovery** when treated ensovibep vs. placebo (day 29 cutoff)
- No unexpected safety findings were observed in Part A

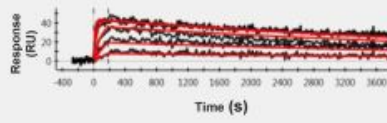
* was not a pre-defined endpoint

Cooperative Target Engagement Leads to Super Affinity

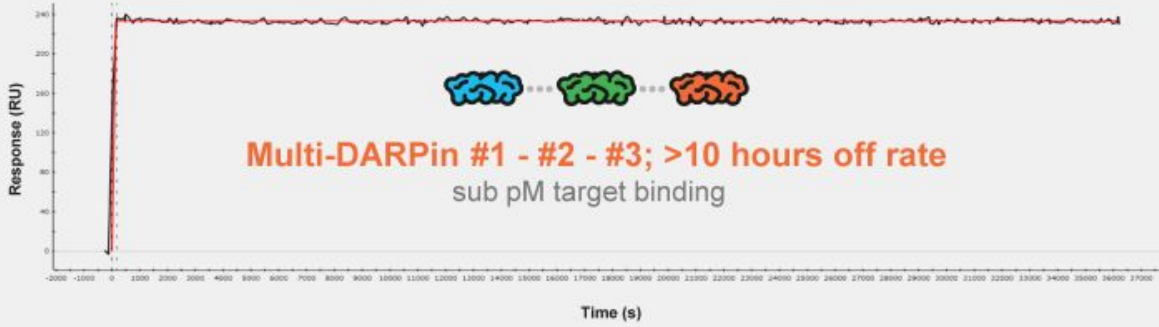
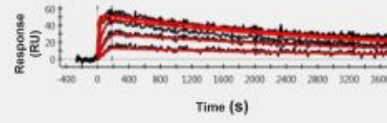
DARPin #1; 1 hour off-rate 



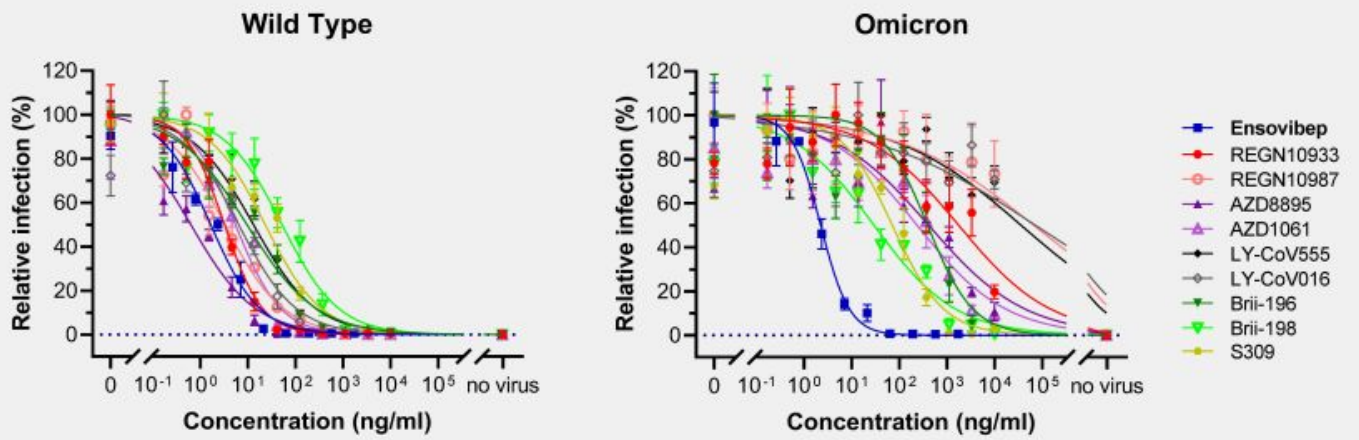
DARPin #2; 1 hour off-rate 



DARPin #3; 1 hour off-rate 



Ensovibep Retains Full Activity Against Omicron



Ensovibep Retains Full Activity Against Omicron – Table

Compound	Wild Type	Omicron (Q493R)	
	IC ₅₀ (ng/mL)	IC ₅₀ (ng/mL)	fold change to wt
Ensovibep	1.6	2.2	1.4
REGN10933	3.2	>1000	>100
REGN10987	3.3	>1000	>100
LY-CoV555	13	>1000	>100
LY-CoV016	6.4	>1000	>100
S309	23	72	3.1
AZD8895	0.6	415	>100
AZD1061	5.5	237	43
Brii-196	9.5	392	41
Brii-198	52	30	0.6

*Publicly available sequences of variable domains from monoclonal antibodies were used to generate a panel of antibodies used in this assay

Ensovibep: Tri-Specific Antiviral for COVID-19

Target Patient



- Presently millions of new cases every day globally, despite vaccines and boosters
- Currently – COVID related hospitalizations remain near all-time highs
- Over 5 million reported deaths in the world

Disease Biology



- Viral entry dependent on viral spike protein binding to ACE2 receptor
- Spike protein is a trimer with three identical subunits
- Multiple variants evolving mutations in the spike protein and other locations

DARPin Advantage

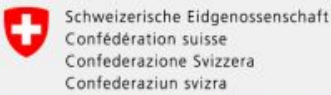


- First and only tri-specific antiviral in development, able to bind all three subunits at once
- Designed for greater viral inhibition through cooperative binding
- Retains full potency against all variants of concern, to date, including delta and omicron

Ensovibep Upcoming Milestones

- **EMPATHY (Novartis / MP)**
 - 407 patients enrolled, Part A results - **positive**
 - EUA submission expected early 2022
 - Discussion with appropriate federal agencies regarding supplies of ensovibep
 - Part B initiate (N≥1,700)
- **Large-scale commercial manufacturing established at Novartis**
 - Microbial production in e. coli
- Planned initiation of subcutaneous Phase 2/3 study (led by Novartis)

Acknowledgments



Covid Project Team (Novartis & Molecular Partners)

Spiez Laboratory – Federal Office of Civil Protection (FOCP)
Group of Olivier Engler

CHUV Lausanne-
Sylvia Rothenberger's group, for performing PsV and authentic virus assays.

University Utrecht
Group of Berend-Jan Bosch for cryo-EM analysis.

National Institute of Health (NIH)
ACTIV team for conducting PsV neutralization assays in collaboration with the Carol Weiss group.

Bundesamt für Gesundheit – BAG



Ensovibep – Summary of EMPATHY Results

- **EMPATHY Phase 2b met its primary endpoint**
 - A statistically significant dose-response signal of ensovibep based on change in viral load from baseline, through Day 8
- **Clinically relevant secondary endpoints:**
 - Combined risk reduction (hospitalization, ER visits, and death) of **approximately 80%**
 - Faster recovery and more complete recovery for patients receiving ensovibep vs. placebo
- **75mg identified** as the lowest efficacious and safe dose, to be **taken forward in Phase 3 and for EUA submission**
- **EMPATHY results confirm ensovibep as safe and well-tolerated at all dose levels**
- Ensovibep has shown **pan-variant-activity**, including Omicron



Licensing Agreement with Novartis and Financial Guidance Update

Summary and Terms

Novartis Deal Terms and Updated Financial Guidance









- **Novartis has informed Molecular Partners that it will exercise option for in-licensing of ensovibep**
 - Completion of in-licensing will trigger CHF 150m milestone payment
 - CHF 60m previously received at signing of option agreement (20m cash/40m MOLN shares)
- **22% royalty on sales in commercial countries payable by Novartis following completion of in-licensing**
 - 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.
- **Molecular Partners expects approximately CHF 133 million cash and cash equivalents* as per December 31, 2021**
- **Upon receipt of the CHF 150 million option exercise milestone from Novartis, Molecular Partners now estimates its cash runway to extend well into 2025**
 - Excluding any potential royalty income as well as excluding potential further cash flows to or from R&D partners

Summary:

- **Positive EMPATHY results represent a potential immediate and impactful solution in a constantly evolving pandemic**
 - Statistically significant reduction in viral load, reduction in risk of hospitalization and death, and time to recovery.
 - Continued evidence of 'pan-variant' activity across all variants of concern
 - Acceleration of EUA filing, initiate discussions with authorities about stockpiling of ensovibep
- **Novartis' execution of license agreement**
 - CHF 150m option
 - Flat 22% royalty rate in commercial markets
- **Validation of DARPin Platform and Molecular Partners capabilities**
 - 1st multi-DARPin moving to potential approval, paves the way for other multi-specific solutions to any number of biological problems including oncology, infectious diseases or other applications

Pipeline

■ Infectious disease ■ Discovery Oncology
■ Oncology ■ Ophthalmology

Pipeline						
CANDIDATE / FOCUS	RESEARCH	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	RIGHTS
Ensovibep – Covid	Covid ambulatory – Empathy					 
Next Gen Covid	Future VoC*					
AMG506 / MP0310 FAP x 4-1BB	Solid tumors					
MP0317 FAP x CD40	Solid tumors					
MP0533 CD3 x CD33+CD70+CD123	AML					
Abicipar VEGF	wet AMD – Cedar & Sequoia					
Radio Ligand Therapy	Solid tumors					
Platform Discovery						
Radical simplicity & Conditional Activation						
Additional Infectious Diseases						

Questions?