



Molecular Partners Reports Corporate Highlights From Q4 2021 and Key Financials for Full Year 2021

March 15, 2022

Research & Development Highlights:

- In January of 2022, announced positive topline results from Phase 2 EMPATHY clinical trial of ensovibep for the treatment of non-hospitalized COVID-19 patients, resulting in the option exercise of the program by Novartis triggering the receipt of CHF 150 million in January 2022
- Continued to confirm ensovibep's pan-variant activity in *in vitro* studies demonstrating maintained high potency against all known SARS-CoV-2 variants of concern, including Omicron, Delta and Lambda
- Received FDA Fast Track designation for ensovibep for the treatment of COVID-19
- Dosed more than 560 patients across clinical studies for ensovibep
- Announced collaboration with Novartis to develop DARPin-conjugated radioligand therapies for oncology
- Initiated enrollment in Phase 1 study of MP0317 targeting FAP and CD40
- Nominated MP0533 for development for acute myeloid leukemia (AML), targeting CD3, CD33, CD70 and CD123
- Presented data supporting oncology portfolio programs at AACR, ESMO Immuno-Oncology, ASH and Company's Virtual Oncology Day

Leadership & Governance:

- Elected Agnete Fredriksen and Dominik Höchli to the Board of Directors at the Annual General Meeting of April 21, 2021
- Promoted Alexander Zürcher to Chief Operating Officer, and Renate Gloggner to EVP People and Community. Both will be appointed to the Management Board effective July 1, 2022

Financial:

- Successfully completed initial public offering of American Depositary Shares ("ADSs") on the Nasdaq Global Select Market, raising \$63.8 million (CHF 58.8 million) in gross proceeds in June 2021.
- Following positive topline data from the Phase 2 EMPATHY clinical trial, in January 2022 Novartis exercised its option to in-license global rights to ensovibep, which triggered a CHF 150 million payment to the Company.
- Under the license agreement, Molecular Partners is entitled to receive 22% royalties on sales of ensovibep in relevant territories while Novartis leads further development and commercialization.
- Additional collaboration with Novartis in the field of radioligand therapies (RLTs), resulting in an upfront payment of \$20.0 million received in January 2022.
- Net cash outflow from operating activities of CHF 91.0 million in 2021.
- Ongoing strong financial position with CHF 291.3 in cash and short-term deposits as of February 28, 2022 (year-end 2021: CHF 132.8 million), with the Company's cash runway expected to extend into 2025. Full year 2022 expense guidance of CHF 75-85 million, reflecting ambition to further broaden the pipeline both in oncology as well as in virology.

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., March 15, 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 proteins known as DARPins therapeutics, today announced its corporate highlights and audited financial results for 2021.

"Ensovibep is our first antiviral DARPin, set to face one of the greatest medical challenges of our time, the COVID pandemic," said Patrick Amstutz, Ph.D., CEO of Molecular Partners. "Our strong clinical data represent not only a clinical win against the virus, but also constitute a major milestone for DARPins as a new class of protein drugs. Along with the development of ensovibep, we were able to continue advancing our oncology DARPin programs and initiate additional virology programs, underlining the versatile potential of our platform. As we enter 2022, we have never been better positioned to deliver on the promise of DARPins to help patients around the world living with serious diseases."

Antiviral program

In early January, Molecular Partners and Novartis announced positive topline data from the randomized, double-blind, placebo-controlled EMPATHY Part A study of ensovibep for acute COVID-19 ambulatory patients.

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. The secondary endpoint of ER visits, hospitalization or death related to COVID-19 showed an overall 78% reduction in risk of events across ensovibep arms compared to placebo. Ensovibep also demonstrated a clinically meaningful time to sustained recovery benefit over placebo. No deaths occurred in any of the patients treated with ensovibep. All three dosing arms met the primary endpoint of viral load reduction over time, were

well-tolerated with no unexpected safety issues, allowing for selection of the lowest dose of 75mg for future development.

Following these results, Novartis exercised its option to in-license the global rights to ensovibep, triggering a milestone payment of CHF 150 million to Molecular Partners. These data are part of a submission to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), which was announced in February 2022. Novartis has also indicated its intentions to submit ensovibep for review in the E.U. and additional relevant territories.

If approved or authorized, ensovibep would be the first multi-specific antiviral candidate approved for the treatment of COVID-19 and Molecular Partners' first DARPin therapy approved by a regulatory agency.

Ensovibep has continued to show retained potency against all variants of concern throughout the pandemic in *in vitro* studies. In December of 2021, preclinical studies confirmed that ensovibep maintains full neutralization of Omicron pseudoviruses that contain the identical mutations of the viral variant. In a panel of biologic drugs tested against the original (wild type) and Omicron variants of SARS-CoV-2, ensovibep maintained a uniformly high neutralizing potency across variants, while substantial reduction in potency was observed for numerous antibody drugs, both approved and investigational. The study design and results are [published in BioRxiv](#), and have been submitted for peer-review publication.

As a DARPin candidate, ensovibep is uniquely designed to retain pan-variant activity across all variants of COVID-19, including most recently the Omicron BA.2 variant, by engaging three domains of the SARS-CoV-2 virus simultaneously to inhibit viral entry into cells. This allows for a potentially broader efficacy and reduces the likelihood for the development of viral drug resistance. In addition, DARPins candidates are produced through rapid, high-yield microbial fermentation for potential speed and logistical advantages over mammalian cell production employed for antibodies.

In November of 2021, Molecular Partners also announced that a planned futility analysis of ensovibep in the NIH-sponsored ACTIV-3 clinical study did not meet the thresholds required to continue enrollment of adults with COVID-19 in the hospitalized setting.

Oncology programs: New programs launched in AML and radioligand therapies

MP0533 nominated as AML candidate

Molecular Partners nominated MP0533 in 2021 as a new candidate for development for the treatment of acute myeloid leukemia (AML). MP0533 is a multi-specific DARPin T-cell engager candidate designed to deliver a highly potent and specific anti-tumor response to AML cells, with a reduced effect on healthy normal cells, and with the potential to counteract target escape mechanisms expected due to tumor heterogeneity. MP0533 is designed to engage CD3 on T cells and target AML cells via the tumor associated antigens CD33, CD123 and CD70.

At the 63rd American Society of Hematology (ASH) Annual Meeting, Molecular Partners presented preclinical data from MP0533 demonstrating a significant decrease cytokine release syndrome (CRS) when compared to other mono-targeting T-cell engager therapies, confirming MP0533's potential for an improved safety profile compared to other approaches. In an *ex vivo* assay using fresh blood from healthy donors, the candidate induced significantly lower inflammatory cytokine production and reduction in platelet counts than T-cell engager candidates in development by other parties.

The Company announced a research collaboration with the University of Bern in December 2021 to advance the development of MP053 into clinical studies, leveraging the Bern group's expertise in leukemic stem cells, a hard-to-target cancer progenitor cell population relevant to AML. The Company plans to initiate a Phase 1 clinical study of MP0533 in 2022.

MP0317 study initiation

In November 2021, Molecular Partners announced the first patient had been dosed in its Phase 1 clinical trial evaluating the safety and tolerability of MP0317, which targets both the fibroblast activation protein (FAP) and the immunostimulatory protein CD40 to enable tumor-localized immune activation. MP0317 is the second DARPin therapeutic candidate in the company's immuno-oncology pipeline to enter clinical trials. Through this mechanism of action, MP0317 is designed to activate immune cells specifically within the tumor microenvironment, potentially delivering greater efficacy with fewer side effects compared to other CD40-targeting agents.

The open-label dose escalation study is designed to assess the safety and tolerability as well as pharmacokinetics and pharmacodynamics of MP0317 as a monotherapy in patients with solid tumors known to express fibroblast activation protein (FAP). Enrollment is taking place in the Netherlands and France. A total of up to 30 patients are expected to be enrolled across six dosing cohorts and up to 15 patients will be enrolled in a dose expansion cohort. In addition to evaluating monotherapy dynamics, the study will gather a wide variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications.

In December 2021, Molecular Partners presented data on MP0317 and the Phase 1 clinical trial design at the ESMO Immuno-Oncology Congress. Initial data from this clinical study is expected in the second half of 2022.

MP0310 clinical progress

The ongoing Phase 1 clinical trial of MP0310 progressed in 2021, evaluating the optimal dosing regimen of MP0310. MP0310 is the second DARPin therapeutic candidate in the company's immuno-oncology pipeline to enter clinical trials targeting FAP and 4-1BB. It is designed to activate immune cells specifically in the tumor expressing these targets and not in the rest of the body, potentially delivering greater efficacy with less toxicity.

Molecular Partners expects to share initial clinical data from the Phase 1 trial with Amgen in the first half of 2022.

In April of 2021, Molecular Partners presented four posters highlighting research across its immuno-oncology programs at the American Association for Cancer Research (AACR) virtual Annual Meeting.

New radioligand collaboration

In December 2021, Molecular Partners announced a collaboration with Novartis in the form of a license agreement to develop, manufacture and commercialize DARPIn-conjugated radioligand therapies (DARPIn-RLTs). The collaboration combines DARPins' unique properties, including small size (under 20kDa) and very high affinities (low picomolar), with the RLT capabilities and expertise of Novartis. DARPIn-RLTs have the potential to deliver molecularly targeted radiation deeply into the tumor thereby harnessing the power of radioactive atoms for precise tumor-killing. Under the terms of the agreement, Molecular Partners will collaborate with Novartis to discover DARPIn-RLTs that target specific tumor-associated antigens. Both parties will collaborate on the discovery and optimization of the therapeutic candidates for further development.

Ophthalmology program: Meeting with FDA signals further development pathway for abicipar

In August 2021, Molecular Partners regained global development and commercial rights to abicipar for the treatment of neovascular age-related macular degeneration (nAMD) and Diabetic Macular Edema (DME). The Company has reported two positive Phase 3 studies of abicipar, CEDAR and SEQUOIA, which supported the non-inferior efficacy of its quarterly dosing regimen with 50 percent fewer injections than ranibizumab.

Molecular Partners has formed a special committee to evaluate the further development of abicipar, and correspondence with the FDA is underway. Feedback obtained from the agency in February of 2022 provided clinical guidance which is now being further evaluated.

Corporate Governance further strengthened

- Agnete Fredriksen and Dominik Höchli were elected to the Board of Directors at the Annual General Meeting of April 21, 2021.
- Alexander Zürcher has been promoted to Chief Operating Officer. Alexander has most recently served as SVP Development of Molecular Partners and oversaw project and portfolio management, manufacturing, pharmacology, and quality assurance activities and has more than 20 years of industry experience.
- Coinciding with Alexander's promotion, Michael Stumpp, the Company's current COO, will transition to the newly formed position of EVP Projects and will continue to be a member of the Management Board.
- Renate Gloggnier has been promoted to EVP People and Community. Renate was most recently Senior Vice President, Human Resources of Molecular Partners. She joined the company in October 2021. Prior to joining Molecular Partners, Renate held European and International Human Resource leadership positions at two US companies, Global Blood Therapeutics and Tesaro Bio.
- Both Alexander and Renate will be appointed to the Management Board effective July 1, 2022.

ESG initiative expanded

At Molecular Partners our values support three core activities: developing treatments for patients suffering from serious diseases; cultivating a culture of initiative, integrity and excellence; and creating a socially interactive, environmentally aware company culture.

As an innovative biotechnology company, our purpose is to find, develop and bring to market novel therapeutics to improve the lives of patients in need. Our company-wide efforts to develop a COVID-19 treatment for the world, ensovibep, exemplify this value well. When partnering with Novartis to fight COVID-19, we and Novartis agreed to waive all profits from ensovibep in developing regions as part of a commitment to corporate social responsibility in a time of urgent global medical need. In oncology, we are focusing the powers of our platform toward finding truly innovative therapeutics for diseases that currently have no sustainable solution, such as in our recent work in AML, a blood cancer with no reliably effective treatment where we are advancing a truly differentiated potential option for patients through DARPins.

We believe that our growth and constant improvement as a company are closely linked to the well-being and growth of our employees. As a part of that, we are focused on programs to support our internal culture, encouraging employees to show initiative, integrity and to strive to excellence in their work. Further, we are applying employee engagement and retention programs, including a reinforced focus on executive-led initiatives in these areas.

Finally, we find it important to foster a socially and environmentally aware company culture, which we believe helps our team to better appreciate their contribution to society and the importance of their work. To help accomplish all of this, we have engaged external support to help guide our ESG journey, and we are currently in the process of collecting a baseline status evaluation as the next step toward applying an ESG plan with measurable metrics.

Financial Highlights: Company extends cash runway into 2025

Following its initial public offering of ADSs in the United States in June 2021, and Novartis' licensing of ensovibep in January 2022, Molecular Partners remains well funded to capture upcoming value inflection points in 2022. In the financial year 2021, Molecular Partners recognized total revenues and other income of CHF 9.8 million (2020: CHF 9.3 million) and incurred total expenses of CHF 73.2 million (2020: CHF 67.7 million). This led to an operating loss of CHF 63.4 million for 2021 (2020: Operating loss of CHF 58.3 million). The net financial loss recorded in 2021 was CHF 0.4 million, compared to a net financial loss of CHF 4.4 million in 2020. This resulted in a 2021 net loss of CHF 63.8 million (2020: Net loss of CHF 62.8 million).

The net cash used for operating activities in 2021 was CHF 91.0 million (2020: net cash used of CHF 29.0 million). Including short-term time deposits, the cash and cash equivalents position decreased by CHF 40.9 million as compared to year-end 2020, to CHF 132.8 million as of December 31, 2021 (December 31, 2020: CHF 173.7 million). Total shareholders' equity stood at CHF 107.3 million as of December 31, 2021, a rounded increase of CHF 0.1 million (December 31, 2020: CHF 107.2 million).

On January 7, 2022, Novartis informed the Group of its intention to exercise the option under the option and equity rights agreement. This was followed by the signing of a license agreement between the two parties on January 17, 2022. This license agreement resulted in the Group becoming eligible to receive CHF 150 million for the option exercise payment and in addition the Group was allowed to charge Novartis CHF 13.1 million for items related to the commercial supply of ensovibep and drug substance secured by the Group.

The proceeds from the Company's initial public offering in the United States further increased the Company's solid cash position with no debt on the balance sheet. The Company's cash position as per December 31, 2021, together with the funds received from Novartis in early 2022, continues to

provide the Company with financial flexibility and a forecasted cash runway into 2025.

The Company's balance sheet continued to be debt-free in 2021. As of December 31, 2021, the Company employed 163.2 FTE (full time equivalents), up 12% year-on-year. About 82% of the employees are employed in R&D-related functions.

Key figures as of December 31, 2021

Key Financials (CHF million, except per share, FTE data)	FY 2021	FY 2020	Change
Total revenues and other income	9.8	9.3	0.4
R&D expenses	(55.7)	(56.1)	0.4
SG&A expenses	(17.5)	(11.6)	(5.9)
Operating result	(63.4)	(58.3)	(5.5)
Net finance result	(0.4)	(4.4)	4.1
Net result	(63.8)	(62.8)	(1.0)
Basic and diluted net result per share (in CHF)	(2.06)	(2.51)	0.45
Net cash from (used in) operating activities	(91.0)	(29.0)	(62.0)
Cash & cash equivalents (incl. short-term time deposits)	132.8	173.7	(40.9)
Total shareholders' equity	107.3	107.2	0.1
Number of total FTE	163.2	145.4	17.8

Business outlook and priorities

In 2022, we look forward to working in close collaboration with Novartis to support an expedited regulatory review process for ensovibep, first via the U.S. FDA's EUA process. By entering into the licensing agreement, Novartis will now lead all further development and commercialization efforts for the program. The global Phase 3 trial is expected to be initiated in parallel with expedited submissions to global regulatory bodies. The trial is expected to enroll patients around the world, using the 75mg dose of ensovibep, the lowest dose identified in Part A of the EMPATHY trial.

If approved or authorized, ensovibep will be the first multi-specific antiviral candidate for the treatment of COVID-19 and Molecular Partners' first DARPin therapy approved by a regulatory agency. Molecular Partners is assessing further viral disease areas where DARPins can offer advantages over existing antivirals or where no effective antivirals exist and plans to showcase such programs in a "Virology Day" targeted for mid-2022. We look forward to making continued progress across our oncology programs and anticipate sharing clinical data from AMG 506 (MP0310) with Amgen and reporting initial data from MP0317 in the first and second half of this year, respectively. We also plan to initiate a Phase 1 clinical study of MP0533 in 2022. In addition to our collaborations with Novartis, Amgen, AbbVie and the University of Bern, in 2022 we also plan to seek out additional partnerships with leading biopharmaceutical organizations or academic institutions to bring the class's power to bear across diverse disease areas.

The Company plans to detail the path forward for its registrational-stage ophthalmology asset, abicipar following internal strategic assessments that will incorporate any feedback received from regulators.

Financial outlook 2022

For the full year 2022, at constant exchange rates, the Company expects total P&L expenses of CHF 75-85 million, of which around CHF 8 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This cash flow guidance does not include any potential payments from R&D partnerships.

Based upon the 2022 year to date received payments from Novartis, the Group currently anticipates reporting an operating profit as well as positive cash flows from operations for the year ended December 31, 2022. There is no assurance that such positive metrics will be achieved or maintained in future periods, as the Group plans to continue to invest into research and development activities as they are fundamental to executing Molecular Partners' strategic objectives.

Based on the Company's cash position as of December 31, 2021, together with the payments received from Novartis in January 2022 and no debt, the Company expects its cash runway to extend into 2025, excluding any potential receipts from R&D partners.

Documentation

This press release, the Company's Annual Report on Form 20-F for the year ended December 31, 2021 to be filed with the U.S. Securities and Exchange Commission (SEC), and the Company's annual report 2021 will be made available through www.molecularpartners.com after 9:30 pm (CET) on March 15, 2022.

Full year 2021 conference call & audio webcast

Molecular Partners will hold a conference call and audio webcast on March 16, 1 pm CET (8 am EST). To register for the full year 2021 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland / Europe	+41 800 83 6507
USA	+1 844 865 3856
Conference ID	5295679

Participants in the conference call will have the opportunity to ask questions after the presentation.

Audio webcast

The full year 2021 results 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.

Financial calendar

April 13, 2022	Annual General Meeting
May 12, 2022	Interim Management Statement Q1 2022
August 25, 2022	Half-year results 2022 (unaudited)
October 27, 2022	Interim Management Statement Q3 2022

The latest timing of the above events can always be viewed on the [investor section](#) of the website.

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 infectious disease oncology, 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

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 for reporting data from ongoing clinical trials or the initiation of future clinical trials, the potential therapeutic and clinical benefits of Molecular Partners' product candidates, the selection and development of future antiviral or other programs, Molecular Partners' pursuit of its ESG initiatives, and Molecular Partners' expected expenses and cash utilization for 2022 and that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into 2025. These statements may be identified by words such as "anticipate", "believe", "could", "expect", "intend", "may", "plan", "potential", "will", "would" and similar expressions, although not all forward-looking statements may contain these identifying words, and are based on Molecular Partners' 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 Molecular Partners' or its collaborators' plans to develop and potentially commercialize Molecular Partners' product candidates; Molecular Partners' reliance on third party partners and collaborators over which it may not always have full control; Molecular Partners' ongoing and planned clinical trials and preclinical studies for its product candidates, including the timing of such trials and studies; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; the timing of and Molecular Partners' ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Molecular Partners' product candidates; the clinical utility and ability to achieve market acceptance of Molecular Partners' product candidates; the potential impact of the COVID-19 pandemic on Molecular Partners' operations or clinical trials; Molecular Partners' plans and development of any new indications for its product candidates; Molecular Partners' commercialization, marketing and manufacturing capabilities and strategy; Molecular Partners' intellectual property position; Molecular Partners' ability to identify and in-license additional product candidates; the adequacy of Molecular Partners' cash resources and its anticipated cash utilization; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners' Annual Report on Form 20-F for the year ended December 31, 2021, which Molecular Partners expects to file with the SEC on March 15, 2022, 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 except to the extent required by law, 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.

For further details please contact: Seth Lewis, SVP IR, Comms & Strategy seth.lewis@molecularpartners.com Tel: +1 781 420 2361 Shai Biran, Ph.D., Associate Dir. IR & Comms shai.biran@molecularpartners.com Tel: +1 978 254 6286 Thomas Schneckenburger, European IR & Media Thomas.schneckenburger@molecularpartners.com Tel: +41 79 407 9952