

medigene

Quarterly Statement Q3 2023

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OF MEDIGENE AG, PLANEGG/MARTINSRIED, FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2023

DEAR SHAREHOLDERS,

The biotech sector continues to navigate turbulent times with macro-economic and geopolitical headwinds creating a challenge for many biotechs. While the S&P 500 was up 13% YTD (end of Q3 2023), the healthcare components were down 4%, underperforming the S&P by the widest margin since 1999. Biotech stocks specifically remain under pressure with the XBI being down 12% YTD and set to fall for the 3rd straight year.

Throughout this challenging environment, Medigene has remained focused on developing best-in-class, differentiated T cell receptor engineered T cell (TCR-T) therapies for multiple solid tumor indications that are armored, enhanced and optimized for safety, efficacy and durability.

During the third quarter, we continued to advance our pipeline of TCR-T therapies for the treatment of patients with solid tumors. Our lead program, MDG1015, a first-in-class, third generation NY-ESO-1 / LAGE-1a targeted TCR-T therapy combining a sensitive, specific and potentially safer (3S) TCR with our PD1-41BB costimulatory switch protein, is currently undergoing Investigational New Drug (IND) and Clinical Trial Application (CTA) enabling experiments. We aim for IND / CTA approval in the 2nd half of 2024. Additional MDG1015 pre-clinical data was presented at the European Society for Medical Oncology (ESMO) Congress 2023 held October 20-24, 2023, in Madrid, Spain (for more information, please refer to below as well as the poster presentation on our website <https://medigene.com/science/abstracts/>).

In September, we delivered on our commitment to select a lead candidate for our second TCR-T therapy program in solid tumors, MDG2011, targeting KRAS (Kirsten rat sarcoma viral oncogene homologue) G12V with HLA-A*11 (HLA, human leukocyte antigen) and being developed in combination with our PD1-41BB costimulatory switch protein technology. Medigene's End-to-End (E2E) Platform has successfully generated not one but three KRAS G12V-HLA-A*11-directed TCRs, each with distinct, multiple HLA-A*11 subtype recognition patterns that exceed our selection criteria for 3S TCRs. After deploying our proprietary algorithms for evaluation of the unique characteristics of each of the 3S TCRs, including peptide specificity, tumor cell recognition and off-target toxicity, we have prioritized one of the 3S TCRs as the lead to move forward to the pre-clinical stage for our MDG2011 program.

Subsequent to the quarter, first pre-clinical data on MDG2011 was presented at ESMO held in Madrid in October 2023. We are very pleased with the pre-clinical data presented showing significantly enhanced T cell activity and tumor killing when combining the PD1-41BB costimulatory switch protein with recombinant TCRs not only when directed at the cancer-testis antigen NY-ESO-1/LAGE-1a (MDG1015), but also, presented for the first time, against the neoantigen mutant KRAS G12V. These data confirm that armoring and enhancing our optimal affinity KRAS G12V-targeted TCR or NY-ESO-1/LAGE-1a targeted TCR with the PD1-41BB costimulatory switch protein has significant potential to overcome an immunosuppressive solid tumor microenvironment, leading to TCR-T therapies that improve safety, efficacy and durability outcomes for patients. Additional data on Medigene's emerging

library of KRAS mutation-specific TCRs will be presented at the Society of Immunotherapy of Cancer (SITC) 38th Annual Meeting held in San Diego, November 1 to 5, 2023.

During the quarter, we continued to expand our E2E Platform. In August, we announced the expansion of the intellectual property (IP) license for our PD1-41BB and CD40L-CD28 costimulatory switch proteins, enabling their application to additional cell types and for use in Chimeric Antigen Receptor T cell (CAR-T) therapies. With the expansion of the IP license to include various cell types beyond TCR-T cells, we significantly enhance the potential use of both costimulatory switch proteins, which are currently could be combined with the Medigene's 3S TCRs, across various cell types beyond T cells. This provides an opportunity to leverage the advantages of other immune cells and enhance the tumor cell killing activity, proliferation and persistence of our TCR-based therapies. Further, we also aim to selectively partner this technology with companies with demonstrated CAR-T expertise to further develop this novel therapeutic approach. This may open up opportunities for new treatment modalities that could help address current unmet needs in difficult-to-treat malignancies

In September, we were granted a patent by the European Patent Office protecting our PD1-41BB costimulatory switch protein technology. The patent complements our PD1-41BB IP-portfolio with similar patents already granted in the United States, China and Japan, and strengthens our patent portfolio worldwide.

Scientific as well as development partnerships provide important scientific validation of our technology and assets. Since the commencement of the agreement in February 2022, our global strategic partnership with BioNTech has been making good progress. In September this year, our partner 2seventy bio, together with JW Therapeutics, announced the acceleration of their T cell-based immunotherapy projects in Greater China. Specifically, the program containing Medigene's MAGE-A4-targeted TCR is on track to initiate an investigator-initiated study in China by the end of 2023. We are excited about our partner's accelerated timeline, as moving this program into clinical development will provide additional clinical proof of concept alongside Medigene-owned programs.

Due to the prolonged funding and development pause by Hongsheng Sciences of the partnered program that included Medigene's NY-ESO-1-targeted TCR, the parties have mutually agreed to terminate the partnership agreement as it relates to the NY-ESO-1 asset in Q3 2023. The return of this asset to Medigene allows us to find a new strategic development partner in Asia, but now for our first-in-class MDG1015 program containing our optimal affinity NY-ESO-1-targeted TCR.

Describing in detail our E2E Platform approach, the paper [Evolution by Innovation as a Driving Force to Improve TCR-T Therapies](#), by Dolores J. Schendel, was published in *Frontiers in Oncology*, section Molecular and Cellular Oncology in September 2023.

Medigene also participated in several investor conferences in Europe & the US, as well as presented at scientific conferences demonstrating our deep expertise and experience discovering and developing differentiated TCR-T therapies that can address current unmet needs for patients with solid tumors.

In terms of financials, we generated EUR 1.6 million in revenue in the third quarter of 2023 compared to EUR 1.4 million in the previous year period (9-month period 2023: EUR 4.6 million) primarily from the partnership with BioNTech. Our R&D expenses for the quarter were EUR 3.2 million compared to EUR 3.3 million in the prior year period (9-month period 2023: EUR 8.4 million), reflecting our ongoing commitment to advancing our pipeline. We have also carefully managed our expenses to maintain strong liquidity of EUR 21.2 million as of September 30, 2023 (Dec 31, 2022: EUR 33.2 million), with cash & cash equivalents in the amount of EUR 13.2 million and time deposits of EUR 8.0 million.

As such, and unchanged from previous guidance, I can confirm that we retain our expectations for a cash runway until the fourth quarter of 2024 based on current plans. We remain confident that our partnerships will continue to progress, thus generating additional milestone payments and revenues for Medigene. Given the uncertainty of several factors both in our control and out of our control, we are continuing with our efforts to raise additional capital to extend our cash runway into 2026 and beyond, in order to support continued investment in our research and development activities. Management is diligently exploring all options and preparing accordingly.

Overall, we are pleased with the considerable R&D progress we have made in the first nine month of 2023 and remain confident in our ability to execute on our strategic plan and create additional value to our shareholders. We look forward and thank you for your continued support.

Sincerely,

Selwyn Ho

CEO

FINANCIAL GUIDANCE

Performance in the third quarter of 2023 was in line with the Executive Management Board's expectations. The Management Board therefore maintains its guidance for fiscal year 2023 published in the annual report 2022 on March 29, 2023, in its entirety. Accordingly, the Executive Management Board expects revenue in 2023 to be between EUR 5 and 7 million. The Company expects R&D costs ranging from EUR 13 to 16 million. Based on current planning, the Company is funded until the fourth quarter of 2024.