Press Release

adivo receives limited market authorization status from European Medicines Agency (EMA) for lead oncology program

adivo's CAESAR-derived cancer immunotherapy could benefit from a significantly shortened development path to a first market entry

Martinsried/ Munich, Germany, December 19, 2022 – adivo GmbH, a leader in discovering species-specific therapeutic antibodies for pets, today announced that the company has been granted the limited market authorization status by the Committee for Veterinary Medicinal Products (CVMP) of the European Medicines Agency (EMA) for its most advanced proprietary pipeline program. The cancer antibody addresses a well-established immune-oncology pathway in dogs and may now benefit from an accelerated approval pathway toward a first market approval in a specific oncology subsegment. The cancer program is one of two proprietary assets progressing towards first-in-animal studies within the next 12 months, driving the transformation of adivo into a clinical-stage biopharmaceutical company in the companion animal therapeutics space.

"Today's news further underscores our ability to build value in our proprietary pipeline by exploring regulatory pathways that strengthen the program's commercial potential. The possibility to expedite first market entry in a specific subsegment of the wider accessible oncology market allows us and our potential partners to generate real-world datasets and make a positive impact in pet owners' and patients' lives early on," commented Dr. Markus Waldhuber, Co-Founder and Chief Development Officer of adivo.

Early 2022, the Veterinary Medicinal Products Regulation introduced a specific authorization route for medicines intended for veterinary limited markets in the European Union. The regulatory pathway aims to stimulate the development of veterinary medicines for serious or life-threatening animal diseases and unmet veterinary medical needs. It enables the regulatory authorities to recommend granting a marketing authorization based on less comprehensive data than normally required. The benefits for applicants, such as adivo, comprise shortened go to market timelines due to the reduced data requirements and enhanced regulatory assistance.

The adivo technology platforms allows de-novo identification of species-specific antibody panels to select drug candidates with optimal functionality, developability and low risk of immunogenicity. adivo has established CAESAR, the first fully canine phage display platform in the veterinary medicines market for selecting therapeutic candidates against a broad range of diseases. Powered by more than two decades of combined therapeutic antibody discovery expertise gained in human medicine, the adivo leadership team is ideally positioned to bring forth developable candidates with best-in-class drug properties and molecular profiles tailored to the targeted species.

About adivo

adivo is forging a new era for companion animal health. Our proprietary phage display antibody libraries deliver species-specific drugs for a growing market need. We apply our extensive drug discovery and protein engineering know-how to address cancer, chronic inflammatory diseases and other serious conditions in pets. Together with our partners, we create the best possible therapeutics for our beloved furry friends. For further information, please visit: www.adivo.vet.

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