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Genflow Biosciences PLC
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Genflow Biosciences Plc

Genflow Biosciences Strengthens Pre-Clinical Efforts with FDA Guidance and CDMO and CRO Selection

Genflow Biosciences Plc (LSE:GENF) (OTCQB:GENFF) ("Genflow" or "the Company") an emerging leader in the field of longevity research, focused on developing therapeutic solutions for the prevention of age-related diseases is pleased to report advancements in its pre-clinical programs.

Genflow has initiated a feasibility study with a Contract Development Manufacturing Organization (CDMO), Exothera S.A, to assess the ability to produce its future MASH clinical lot in accordance with Good Manufacturing Practices (GMP).

Genflow is also in the process of selecting Contract Research Organizations (CROs) to conduct its upcoming dog clinical trial, aimed at studying its promising drug candidate, GF-1004. The Company is currently evaluating requests for proposals (RFPs) and is working diligently to finalize a definitive agreement next month.

In addition, Genflow has received research guidance from the FDA's Initial Targeted Engagement for Regulatory Advice on CBER Products (INTERACT). The Company submitted a comprehensive briefing package detailing all preclinical (in vitro and in vivo) studies conducted with its lead drug candidate, GF-1002, for the treatment of Metabolic Associated Steatohepatitis (MASH).

The FDA has encouraged Genflow to proceed with its plans to identify appropriate animal models through pilot proof-of-concept (POC) studies. These studies will inform the definitive POC, toxicology, and biodistribution studies necessary for eventual clinical trials. Detailed summaries of the products used in each animal study and their comparability to the intended clinical product are to be included.

Dr. Eric Leire, CEO of Genflow commented: " We are excited by the momentum we have built in moving forward with our pre-clinical programs and the guidance received from the FDA. This encouragement reinforces our commitment to developing effective therapeutic solutions for age-related diseases. As we move forward with our dog clinical trials, we remain focused on our mission to improve healthspan."

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About Genflow Biosciences

Founded in 2020, Genflow Biosciences Plc. (LSE:GENF) (OTCQB:GENFF), a biotechnology company headquartered in the UK with R&D facilities in Belgium, is pioneering gene therapies to decelerate the aging process, with the goal of promoting longer and healthier lives while mitigating the financial, emotional, and social impacts of a fast-growing aging global population. Genflow's lead compound, GF-1002, works through the delivery of a centenarian variant of the SIRT6 gene which has yielded promising preclinical results. Scheduled to begin in 2025, Genflow's clinical trial aims to explore the potential benefits of GF-1002 in treating MASH (Metabolic Dysfunction-Associated Steatohepatitis), the most prevalent chronic liver disease for which there is no effective treatments. Please visit www.genflowbio.com and follow the Company on LinkedIn and Twitter/X.

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