Arecor Therapeutics plc
("Arecor" or "the Company")

AT278 ULTRA-CONCENTRATED ULTRA-RAPID ACTING INSULIN DEMONSTRATES SUPERIORITY IN PHASE I CLINICAL TRIAL IN OVERWEIGHT AND OBESE PEOPLE WITH TYPE 2 DIABETES

- ***AT278 demonstrates significantly accelerated PK/PD profile compared to NovoRapid® and Humulin® R U-500 in people with Type 2 Diabetes and high BMI***
- ***Confirms previous trial results in people with Type 1 diabetes, demonstrating AT278 can maintain fast and superior onset of action and glucose lowering profile irrespective of diabetes type and BMI***
- ***Enables delivery of a highly concentrated, low volume injection, offering more effective mealtime glucose control to meet growing unmet need in patients requiring high daily doses of insulin***
- ***Creates potential to be the first, and only, ultra-concentrated (500 U/mL) ultra-rapid insulin product enabling miniaturisation of next-generation insulin pumps***
- ***Company will host a CEO and key opinion leader webinar to discuss the results on Tuesday 21 May at 14.30 BST***

Cambridge, UK, 20 May 2024. Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical group advancing today's therapies to enable healthier lives, today announces that its ultra-concentrated, ultra-rapid acting insulin candidate, AT278, met all primary and secondary endpoints, and also demonstrated superiority to NovoRapid® and Humulin® R U-500, in a Phase I clinical trial in Type 2 diabetics with a high body mass index (BMI).

AT278 (500 U/mL) is an ultra-concentrated, ultra-rapid acting, novel formulation of insulin that accelerates the absorption of insulin post injection, even when delivered at a high concentration, and hence a lower injection volume. With no concentrated (>200 U/mL), rapid acting insulins on the market, AT278 has potential to be the first, and only, insulin available to the growing number of patients with high daily insulin requirements.

Sarah Howell, Chief Executive Officer of Arecor, said: *"We are delighted with the clinical results from this second Phase I study, demonstrating AT278's superiority over NovoRapid® and Humulin® R U-500 in Type 2 diabetics with a high BMI. They further add to the positive results from our previous clinical study in Type 1 diabetic patients, where superiority was also demonstrated. This is a significant step in AT278's development and extends our confidence in its clear potential to provide a superior insulin treatment option that lowers burden and improves outcomes for people living with diabetes who require high daily doses of insulin. Such patients make up a large segment of the target market. In addition, as the only concentrated, yet very rapid*

acting, insulin in development, AT278 has the capability to disrupt the market by enabling the next generation of truly miniaturised, longer-wear insulin pumps, a key focus for patients, physicians and the industry."

Many Type 2 diabetics with a high BMI are currently not well controlled, and improved treatments options such as AT278 are needed to reduce patient burden through fewer injections per day, reduced injection volumes and dosing flexibility around mealtimes. This lowering of burden for patients improves treatment adherence and, allied with AT278's superior efficacy, should improve both blood glucose control and outcomes. In addition, a truly ultra-rapid, ultra-concentrated insulin is a critical step towards next-generation miniaturised and long-wearing insulin pumps, which are predicted to transform future diabetes management.

Professor Thomas Pieber, Principal Investigator for the ARE-278-104 clinical trial, said: *"These results are highly significant, AT278 has clearly demonstrated faster insulin absorption with an accelerated Pharmacokinetic (PK) and Pharmacodynamic (PD) profile compared to the lower concentration standard insulin aspart (NovoRapid®). The PK/PD profile of AT278 (500 U/mL) was also greatly accelerated compared to Humulin® R U-500 (500 U/mL). Together with its superior profile in the earlier Phase I clinical study in Type 1 diabetic patients[1] AT278 has demonstrated its ability to maintain a fast and superior onset of action and glucose lowering profile irrespective of diabetes type and BMI. This makes AT278 completely unique in the competitive field of insulin analogues. Not only does it have the potential to significantly improve post-prandial glucose control whilst lowering burden for anybody with diabetes who has a high daily insulin need, it can act as a catalyst in the development of miniaturised insulin delivery systems, where the size of existing devices is a significant barrier to use for many patients*."

In the double-blind, randomised, two-way crossover study, the pharmacokinetic (PK)/pharmacodynamic (PD) and safety profiles of a single subcutaneous (SC) dose of 0.5 U/kg AT278 (500 U/mL) were compared with those of a single SC dose of 0.5 U/kg NovoRapid® (100 U/mL), a currently available gold standard, rapid acting insulin treatment, in 39 participants with Type 2 diabetes within a BMI range of 25 and 39 kg/m^2, in a euglycemic clamp setting. The PK/PD profile of 0.5 U/kg AT278 (500 U/mL) was also compared to a single SC dose of 0.5U/kg Humulin® R U-500 (500 U/mL) in an open label manner.

- The trial met the primary endpoint of non-inferiority with respect to glucose lowering actions compared with NovoRapid®
- AT278 (500 U/mL) demonstrated a significantly accelerated (superior) early PK/PD profile compared to NovoRapid® (100 U/mL), despite a 5-fold increase in concentration

- AT278 (500 U/mL) demonstrated a significantly accelerated (superior) PK/PD profile compared to Humulin® R U-500 (500 U/mL), the only other insulin available at a concentration of 500 U/mL
- No safety signals were detected

With around 537m people living with diabetes worldwide, there are growing numbers of people who require insulin to manage their blood glucose and, for many, their diabetes is still poorly controlled. There is a growing need for highly concentrated, much faster, and more physiological insulins to effectively manage diabetes. In the US alone, nearly 10% of insulin scripts written in 2022 were for products with a concentration of >100 U/mL[2]. Furthermore, despite the improvements in outcomes among people with diabetes who use insulin pumps and automated delivery systems, they are still only used by less than 40% of people with Type 1 diabetes and less than 10% of people with Type 2 diabetes in the US[3]. The size and short duration of wear of existing insulin pumps remains a significant barrier to use. AT278 has the potential to be the only highly concentrated, ultra-rapid acting insulin to enable the next generation of miniaturised, longer wear insulin pumps. The insulin pump market is valued at circa $5.5bn market today[4], with a significant opportunity for substantial growth in this market by expanding use across the Type 1 and Type 2 patient population that can be further enabled by AT278 and a next generation insulin pump.

A full analysis of the trial data is now underway to enable the Company to determine and pursue a strategy for AT278 that maximises value for shareholders and patients. Detailed data from the trial will be submitted for publication and presentation at a future international diabetes conference.

AT278 clinical results CEO and KOL webinar - Tuesday 21 May

Dr Sarah Howell, Chief Executive Officer, and Professor Thomas Pieber, Principal Investigator for the ARE-278-104 clinical trial and Professor of Medicine, Head of the Division of Endocrinology and Metabolism and Chairman of the Department of Internal Medicine at Medical University of Graz, Austria will host a CEO and key opinion leader webinar to discuss the clinical results on Tuesday 21 May at 14.30 BST.

To register to join the live webcast click here and to register for the conference line to ask questions click here.

Please contact ICR Consilium for details on arecor@consilium-comms.com.

This announcement contains inside information for the purposes of the retained UK version of the EU Market Abuse Regulation (EU) 596/2014 ("UK MAR").

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References

1. Pharmacokinetics and Pharmacodynamics of a Novel U500 Insulin Aspart Formulation: A Randomized, Double-Blind, Crossover Study in People With Type 1 Diabetes Care 2023;46(4):757–764: https://doi.org/10.2337/dc22-1054
2. 2022 reports from Symphony. Retrieved October 2023
3. Seagrove Partners Diabetes Bluebook 2022
4. Insulin pump company annual reports and Company estimates

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Notes to Editors

About Arecor

Arecor Therapeutics plc is a globally focused biopharmaceutical company transforming patient care by bringing innovative medicines to market through the enhancement of existing therapeutic products. By applying our innovative proprietary technology platform, Arestat™, we are developing an internal portfolio of proprietary products in diabetes and other indications, as well as working with leading pharmaceutical and biotechnology companies to deliver therapeutic products. The Arestat™ platform is supported by an extensive patent portfolio.

For further details please see our website, www.arecor.com