Arecor Therapeutics plc

("Arecor", the "Company" or the "Group")

ARECOR PRESENTS POSITIVE DATA FROM PHASE I CLINICAL TRIAL OF ULTRA-CONCENTRATED ULTRA-RAPID ACTING INSULIN AT278 IN OVERWEIGHT AND OBESE PEOPLE WITH TYPE 2 DIABETES IN LATE-BREAKING ORAL PRESENTATION AT EASD 2024

- ***AT278 delivers significantly accelerated early PK/PD profile compared with NovoRapid® in people with Type 2 Diabetes and high BMI***
- ***Results confirm previous findings in people with Type 1 diabetes and show that AT278 can maintain the faster action profile irrespective of diabetes type and BMI***
- ***Critical enabler in development of miniaturised next-generation insulin pumps***
- ***Favourable safety profile with no safety signals detected***

Cambridge, UK, 11 September 2024: Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical group advancing today's therapies to enable healthier lives, today presents positive results from its Phase I clinical trial of the ultra-concentrated, ultra-rapid acting insulin candidate, AT278, in Type 2 diabetics with a high body mass index (BMI), at the 60th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Madrid.

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 and to be a critical enabler of next-generation miniaturised and longer wear insulin pumps.

Professor Thomas Pieber, Principal Investigator for the ARE-278-104 study, said: *"The clinical significance of these findings is considerable. AT278's accelerated early PK/PD profile compared with NovoRapid® in overweight and obese people with type 2 diabetes confirms previous findings in people with type 1 diabetes and shows that AT278 can maintain its faster action profile irrespective of diabetes type and BMI. The faster onset and stronger early glucose-lowering effect, consistent across BMI subgroups, indicate that AT278 could provide significantly better post-prandial glucose control and improved convenience for anyone with diabetes who has a high daily insulin need. It also, clearly, can be a catalyst in the progress towards miniaturised next-generation insulin pumps, where the size of existing devices remains a major hurdle for development."*

Sarah Howell, Chief Executive Officer of Arecor, added: *"Despite the improvements in outcomes among people with diabetes who use insulin pumps and automated insulin delivery systems they are still used by only 40% of people with Type I diabetes and less than 10% of people with Type 2 diabetes in the US where use is greatest. A critical barrier to further uptake is the size and short duration of wear of existing insulin pumps. We believe the results we are presenting today clearly demonstrate that AT278 has the potential to break this barrier and make miniaturised, longer wear insulin pumps a reality and thereby meet the needs of patients, and of device companies as they seek to grow a market which is valued at c. $5.5 billion today and forecast to reach more than $15.8bn by 2030."*

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, in 41 participants with Type 2 diabetes and a median BMI of 29.7 kg/m^2. The trial was conducted in a glucose clamp setting at the Medical University of Graz and Joanneum Research in Austria, an internationally recognised centre of excellence in the field of diabetes research.

The PK/PD profile for AT278 was accelerated compared with NovoRapid®. AT278 demonstrated a 1.7-fold (95% CI 1.32; 2.96) higher glucose-lowering effect within the first 60 minutes which was statistically superior to NovoRapid® ($p< 0.0001$). The glucose-lowering effect remained higher up to 2 hours post-dosing (treatment ratio [95% CI] 1.19 [1.02; 1.39]). AT278 showed a faster onset of glucose-lowering effect, with a 5-minute earlier onset of action and 25-minute earlier $t_{Early50\%GIRmax}$ than NovoRapid®. It also showed a faster onset of insulin exposure compared with NovoRapid, with a 5-minute faster insulin appearance and 24-minute faster $t_{Early50\%Cmax}$. Insulin exposure with AT278 was 1.5-fold higher within the first 60 minutes (95% CI 1.28; 1.71). The superior early glucose-lowering effect of AT278 was maintained when the population was divided into BMI subgroups.

Both insulins were well tolerated. Adverse events were mostly mild to moderate and not related to the study drugs.

Arecor is continuing to explore funding options for AT278, including but not limited to co-development arrangements, to conduct a clinical pump study to further demonstrate the potential of AT278 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.

Headline data from this clinical trial were previously announced by the Company in May 2024.

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Notes to Editors
The abstract, *"Pharmacokinetic and pharmacodynamic properties of highly concentrated insulin aspart AT278 U500 in overweight and obese people with type 2 diabetes"* is available on the EASD 2024 website.

About the EASD
The European Association for the Study of Diabetes (EASD) is a non-profit, medical scientific association, founded in 1965 to encourage and support research in the field of diabetes, the rapid diffusion of acquired knowledge and to facilitate its application. EASD holds its Annual Meeting in a different European city each year with more than 15,000 delegates from over 130 countries attending. The scientific programme includes more than 1,200 talks and presentations on the latest results in diabetes research by leading experts in the field.

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