



Arecor Therapeutics plc

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

**ARECOR PRESENTS DATA FROM POSITIVE PHASE I CLINICAL TRIAL OF
AT278 ULTRA-CONCENTRATED ULTRA-RAPID ACTING INSULIN FOR DIABETES AT EASD 2022**

- ***Delivers significantly accelerated absorption of insulin compared to gold standard, NovoRapid® (100U/mL), even with a 5-fold increase in concentration***
- ***Potential to significantly improve post prandial glucose control and reduce number of daily injections for people with diabetes who have high insulin needs***
- ***Critical enabler in development of next generation miniaturised insulin-delivery systems***
- ***Favourable safety profile with no safety signals detected***

Cambridge, UK, 20 September 2022. Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical company advancing today's therapies to enable healthier lives, today presents positive results from the Phase I clinical trial of its ultra-rapid acting, ultra-concentrated insulin product candidate, AT278, at the European Association for the Study of Diabetes (EASD) Annual Meeting.

The abstract, "Phase I study investigating PK and PD of highly-concentrated insulin aspart AT278 U500", is being presented as part of the Short Oral Discussion Session A, "How complicated is type 1 diabetes?" (11:45-12:45 CEST).

AT278 is Arecor's ultra-concentrated (500 U/mL), ultra-rapid acting insulin candidate, formulated using the Company's Arestat™ technology and designed to significantly accelerate insulin absorption post injection to enable more effective and convenient management of blood glucose levels in people with high daily insulin requirements.

Dr Thomas Pieber, investigator for the ARE-278-102 study, Professor of Medicine, Head of the Division of Endocrinology and Metabolism and Chairman of the Department of Internal Medicine, Medical University of Graz, Austria, said: *"The rapid-acting characteristics of AT278, even with its 5-fold increase in concentration, are clinically significant, suggesting that AT278 has the potential to significantly improve post prandial glucose control and reduce the number of daily injections for people with diabetes who have high insulin needs."*

Sarah Howell, Chief Executive Officer of Arecor, added: *"By enabling reduced injection volumes and fewer injections per day, whilst offering the potential for improved blood glucose control with its superior PK/PD profile, AT278 has the potential to become the gold standard insulin treatment for the growing population of people living with diabetes, who have high daily insulin needs, particularly those with type 2 diabetes. A truly rapid acting*



concentrated insulin such as AT278 is also critical to the development of next generation miniaturised insulin delivery devices, where the size of such devices is often a barrier to use by patients.”

In the double-blind, randomised, single dose, two-period cross over Phase I clinical study (EudraCT:2020-002033-15) the pharmacokinetic (PK) and pharmacodynamic (PD) profile of AT278 was compared to NovoRapid®, the current gold standard treatment, in 38 patients with type 1 diabetes. 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®. Following dosing, AT278 showed a faster onset of insulin exposure compared with NovoRapid®, as demonstrated by an earlier onset of appearance (-6.0 min, $P < 0.0001$), earlier $t_{\text{Early50\%Cmax}}$ (-23.0 min, $P < 0.0001$) and 4.0 times higher $\text{AUC}_{\text{Insulin},0-30\text{min}}$ (95% CI: 3.29; 4.90). AT278 also showed a more rapid onset of glucose-lowering effect compared with NovoRapid® as demonstrated by an earlier onset of action (-9.5 min, $P < 0.0001$) and earlier $t_{\text{Early50\%GIRmax}}$ (-20.0 min, $P < 0.0001$). Overall insulin exposure and glucose-lowering effect were comparable between both insulins ($\text{AUC}_{\text{Insulin},0-8\text{h}}$ treatment ratio 0.98 [95% CI: 0.92; 1.00]; $\text{AUC}_{\text{GIR},0-8\text{h}}$ treatment ratio 1.02 [95% CI: 0.95; 1.09]). All reported adverse events were mild in intensity and no safety signals were detected.

A further clinical trial of AT278, in people living with type 2 diabetes, is expected to be initiated later this year. The randomised, double-blind Phase I study in obese type 2 diabetes patients will recruit approximately 28 adult patients with each receiving one subcutaneous dose (0.5 U/kg) of AT278, NovoRapid® and Humulin® R U 500 in three separate treatment periods. The PK/PD profile will be measured in each treatment period in a glycemic clamp setting.

The abstract, “Phase I study investigating PK and PD of highly-concentrated insulin aspart AT278 U500” is available on the [EASD 2022 website](#). These data were first presented at the 15th International Advanced Technologies and Treatments for Diabetes (ATTD) meeting in May 2022.

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Notes to Editors

About Areacor

Areacor 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 formulation 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 enhanced formulations of their therapeutic products. The Arestat™ platform is supported by an extensive patent portfolio.

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