



**Arecor Therapeutics plc**  
(“Arecor”, the “Company” or the “Group”)

**ARECOR ANNOUNCES POSITIVE HEADLINE RESULTS FROM FIRST PHASE I CLINICAL TRIAL OF AT278 ULTRA-CONCENTRATED ULTRA-RAPID ACTING INSULIN CANDIDATE FOR DIABETES**

- ***AT278 delivers significantly accelerated PK/PD profile compared to NovoRapid®***
- ***Potential to be first concentrated (500U/mL) ultra-rapid acting insulin product enabling miniaturisation of next generation insulin delivery devices***
- ***Potential to enable more effective disease management for insulin resistant patients requiring >200 units of insulin per day***

**Cambridge, UK**, 20 September 2021. Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical company advancing today’s therapies to enable healthier lives, today announces that its ultra-concentrated ultra-rapid acting insulin, AT278 met all of its primary and secondary endpoints with positive headline results from the Phase I clinical trial.

**Sarah Howell, Chief Executive Officer of Arecor, said:** *“The successful completion of our AT278 Phase I clinical trial is an important milestone for Arecor. AT278 has the potential to disrupt the market for insulin treatment in people with diabetes, as the first concentrated, yet rapid acting, insulin – a critical enabler in the development of next generation miniaturised insulin delivery systems. The study had been designed to achieve PK/PD equivalence with a comparable dose of lower concentration NovoRapid®. The achievement of a superior PK/PD profile goes beyond our expectations and for that we are delighted.*

*“These positive data for AT278, the second product in our diabetes franchise, follow the earlier positive results from the Phase I clinical trial of AT247, our ultra-rapid acting insulin for diabetes. Together they position Arecor with a unique combination of ultra-concentrated and ultra-rapid insulin candidates offering the potential to meet the broad needs of patients across the growing diabetes market.”*

AT278 is an ultra-concentrated (500 U/mL) novel formulation of insulin that has been designed to accelerate the absorption of insulin post injection, even when delivered at a high concentration, and hence via a lower injection volume. Currently, there are no concentrated (>200 U/mL) rapid acting insulin products on the market and therefore AT278 has the potential to be the first such product available to patients. It has the potential to enable more effective management of blood glucose levels to the increasing number of people with diabetes with high daily insulin requirements (>200 units/day) whilst maintaining the convenience and



compliance benefits of being able to deliver these high insulin doses in a lower injection volume via a single injection. In addition, a truly rapid acting concentrated insulin is also a critical step towards the advancement and miniaturisation of the next generation of insulin delivery devices.

In the double-blind, randomised, two-way crossover Phase I clinical study in 38 participants with Type I diabetes, the pharmacokinetics (PK), pharmacodynamics (PD) and safety of a single subcutaneous (SC) dose of 0.3 U/Kg AT278 (500 U/mL) were compared with those of a single SC dose of 0.3 U/Kg NovoRapid® (100 U/mL), a currently available gold standard rapid acting insulin treatment, in a euglycemic clamp setting. The trial met the primary endpoint of non-inferiority with respect to glucose lowering action as compared with NovoRapid®. In addition to meeting this primary endpoint, AT278 (500 U/mL) also demonstrated a significantly accelerated early PK/PD profile compared to NovoRapid® (100 U/mL), despite a 5-fold increase in concentration. No safety signals were detected.

These Phase I clinical results in diabetes patients are clinically significant, and, as currently there are no concentrated (>200U/mL) rapid acting insulin products on the market, AT278 has the potential to be the first such product available to patients. AT278, enabled by Arecor's proprietary Arestat™ technology platform, has been developed to overcome the challenge whereby increasing the concentration of insulin typically results in a slower absorption and delayed glucose lowering profile.

**Professor Thomas Pieber, Principal Investigator for the ARE-278-102 clinical trial, said:** *"AT278 has clearly demonstrated faster insulin absorption with an accelerated Pharmacokinetic (PK) and Pharmacodynamic (PD) profile compared to the lower concentration NovoRapid®. With this superior PK/PD profile, AT278 has the potential to significantly improve post prandial glucose control as well as reducing the injection volume and/or number of daily injections for people with diabetes that have a high daily insulin need. In addition, AT278 has the potential to catalyse the development of miniaturised insulin delivery devices where the size of existing devices is a barrier to use for many patients."*

The next step will be further clinical investigation of the potential benefits of the ultra-rapid acting profile of AT278 to further optimise the positive results obtained in this first clinical study.

Detailed data from the trial will be submitted for presentation at a future international diabetes conference.



This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR)

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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.areacor.com](http://www.areacor.com)