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

ARECOR TO COMMENCE SECOND CLINICAL TRIAL WITH AT278 ULTRA-CONCENTRATED ULTRA-RAPID ACTING INSULIN CANDIDATE FOR TYPE 2 DIABETES

Clinical Trial Application approved

EU Phase I clinical trial expected to commence in December 2022

Cambridge, UK, 22 November 2022: Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical group advancing today's therapies to enable healthier lives, today announces the BASG (Bundesamt für Sicherheit im Gesundheitswesen) clearance of the Group's Clinical Trial Application (CTA) for AT278, an ultra-rapid acting, ultra-concentrated (500 U/mL) insulin candidate, in Type 2 diabetic patients, the primary target population.

The approval of the CTA means that Arecor may now initiate the second Phase I clinical trial for AT278, to further explore the potential for AT278 to disrupt the market for insulin treatment, as the first concentrated, yet rapid acting insulin. AT278 has previously demonstrated a faster insulin absorption with an accelerated Pharmacokinetic (PK) and Pharmacodynamic (PD) profile compared to the lower concentration NovoRapid® (100 U/mL) in a Phase I clinical study in Type 1 diabetic patients. This type 2 diabetes trial will also focus on exploring the PK/PD profile of AT278 compared with NovoRapid® (100 U/mL), as well as Humulin-R U500®.

The trial is a double blind, randomised, crossover study comparing the PK/PD profile following a single subcutaneous dose of 0.5 U/Kg of AT278 (500 U/mL) with NovoRapid® (100 U/mL) in 32 people with Type 2 diabetes in a euglycemic clamp setting. In addition, the PK/PD profile following a single subcutaneous dose of 0.5 U/Kg Humulin-R U500® will be evaluated in each of the participants. The trial will be conducted at the Medical University of Graz, Austria, an expert clinical research facility in metabolic diseases research and euglycaemic clamp methodology, with Professor Thomas Pieber as the trial's Principal Investigator. This trial is expected to initiate within 2022 and complete within Q4 2023.

Sarah Howell, Chief Executive Officer of Arecor, said: *"With regulatory approval to commence our second clinical trial for AT278, we can continue the rapid progress we are making across our proprietary diabetes focused portfolio. With its very promising profile already demonstrated in our previous study, AT278 has the potential to disrupt the market for insulin treatment as the first concentrated, yet very rapid acting insulin and to become the gold standard insulin for the growing population of people with diabetes with high daily*

insulin needs as well a critical enabler in the development of next generation miniaturised insulin delivery systems. With approximately 537 million people living with diabetes worldwide, of which approximately 56 million are insulin users, there has never been a greater need for improved treatment options."

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 previous Phase I clinical study in people with Type I diabetes, AT278 (500U/mL) clearly demonstrated faster insulin absorption with an accelerated pharmacokinetic (PK) and pharmacodynamic (PD) profile compared to gold-standard insulin NovoRapid® (100U/mL) despite a 5-fold increase in concentration.

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

-ENDS-

For more information, please contact:

Arecor Therapeutics plc Dr Sarah Howell, Chief Executive Officer	www.arecor.com Tel: +44 (0) 1223 426060 Email: info@arecor.com
Susan Lowther, Chief Financial Officer	Tel: +44 (0) 1223 426060 Email: info@arecor.com
Mo Noonan, Communications	Tel: +44 (0) 7876 444977 Email: mo.noonan@arecor.com
Panmure Gordon (UK) Limited (NOMAD and Broker) Freddy Crossley, Emma Earl (Corporate Finance) Rupert Dearden (Corporate Broking)	Tel: +44 (0) 20 7886 2500

Consilium Strategic Communications
Chris Gardner, David Daley, Angela Gray

Tel: +44 (0) 20 3709 5700
Email: arecor@consilium-comms.com

Notes to Editors

About Arecor

Arecor Therapeutics plc is a globally focused biopharmaceutical group 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