



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

**FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR AT247, AN ULTRA-RAPID INSULIN
FOR THE TREATMENT OF DIABETES**

Cambridge, UK, 9 September 2021. Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical group advancing today's therapies to enable healthier lives, today announces U.S. Food and Drug Administration (FDA) clearance of the Group's Investigational New Drug (IND) application for AT247, the Group's proprietary wholly owned ultra-rapid insulin for the treatment of diabetes.

The IND supports a Phase I clinical trial in the US in approximately 24 participants with type I diabetes, to further explore the clinical benefits of AT247. The trial is a double blind, randomised, three way crossover study comparing the pharmacokinetics (PK) and pharmacodynamics (PD) of AT247 with Novo Nordisk's NovoRapid® and Fiasp®, two market-leading rapid acting insulin treatments. It will be the first trial to investigate the product's potential when delivered by continuous subcutaneous infusion via insulin pump over a period of 3 days and follows a previous successful first-in-man clinical study.

AT247, a novel formulation of insulin, aims to accelerate insulin absorption, post injection, to enable more effective management of blood glucose levels for people living with diabetes. AT247 has the potential to significantly improve post prandial glucose control so avoiding episodes of both hypo and hyperglycemia. In a recently published European Phase I clinical study in Type I diabetic patients, AT247 exhibited an earlier insulin appearance, exposure, and offset, with corresponding enhanced early glucose-lowering effect compared with NovoRapid® and Fiasp®. This Phase I clinical data suggests that AT247 may also facilitate a fully closed loop artificial pancreas, a potentially life changing treatment option for people living with diabetes. This trial is expected to complete in 2022.

Sarah Howell, Chief Executive Officer of Arecor, said: *"FDA clearance of the IND for AT247 marks an important milestone for this product, which has been enabled with our proprietary formulation technology platform, Arestat™. We look forward to initiating the next clinical study, which will be our first study in the US, and has been designed to further demonstrate the superiority of AT247 compared to current market leaders. With c. 463 million people living with diabetes world-wide, of which approximately 56 million are insulin users, the management of blood glucose control remains a serious issue. We believe that AT247 has the potential to help patients lead healthier lives."*



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 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