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Arecor Therapeutics PLC
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# Arecor Therapeutics plc

("Arecor" or the "Company")

## Positive FDA feedback on Phase 2 clinical study design for ultra-concentrated and ultra-rapid acting insulin, AT278, in combination with an Automated Insulin Delivery (AID) system

- ***First-of-a-kind study of ultra-concentrated (500 U/mL) ultra-rapid insulin in combination with an AID system***
- ***Primary efficacy endpoint will use Time-in-Range (TIR), enabling much faster development than using standard HbA1c***
- ***Arecor on track to commence Phase 2 study in mid-2026, subject to further funding***
- ***Strategy to partner with US insulin pump company to conduct the Phase 2 study as a key step towards developing a unique next generation AID system addressing unmet needs in diabetes treatment***

**Cambridge, UK, 4 September 2025** Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical company focused on drug development and delivery in diabetes and other cardiometabolic diseases, announces that it has concluded a positive Type C meeting with the US Food and Drug Administration (FDA) for AT278 in people with both type 1 and type 2 diabetes with high daily insulin needs.

The purpose of the meeting was to discuss the design of a proposed Phase 2 clinical study for AT278 delivered by continuous infusion via an AID system, ahead of a planned Investigational New Drug (IND) submission.Positive FDA feedback and guidance on the clinical trial design is a major achievement for Arecor and a significant step toward a successful Phase 2 study.

Key features of the study include using TIR as a primary efficacy endpoint which will provide real-time information on glycaemic variability and alongside continuous glucose monitoring (CGM)-derived metrics will provide meaningful insights on drug effect to help optimize further development. This primary end-point data can also be generated over a 6-week dosing period compared with a minimum 12-week dosing period for HbA1c, enabling much faster development. The design of the trial in combination with an AID system, will also generate key data that will lay the foundations in demonstrating the benefit to patients and the economic value of this new treatment option.

AT278 is Arecor's proprietary formulation of an ultra-concentrated (500 U/mL) and ultra-rapid acting insulin and is the only insulin in development with the potential to enable longer-wear for high daily insulin users in existing AID systems as well as future insulin pump miniaturisation. With its best-in-class profile, it has the potential to disrupt the market for insulin treatment in a growing population of people with diabetes.

AT278 combines two fundamental properties, ultra-high concentration and an ultra-rapid profile, which provide the potential to enable next generation AID systems that address strong unmet needs in diabetes treatment. This will be the first time that such an insulin will be assessed in combination with an AID system in a clinical study.

Arecor plans to submit the Phase 2 IND to the FDA during 2026 with the aim of commencing enrolment for the Phase 2 study later in that year. The proposed study will be conducted in the US and is a Phase 2 six week cross-over study comparing AT278 (500 U/mL) with NovoLog® (100 U/mL) expected to be in less than 100 subjects with type 1 and type 2 diabetes. Continuous glucose monitoring (CGM) derived percentage time-in-range (TIR) will be used as the primary efficacy endpoint.

The study will build upon the positive Phase 1 data already generated on AT278 in both type 1 and type 2 diabetes where it demonstrated superiority to existing insulin products, NovoRapid® (NovoLog® in the US) and Humulin® R U-500.

**Sarah Howell, CEO of Arecor said:**

*"Such positive and constructive feedback from the FDA for our first-of-a-kind insulin and AID system combination study represents a significant milestone in our drug development program. We believe we will generate crucial data towards demonstrating the economic value of AT278 in combination with an innovative AID system.*

*"This FDA response, coupled with our Phase 1 data, means that we are on track to commence our Phase 2 trial next year, once further financing has been secured, options for which are already being assessed. We are aiming to establish a new frontier for the treatment of diabetes, and to bring more accessible next generation treatment options, that simplify care and improve outcomes for people living with diabetes."*

**-ENDS-**

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**Notes to Editors**

**About Arecor**

Arecor Therapeutics plc is a clinical stage biopharmaceutical company focused on drug development and delivery in diabetes and other cardiometabolic diseases. The Company is applying its proprietary technology platform, Arestat®, to develop a portfolio of proprietary products, as well as working with leading pharmaceutical and biotechnology companies to deliver therapeutic products. Its lead product is AT278, the only ultra-concentrated (500U/mL) ultra-rapid acting insulin. Arecor is also developing a novel oral delivery platform for peptides (e.g. GLP-1 receptor agonists) targeting the obesity and diabetes markets. The Company is listed on AIM (AIM: AREC) and is based in Cambridge, UK. For further details please see www.arecor.com.





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