Arecor Therapeutics plc

("Arecor" or the "Group")

ARECOR ANNOUNCES POSITIVE PRE-IND MEETING WITH FDA FOR NOVEL READY-TO-USE MEDICINE AT307 LICENSED TO HIKMA

- ***Positive feedback from pre-IND meeting with FDA confirms Hikma's continued development of AT307 under the 505(b)(2) regulatory pathway***
- ***Abbreviated 505(b)(2) submission offers an efficient and streamlined development pathway with reduced risk***

Cambridge, UK, 7th September 2023: Arecor Therapeutics plc (AIM: AREC), the biopharmaceutical group advancing today's therapies to enable healthier lives, is pleased to announce further progress from Hikma in the development of ready-to-use ("RTU") injectable medicine AT307, following a recent positive pre-investigational new drug application (pre-IND) meeting between Hikma and the US Food and Drug Administration (FDA).

In January 2023, Arecor transferred all rights and responsibility for future development and commercialisation of AT307 to Hikma as part of an earlier co-development and license agreement in which Arecor used its proprietary drug formulation technology platform, Arestat™, to develop a novel RTU formulation of an existing therapeutic product.

Based on positive feedback from a pre-IND meeting held with the FDA, Hikma has communicated to Arecor its intention to continue development of AT307 in the US using the FDA's 505(b)(2) regulatory pathway. This pathway provides companies with an abbreviated regulatory review process when evidence of safety and clinical efficacy generated for an originator product is deemed suitable to be relied upon in new marketing applications.

Sarah Howell, Chief Executive Officer at Arecor, said: *"We are very pleased with this confirmatory news that Hikma is able to pursue an abbreviated 505(b)(2) approval pathway for AT307, providing an opportunity to progress the development and regulatory review process and bring this medicine to patients more rapidly than through a traditional new drug approval route. This also further validates a fundamental assumption within our business that the abbreviated 505(b)(2) pathway can be utilised across our specialty hospital*

portfolio where we are developing enhanced, ready-to-use and ready-to-administer formulations of existing therapeutic products."

Bill Larkins, President of Injectables at Hikma, said: *"The FDA's feedback supports our intention to pursue a 505(b)(2) pathway to market for AT307, so we can bring this important new ready-to-use treatment option to patients. It also further demonstrates the strength of the Hikma and Arecor strategic partnership where we are leveraging our respective strengths to bring this important treatment option to patients and healthcare providers and further position our business for continued long-term growth. We look forward to advancing AT307 through further development and to continuing our highly productive strategic collaboration with* Arecor."

Under the terms of Arecor's 2020 co-development and license agreement with Hikma, the Group is eligible to receive development milestone payments in addition to future recurring revenue from royalty payments upon commercialisation.

-ENDS-

For more information, please contact:

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Notes to Editors

About RTU and RTA medicines

Ready-to-use (RTU) and ready-to-administer (RTA) medicines are becoming increasingly important to enable fast, safe and effective treatment of patients at point of care in a hospital setting. These RTU and RTA new stable liquid product formulations improve safe medication practices and simplify care by eliminating the need for reconstitution. The lack of a RTU or RTA version of a product is usually due to technical challenges in developing stable and efficacious liquid formulations.

Arecor has demonstrated its capability to leverage the Arestat™ platform to reformulate existing products into RTU and RTA injectables. This market thus offers Arecor the opportunity to deliver differentiated products and with it's partners target market share in a valuable, but often competitive space.

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