



# ARECOR AND JDRF ANNOUNCE SUCCESSFUL PRE-CLINICAL DEVELOPMENT OF STABLE RAPID-ACTING, ULTRA-CONCENTRATED INSULIN FOR THE SIGNIFICANTLY ENHANCED TREATMENT OF TYPE 1 DIABETES

"Arecor's proprietary insulin product to progress into human clinical trials in 2018"

**Cambridge (UK), New York (USA),** 4<sup>th</sup> January 2018: Arecor Limited, a leader in developing superior biopharmaceuticals through the application of an innovative formulation technology platform, and JDRF, the leading global organisation funding type 1 diabetes research, are pleased to announce the successful completion of their partnered programme and the pre-clinical development of an ultra-concentrated, rapid-acting insulin product ("the product") for the significantly enhanced treatment of insulin-requiring diabetes, particularly type 1 diabetes.

The product, which is scheduled to progress into a first-in-human clinical study in people with type 1 diabetes in 2018, is a significant step toward enabling miniaturization of next-generation insulin delivery technologies that are promising to transform the life of people with diabetes. The product will also offer superior treatment and quality of life for people requiring large doses of insulin to manage their condition.

More specifically, the product will significantly improve the treatment of patients requiring more than 200 Units of insulin per day. Development of an ultra-concentrated insulin product, capable of delivering up to 1,000 Units/mL, was hitherto a considerable scientific challenge, but is one that has now been successfully addressed during the development programme, by applying Arecor's proprietary formulation technology, Arestat™, to existing off-patent rapid acting insulin analogues at concentrations of up to 1,000 Units/mL.

The product has been shown to demonstrate a similar rapid onset of action, in comparison to the currently marketed low-concentration analogues. The product has also demonstrated excellent stability, which is always a pre-requisite for any commercially viable product. Indeed, during the programme, a number of considerable challenges associated with increasing insulin concentration, such as poor stability and the slow onset of insulin action, have been overcome using the Arestat™ technology. The technology has furthermore delivered excellent rapid pharmacokinetic and pharmacodynamic profiles in validated animal models, in comparison to currently marketed, competitor rapid-acting products.





# Sanjoy Dutta, JDRF commented:

"We are pleased at the progress being delivered as a result of JDRF's partnership with Arecor, as we seek to improve the delivery and control of insulin," said Sanjoy Dutta, JDRF Assistant Vice President, Research. "People with type 1 diabetes are looking forward to smaller devices that can help them maintain glucose control safely and conveniently. Achieving miniaturized technologies, and therefore an improved quality of life, will require ultra-concentrated insulins such as the one being developed through this research."

# Arecor's CEO, Sarah Howell, commented:

"The successful development of the ultra-concentrated rapid acting insulin is a very important milestone in Arecor's mission to develop superior proprietary products that will significantly improve the treatment options and ultimately the quality of life of people living with diabetes. Having already succeeded in developing a pre-clinical proof-of-concept insulin with ultra-fast onset, the ultra-concentrated rapid acting insulin is another key product within our diabetes portfolio. The support from JDRF has been invaluable and we look forward to continuing to build this fruitful partnership to deliver our shared common future objectives – namely to deliver substantially improved treatment options for people living with diabetes".

\*\*\* ENDS \*\*\*

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### **Notes to Editors**

## **About diabetes**

Diabetes mellitus, often shortened to "diabetes", is a chronic condition that affects the body's ability to control blood sugar level and use energy from food. In a healthy body, carbohydrates from nutrition are broken down to glucose, which in turn provides energy for the cells. This process is controlled by a hormone called insulin. Diabetes is due to the inability of the body to produce enough insulin (Type 1 diabetes) or to use it properly (Type 2 diabetes). If left untreated, diabetes leads to serious health complications, including heart disease, kidney failure, nerve damage or blindness. The incidence of diabetes is increasing very rapidly, putting a significant financial burden on healthcare systems around the world. Worldwide, there are currently about 415 million people with diabetes, expected to grow to about 642 million diabetics by 2040 (*International Diabetes Federation, Diabetes Atlas, 2015*).

# **About insulin treatment**

The key goal of diabetes treatment is to keep blood glucose levels in a healthy range so as to reduce the risk of organ damage and other complications that result from chronic hyperglycaemia. Insulin is a critical part of the diabetes treatment, particularly Type 1 diabetes. To ensure more effective treatment a variety of insulin analogues have been developed, including analogues that act very rapidly to ensure an effective reduction of blood glucose after meals. Different delivery methods for insulin have also been developed over time to ensure convenience for the patients and the best possible therapeutic outcomes. Traditional syringes have been gradually replaced by more convenient insulin pens that use pre-filled cartridges and a fine needle and insulin pumps that dispense insulin through flexible tubing to a catheter under the skin of the abdomen are increasingly used. New generation pumps are currently being developed to ensure greater convenience by more discrete size and design as well as their useful connectivity to external devices such as smart phones. The key parameter that prevents development of truly miniaturised pumps is the size of the insulin cartridge. Therefore, there is a strong unmet critical need for concentrated insulin that would enable keeping a given amount of insulin in as small a volume as possible. The product developed by Arecor in partnership with JDRF is a critical step toward meeting this need.

# **About JDRF**

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested more than \$2 billion in research funding since our inception. We are





an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF.

## **About Arecor**

Arecor Ltd is a leader in developing superior biopharmaceuticals through the application of an innovative formulation technology platform. Arecor is leveraging this platform to develop a portfolio of proprietary products that will enable improved treatments for diabetes via the innovative reformulation of approved proteins and peptides. Arecor's product portfolio also includes:

- Stable aqueous glucagon for emergency and artificial pancreas use,
- Novel insulin formulations to deliver ultra-rapid acting insulin analogs and;
- Ultra-concentrated rapid acting insulin to enable the miniaturisation of devices, and
- A series of undisclosed pre-clinical programmes.

In addition, Arecor partners with leading pharmaceutical and biotech companies to deliver superior reformulations of their proprietary products, which would otherwise not be possible using conventional formulation science.

(www.arecor.com)

# About Arestat<sup>TM</sup>

Arecor has significant experience and a proven track record in applying the Arestat<sup>TM</sup> formulation technology platform to deliver superior biopharmaceutical product profiles across a broad range of proteins, peptides and vaccines.