



## PRESS RELEASE

## Adocia Announces a Clinical Trial Evaluating BioChaperone® Lispro and Other Rapid-Acting Insulin Analogs Using iLet™ Bionic Pancreas

- **First trial to test the ultra-rapid insulin BioChaperone Lispro with automated insulin delivery**
- **Using the insulin-only configuration of the iLet Bionic Pancreas system, this trial will investigate effect of different pharmacokinetic characteristics of insulin aspart, insulin lispro, and ultra-rapid BioChaperone Lispro on glycemic control**

**Lyon, France, January 3rd 2019** – 6:00 pm CET - ADOCIA (Euronext Paris: FR0011184241 – ADOC), a biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of approved proteins, announced today the first home-use trial to test Adocia's BioChaperone® Lispro in Beta Bionics autonomous insulin delivery system, the iLet™.

Investigators at the Massachusetts General Hospital Diabetes Research Center have designed and will perform the study, which is funded by the Leona M. and Harry B. Helmsley Charitable Trust.

*"We are very excited to explore the potential of ultra-rapid insulin BioChaperone Lispro to improve postprandial glucose control in an autonomous insulin delivery setting, or so-called "artificial pancreas" system," said Dr. Olivier Soula, Deputy General Manager and Director of R&D of Adocia. "Closed-loop insulin delivery systems such as the iLet Bionic Pancreas hold the promise of reducing the impact of the disease for people with diabetes. We are proud to contribute to advancing integrated solutions that may ultimately combine innovative insulin products and cutting-edge insulin management systems."*

*"This trial is exploring new territory by evaluating how differences in the speed of insulin absorption affect the quality of glucose control that can be achieved in people with type 1 diabetes," said Dr Steven J. Russell, MD, PhD, Associate Professor of Medicine at Harvard Medical School and Massachusetts General Hospital and Principal Investigator for this study "We've observed that some patients absorb insulin lispro and insulin aspart at different speeds. We are curious to investigate how those differences and more rapid absorption of an ultra-rapid formulation of insulin lispro affects glycemic control with the bionic pancreas."*

This, multi-arm, cross-over, USA-only clinical trial, will recruit up to 30 people with type 1 diabetes to participate in three 7-day study arms comparing the pharmacokinetic and pharmacodynamic profiles of insulin lispro, insulin aspart, and BioChaperone Lispro in the bionic pancreas between and within subjects. The

co-primary outcomes will be mean continuous glucose monitoring glucose (CGMG) and fraction of time spent with CGMG <54 mg/dl.

The iLet consists of a dual-chamber, autonomous, infusion pump that mimics a biological pancreas by delivering insulin and glucagon to maintain glycemia within a tight normal range. Embedded in the system are clinically tested mathematical dosing algorithms driven by machine learning to autonomously calculate and dose insulin and/or glucagon as needed, based on data from a continuous glucose monitor. The iLet requires only body weight for initialization. Once initialized, the iLet engages its machine-learning, artificial intelligence to autonomously control the individual's blood-glucose levels, and to continuously adapt to the individual's ever-changing insulin needs. The iLet to be used in this trial will be set in an insulin-only configuration and will integrate glucose data from the Dexcom G5 Continuous Glucose Monitoring (CGM) System.

BioChaperone Lispro is an ultra-rapid formulation of prandial insulin lispro that incorporates Adocia's proprietary technology, BioChaperone<sup>®</sup>, designed to enable the acceleration of insulin absorption. BioChaperone Lispro has previously demonstrated an accelerated insulin action profile across multiple Phase 1/2 studies in people with type 1 and type 2 diabetes compared to that of insulin analog lispro (Humalog<sup>®</sup>, Eli Lilly) and insulin aspart (Novolog<sup>®</sup>, Novo Nordisk), when injected with insulin syringes and delivered by insulin pumps.

This trial is registered and appears on Clinicaltrial.gov (NCT03262116).

### About ADOCIA

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins and peptides for the treatment of diabetes and other metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring six clinical-stage products. Additionally, Adocia recently expanded its portfolio to include the development of treatments of obesity and short bowel syndrome.

The proprietary BioChaperone<sup>®</sup> technological platform is designed to enhance the effectiveness and/or safety of therapeutic proteins while making them easier for patients to use. Adocia customizes BioChaperone to each protein for a given application. Adocia's clinical pipeline includes five novel insulin formulations for the treatment of diabetes: two ultra-rapid formulations of insulin analog lispro (BioChaperone<sup>®</sup> Lispro U100 and U200), a combination of basal insulin glargine and rapid-acting insulin lispro (BioChaperone<sup>®</sup> Combo), a rapid-acting formulation of human insulin (HinsBet<sup>®</sup> U100), and a prandial combination of human insulin with amylin analog pramlintide (BioChaperone<sup>®</sup> Pramlintide Insulin). It also includes an aqueous formulation of human glucagon (BioChaperone<sup>®</sup> Glucagon) for the treatment of hypoglycemia. Adocia preclinical pipeline includes combinations of insulin glargine with GLP-1 receptor agonists (BioChaperone<sup>®</sup> Glargine GLP-1) for the treatment of diabetes, a ready-to-use combination of glucagon and a GLP-1 receptor agonist BioChaperone<sup>®</sup> Glucagon GLP1) for the treatment of obesity and a ready-to-use aqueous formulation of teduglutide (BioChaperone<sup>®</sup> Teduglutide) for the treatment of short bowel syndrome.

Adocia and Chinese insulin leader Tonghua Dongbao entered into a strategic alliance. In April 2018, Adocia granted Tonghua Dongbao licenses to develop and commercialize BioChaperone Lispro and BioChaperone Combo in China and other Asian and Middle-Eastern territories. The licensing included 50 million dollars upfront and up to 85 million dollars development milestones, plus double-digit royalties on sales. In June 2018, Tonghua Dongbao agreed to manufacture and supply active pharmaceutical ingredients insulin lispro and insulin glargine to Adocia globally, excluding China, to support Adocia's portfolio development in these territories.

*Adocia aims to deliver "Innovative medicine for everyone, everywhere."*

To learn more about Adocia, please visit us at [www.adocia.com](http://www.adocia.com)



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#### Disclaimer

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