

## PRESS RELEASE

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# Adocia Initiates Phase 2 Clinical Trial for M1Pram in Patients with Type 1 Diabetes

- Phase 2 study evaluates safety and efficacy of M1Pram, assessing weight loss in overweight and obese T1D patients as well as improved HbA<sub>1c</sub>
- The study has been designed to define parameters for the upcoming Phase 3 trial planned for 2022
- This study follows the promising results of the proof-of-concept Phase 1 trial announced on September 15, 2020

6pm CET- Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical stage biopharmaceutical company focused on diabetes treatment and other metabolic diseases, announced today the initiation of a Phase 2 study in type 1 diabetes (T1D). The purpose of the study is to confirm and optimize the safety and efficacy of M1Pram in comparison with insulin lispro (Humalog<sup>®</sup>, Eli Lilly) in regard to glycemic control and body weight reduction.

“We are pleased to launch this ambitious study so rapidly. This Phase 2 study will allow us to evaluate a larger sample size and obtain additional data on M1Pram following the promising results in our previous studies,” said Olivier Soula, Deputy CEO and Director of R&D at Adocia “M1Pram could improve glycemic control and reduce weight for overweight and obese patients, something that no other insulin has been able to offer”.

## About the Phase 2 study

This study evaluates the efficacy of M1Pram on body weight reduction and blood glucose control compared to insulin lispro (Humalog<sup>®</sup>, Eli Lilly) after 16 weeks of treatment in 80 type 1 diabetes patients. Both products are administered in combination with basal insulin. Safety criteria are also being assessed. The study is designed as a multicentric, open-label, randomized, active-

comparator controlled, two parallel arm trial. Glucose homeostasis is assessed using continuous blood glucose monitoring and patient satisfaction is appraised via a questionnaire. The study is conducted in Germany and has been approved by the German regulatory authority, the BfArM.

In September 2020, our Phase 1b study results showed a statistically improved Time-In-Range for patients treated with M1Pram vs. aspart (Novolog<sup>®</sup>, NovoNordisk). Moreover, a significant average weight loss of 1.6 kg compared to baseline was observed in people treated with M1Pram. Patients treated with aspart observed an average weight gain of 0.4 kg. Additionally, after each treatment period, study participants completed a treatment satisfaction questionnaire. The data reflects the beneficial impact of M1Pram on individuals, 87% of them reported an improved appetite control, and 75% of the patients would recommend it to other people with diabetes.

## About M1Pram

M1Pram is a fixed-ratio combination of insulin and amylin analogs, two hormones that are missing or malfunctioning in diabetes patients. In healthy people, insulin plays a hypoglycemic role and glucagon acts as a hyperglycemic agent while amylin has a central position controlling gastric emptying, well-being and glucagon secretion. In type 1 diabetic patients, insulin and amylin are absent due to the destruction of  $\beta$ -cells by the immune system. In type 2 diabetes, patients progressively lose the ability to produce endogenous insulin and amylin as the disease progresses.

Pramlintide, an amylin analog, when administered with insulin, has demonstrated that restoring this missing hormone has tremendous effects improving glycemic control, weight loss in overweight patients and well-being.

Based on 15 years of experience in protein formulation and diabetes, Adocia has overcome the technical challenges to coformulate pramlintide with insulin in one single product. These two hormones normally being incompatible in one formulation.

Combining these two hormones in M1Pram should bring significant medical benefits in comparison with prandial insulin alone with the hope of becoming a new first line prandial insulin treatment for T1D and T2D patients.

## About Adocia

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of therapeutic proteins and peptides for the treatment of diabetes and metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring four clinical-stage products. 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 four novel insulin formulations for prandial 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) and one combination of a prandial insulin with amylin analog pramlintide M1Pram. The clinical pipeline also includes an aqueous formulation of human glucagon (BioChaperone<sup>®</sup> Glucagon) for the treatment of hypoglycemia.

Adocia preclinical pipeline includes four products: combinations of rapid human insulin analogs and Pramlintide (BioChaperone<sup>®</sup> LisPram and BioChaperone<sup>®</sup> AsPram), a combination of insulin glargine with

GLP-1 receptor agonists (BioChaperone® Glargine GLP-1) for the treatment of diabetes and a ready-to-use combination of glucagon and a GLP-1 receptor agonist (BioChaperone® Glucagon GLP-1) for the treatment of obesity.

Adocia recently added a fifth program, a preclinical stage cell therapy initiative focused on development of a hydrogel scaffold for use in people with type 1 diabetes. The first patent application supporting this program has been filed.

## Contact Adocia

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