

## PRESS RELEASE

Lyon, June 21<sup>st</sup>, 2022

---



**ADOCIA**

innovative medicine  
for everyone, everywhere

# ADOCIA announces M1Pram Phase 2 Trial Meets Primary Objective by Reducing Weight in Overweight People with Type 1 Diabetes

- Demonstrated weight loss vs. Humalog® (-2.13kg) over 4 months with progressive and continuous weight loss still ongoing at the end of study period.
- Both treatments were well tolerated and overall good glycemic control is maintained in both groups
- Better control of appetite expressed in patient satisfaction scoring after 16 weeks of treatment (82.4% with M1Pram vs. 43.2% with Humalog®)
- Selected for an oral communication at EASD 2022 (European Association for the Study of Diabetes)

18h00 CEST- Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical-stage biopharmaceutical company focused on the research and development of innovative therapeutic solutions for the treatment of diabetes and other metabolic diseases, announced today positive top-line results in a Phase 2 trial comparing M1Pram to Humalog in people with Type 1 Diabetes.

The fixed-ratio combination of M1 human insulin analog 100 Units/mL and pramlintide 600µg/mL, the only FDA-approved amylin analog (Symlin®, AstraZeneca), demonstrated statistically superior weight loss compared with insulin lispro 100 Units/mL. Full topline results will be communicated at EASD 2022.

*"We are really pleased to confirm that M1Pram ensures weight loss of overweight type 1 patients as pramlintide is the only adjunct to insulin approved by FDA for people with type 1 diabetes."* said Gérard Soula, President & CEO of Adocia, *"Our first objective now is to partner this product to pharmaceutical companies engaged in diabetes."*

## CT041 Topline Results

This parallel arm study, conducted by Profil in Germany, evaluated the efficacy, safety and patient satisfaction of M1Pram on body weight reduction and blood glucose control compared to insulin lispro (Humalog®, Eli Lilly)

after 16 weeks of outpatient treatment in type 1 diabetes patients with BMI ranging between 25 and 35kg/m<sup>2</sup>. Both products were administered at meal-time and in combination with once daily basal insulin. 71 patients completed the study.

- The weight loss of M1Pram vs Humalog over 4 months is -2.13kg (p=0.0045) in total population and -3.1kg (p=0.0155) in a subpopulation of patients with BMI>28kg/m<sup>2</sup>. During the period, a continuous weight decrease was observed and was still ongoing at the end of the study.
- Both treatments maintained HbA1c and Time-in-Range in patient population with mean HbA1c of 7.4% at baseline.
- Hypoglycemic event numbers are similar between the two treatments and no difference in severe hypoglycemia.
- M1Pram demonstrates overall a good safety profile. Total number of adverse events (excluding hypoglycemia) M1Pram vs Humalog, 76 vs. 38 were mainly driven by gastro-intestinal side effects as expected and documented in pramlintide literature.
- The reduction of daily prandial insulin dose for M1Pram treatment compared to baseline is more than 10% (no change in Humalog arm).
- The treatment satisfaction questionnaire clearly demonstrates a better control of appetite with M1Pram for 82.4% of patients (vs 43.2% with Humalog).

*“This phase 2 study of M1Pram shows that a single injection with each meal is as easy to use and as efficient as Humalog for glycemic control without increasing the rate of hypoglycemia.”* declared Dr. Matthew Riddle, Professor of Medicine in the Division of Endocrinology, Diabetes, & Clinical Nutrition at Oregon Health & Science University, *“In addition, weight control is challenging for T1D patients, potentially limiting glycemic control and adding cardiovascular risk. While reducing insulin requirement, M1Pram improved appetite control and had a beneficial effect on weight, particularly in obese T1D patients. These features support a future role for this combination formulation for T1D.”*

*“The results highlight that M1Pram could provide people with type 1 diabetes with the only insulin that improves control of appetite and lowers weight.”*, declared Olivier Soula, Deputy-CEO and Director of R&D of Adocia, *“This is very encouraging and deserves a larger and longer study to reveal the full potential of M1Pram in weight loss, HbA1c and Time-in-Range.”*

Pramlintide is the only product with weight loss effect that the FDA has approved as adjunct to insulin for people with Type 1 Diabetes; GLP1-RA being only approved in Type 2 diabetes. Weight management and obesity is a major burden for people with T1D in the USA where 65% are overweight or obese.

## About M1Pram, an insulin/amylin combination

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, is marketed since 2005 and 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.

M1Pram as a fixed-ratio combination of pramlintide and insulin allows for fewer daily injections in comparison to marketed pramlintide treatment scheme which requires to be injected on top of insulin. Moreover M1Pram improves the safety profile of the use of pramlintide.

It's 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.

## About Adocia

Adocia is a biotechnology company specializing in the discovery and development of therapeutic solutions in the field of metabolic diseases, primarily diabetes and obesity. The company has a broad portfolio of drug candidates based on three proprietary technology platforms:

1) The BioChaperone® technology for the development of new generation insulins and products combining insulins with other classes of hormones; 2) AdOral®, an oral peptide delivery technology; 3) AdoShell® Islets, an immunoprotective biomaterial for cell transplantation with a first application in pancreatic cells transplantation for patients with "brittle" diabetes.

Adocia holds more than 25 patent families.

Based in Lyon, the company has 115 employees. Adocia is listed on the Euronext™ Paris market (Euronext: ADOC; ISIN: FR0011184241).

## Contact

### Adocia

Gérard Soula

CEO

contactinvestisseurs@adocia.com

Tel : +33 4 72 610 610

[www.adocia.com](http://www.adocia.com)

### Adocia Press and Investors Relations

Ulysse Communication

Pierre-Louis Germain

Margaux Puech Pays d'Alissac

Bruno Arabian

adocia@ulyссе-communication.com

+33 (0)6 64 79 97 51



European **Rising Tech**  
LABEL



**ADOCIA**

innovative medicine  
for everyone, everywhere



## Disclaimer

This press release contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers as being reasonable. However, there can be no guarantee that the estimates contained in such forward-looking statements will be achieved, as such estimates are subject to numerous risks including those which are set forth in the "Risk Factors" section of the universal registration document that was filed with the French Autorité des marchés financiers on April 21, 2022 (a copy of which is available at [www.adocia.com](http://www.adocia.com)), in particular uncertainties that are linked to research and development, future clinical data, analyses, and the evolution of the economic

context, the financial markets and the markets in which Adocia operates.

The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not considered as material by Adocia as of this day. The occurrence of all or part of such risks could cause that actual results, financial conditions, performances, or achievements of Adocia be materially different from those mentioned in the forward-looking statements.

This press release and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy Adocia's shares in any jurisdiction.

