

# PRESS RELEASE

# Adocia Reports Topline Results of BioChaperone® Glucagon Phase 1 Study

- BioChaperone Glucagon, a ready-to-inject stable aqueous formulation of human glucagon, was found to be safe and well tolerated in people with type 1 diabetes
- BioChaperone Glucagon has demonstrated efficacy in rescuing participants from medically induced hypoglycemia in a median time of 11 minutes

**Lyon, France, November 20, 2017-** 6 pm CET - ADOCIA (Euronext Paris: FR0011184241 – ADOC – the "Company") a clinical stage biopharmaceutical company focused on diabetes treatment with innovative formulations of approved proteins, today announced top-line results of a Phase 1 study of BioChaperone® Glucagon, its aqueous formulation of human glucagon. The proprietary BioChaperone technology enables solubilization and stabilization of human glucagon at neutral pH. A liquid formulation of human glucagon may hold potential as a ready-to-inject treatment for severe hypoglycemia emergency rescue and as a companion agent to insulin in a dual hormone artificial pancreas.

The main objective of this study was to assess the safety and tolerability of subcutaneous single fixed doses of BioChaperone Glucagon and of GlucaGen® HypoKit® (Novo Nordisk lyophilized powder reconstituted immediately prior to injection) in subjects with type 1 diabetes. Secondary objectives included the comparison of the pharmacokinetic and pharmacodynamic profiles of BioChaperone Glucagon to those of GlucaGen HypoKit.

"We are very pleased to report positive topline results for the first clinical trial of BioChaperone Glucagon, the only stable aqueous formulation of human glucagon in development. Together with positive stability data, this first set of clinical data supports its further development as a ready-to-inject treatment for severe hypoglycemia." said Dr. Stanislav Glezer, Adocia's Chief Medical Officer. "We are currently selecting an easy-to-use, state-of-the-art injection device for BioChaperone Glucagon, which aims to provide fast and reliable relief to patients living with diabetes and their caregivers in a situation of hypoglycemic emergency."

Olivier Soula, Adocia's Deputy General Manager – R&D Director added, "BioChaperone Glucagon shows that BioChaperone formulation technology enables ready-to-inject products

out of unstable proteins that required to be lyophilized, while preserving clinical efficacy. We intend to leverage this unique property of BioChaperone to other potential candidates across multiple therapeutic areas."

In this study of BioChaperone Glucagon, people with type 1 diabetes received continuous intravenous insulin infusion under medically supervised conditions to induce plasma glucose level in the range 56 to 60 mg/dL (hypoglycemic state).

Following a single subcutaneous injection of a 1 mg dose, BioChaperone Glucagon was found to have an acceptable safety and tolerability profile. In both groups, the most frequent adverse event was nausea, with 8 observed events in 25 patients for BioChaperone Glucagon vs. 5 events in 24 patients with Glucagen HypoKit.

Median time to reach a clinically safe blood glucose level of 70 mg/dL was 11 min for BioChaperone Glucagon and approximately 7 min for the commercial Glucagen® drug product, with all subjects achieving resolution of hypoglycemia at the 35 minutes timepoint.

Detailed results of this clinical trial are intended to be submitted for publication at a major diabetes conference at a future date, upon availability.

#### **About Severe Hypoglycemia**

Severe hypoglycemia is a potentially life-threatening side effect of insulin overdose for people living with diabetes. Currently, hypoglycemia rescue treatments are only available as a lyophilized powder, which requires reconstitution prior to use. The complex multi-step process takes several minutes, requires prior training of the user and may result in dosing errors, especially when administered by an acquaintance<sup>1</sup>. Hence, there is a strong medical need for a ready-to-inject formulation that would enable immediate and reliable injection in an emergency situation.

### **About Adocia**

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins. Adocia's portfolio of therapeutic proteins for the treatment of diabetes, featuring four clinical-stage products and six preclinical-stage products, is among the largest and most differentiated in the industry.

The proprietary BioChaperone® 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 in order to address specific patient needs.

Adocia's clinical pipeline includes four novel insulin formulations for the treatment of diabetes: two ultra-rapid formulations of insulin analogs (BioChaperone Lispro U100 and U200), a rapid-acting formulation of human insulin (HinsBet U100) and a combination of basal insulin glargine and rapid-acting insulin lispro (BioChaperone Combo). Adocia is also developing an aqueous formulation of human glucagon (BioChaperone Human Glucagon), two combinations of insulin glargine with GLP-1s (BioChaperone Glargine

<sup>&</sup>lt;sup>1</sup> In a study with 16 instructed caregivers and 15 non-instructed acquaintances, only 13% of caregivers and 0% of acquaintances were able to inject the full dose when using a commercial Glucagon® kit (Eli Lilly). The average time for correct or partial dose administration was 1 min 53 seconds for caregivers and 2 min 24 seconds for acquaintances. *Diabetes Technol Ther. 2017 Jul 1; 19(7): 423–432.* 

Dulaglutide and BioChaperone Glargine Liraglutide), two combinations of insulin lispro with synergistic prandial hormones (BioChaperone Lispro Pramlintide and BioChaperone Lispro Exenatide), and a concentrated, rapid-acting formulation of human insulin (HinsBet U500), all of which are in preclinical development.

Adocia aims to deliver "Innovative medicine for everyone, everywhere." To learn more about Adocia, please visit us at <a href="https://www.adocia.com">www.adocia.com</a>







## For more information please contact:

Adocia

Gérard Soula Chairman and CEO contactinvestisseurs@adocia.com

Ph.: +33 4 72 610 610

Adocia Press Relations Europe

MC Services AG Raimund Gabriel

adocia@mc-services.eu

Ph.: +49 89 210 228 0

Adocia Investor Relations USA

The Ruth Group

Tram Bui

tbui@theruthgroup.com

Ph.: +1 646 536 7035

#### **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 to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the "Risk Factors" section of the Reference Document filed with the French Autorité des marchés financiers on April 11, 2017 (a copy of which is available on www.adocia.com) and to the development of economic conditions, 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 currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Adocia to be materially different from such forward-looking statements.