



## PRESS RELEASE

## Adocia Launches First-in-Man Clinical Study of BioChaperone® Glucagon

- **BioChaperone Glucagon, a ready-to-use stable aqueous formulation of human glucagon, could be used as a rescue treatment for severe hypoglycemia and in a dual hormone artificial pancreas**
- **Study will document the safety and tolerability of BioChaperone Glucagon as well as its pharmacodynamic and pharmacokinetic profiles in people with type 1 diabetes**
- **Results are expected in Q4 2017**

**Lyon, France, June 1<sup>st</sup>, 2017-** 7:30 am CET - ADOCIA (Euronext Paris: FR0011184241 – ADOC – the “Company”) a clinical stage biopharmaceutical company focused on diabetes treatment with innovative formulations of approved proteins, announced today the initiation of a Phase 1 study of BioChaperone® Glucagon, its aqueous formulation of human glucagon. The BioChaperone proprietary technology enables the solubilization and stabilization of human glucagon at neutral pH. A liquid formulation of human glucagon may have utility as a ready-to-inject treatment for severe hypoglycemia as well as in a dual hormone artificial pancreas (DHAP), i.e. a fully automated pump that would deliver both insulin and glucagon as a function of the person’s real-time glycaemia.

This study aims to assess the safety and tolerability of BioChaperone Glucagon (BC Glucagon) as compared to commercially available human glucagon (lyophilized powder reconstituted immediately prior to injection, GlucaGen® HypoKit®, Novo Nordisk). The study will evaluate two different fixed doses, representative of two distinct potential applications, i.e. rescue from severe hypoglycemia and repeated frequent micro-bolus administration in a DHAP system.

*“We are very pleased to initiate the clinical evaluation of BioChaperone Glucagon, the only stable aqueous formulation of human glucagon in development.”* said Olivier Soula, Adocia’s Deputy Manager and Director of R&D. *“Based on positive stability data, our formulation may address the medical need for an emergency ready-to-use treatment of hypoglycemia and for glucagon use in an artificial pancreas. This study will allow, before year end, the documentation of the clinical performance of our product in both indications.”*

Severe hypoglycemia is a significant and ever-present risk for people with diabetes using insulin. Human glucagon is the only product approved as an emergency treatment for severe hypoglycemia. Currently available emergency kits consist of lyophilized human glucagon for reconstitution immediately prior to injection (two available brands: GlucaGen HypoKit, Novo Nordisk and Glucagon, Eli Lilly). The usability of these kits, however, is poor as demonstrated in several clinical studies, due to the numerous steps required for reconstitution and administration. Therefore, there is a strong medical need for a ready-to-use solution in an auto-injector to simplify the injection and ensure the administration of the appropriate dose in an emergency situation.

Adocia's aqueous formulation of human glucagon could address the medical need for a ready-to-use product for rescue from severe hypoglycemia and unlock the use of human glucagon as a chronic treatment in a DHAP. Adocia's formulation strategy builds on the established safety and efficacy data sets for human glucagon. Specifically, BioChaperone technology enables the solubilization and stabilization of human glucagon in pure aqueous solution at physiologic pH, precluding the need for organic solvent or modification of the native amino-acid sequence of this peptide.

In this randomized, double-blind, comparator-controlled, three-period, cross-over study, 27 participants with type 1 diabetes will be randomly allocated to a sequence of three treatments: BC Glucagon formulation 1, BC Glucagon formulation 2 and GlucaGen HypoKit. Each agent will be administered at a fixed dose of 50 µg and 1 mg, as two single subcutaneous injections, on three separate dosing visits. 1 mg is the standard dose for severe hypoglycemia rescue and 50 µg is similar to the micro-boluses used in an artificial pancreas system.

The main objective of this study is to assess the safety and tolerability of subcutaneous single fixed doses of both BC Glucagon formulations and of GlucaGen HypoKit in subjects with type 1 diabetes. Secondary objectives include the comparison of the pharmacokinetic and pharmacodynamic profiles of BC Glucagon to those of GlucaGen HypoKit at two different doses.

Adocia is the sponsor of this study, which will be performed by Profil Neuss in Germany. Results are expected during Q4 2017.

This trial is registered and will appear on [clinicaltrials.gov](http://clinicaltrials.gov).

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



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## Disclaimer

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