

# PRESS RELEASE

# Adocia launches a new clinical study of BioChaperone<sup>®</sup> Combo, its combination of long-acting insulin glargine and fast-acting insulin lispro, in people with type 2 diabetes

**Lyon, France, September 20, 2016** – Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical stage biopharmaceutical company focused on diabetes treatment with innovative formulations of approved proteins, announced today the initiation of a Phase 1b clinical trial evaluating BioChaperone<sup>®</sup> Combo, its proprietary formulation combining insulin analog glargine (Lantus<sup>®</sup>, Sanofi), the gold-standard of long acting insulin, and the fast-acting insulin analog, insulin lispro (Humalog<sup>®</sup>, Eli Lilly and Company). BioChaperone<sup>®</sup> technology enables this combination by solubilizing insulin glargine at neutral pH, at which it is compatible with fast-acting insulin analogs.

This study aims to measure the effect of BioChaperone<sup>®</sup> Combo injected at mealtime on postmeal glycemic control in subjects with type 2 diabetes compared to that of premix insulin Humalog<sup>®</sup> Mix25<sup>TM</sup> (Eli Lilly) and the separate injection of Lantus<sup>®</sup> (Sanofi) and Humalog<sup>®</sup> (Eli Lilly). People with type 2 diabetes who require insulin intensification over basal are either using twice-daily premix insulins, such as Humalog<sup>®</sup> Mix25<sup>TM</sup>, or multiple daily injections (MDI), consisting of up to three mealtime injections of a prandial insulin on top of their basal insulin. BioChaperone<sup>®</sup> Combo is designed to offer a simple and efficient alternative to these two options.

"We are very pleased to have received approval from the German regulatory agency for this new clinical study in which we aim to further demonstrate the potential medical benefit of BioChaperone<sup>®</sup> Combo in patients with type 2 diabetes, a population representing about 90 percent of people living with diabetes," said Simon Bruce, Adocia's Chief Medical Officer. "It is particularly important to compare the mealtime effect of our BioChaperone<sup>®</sup> Combo with that of Humalog Mix<sup>TM</sup> after the positive results obtained in the meal tolerance test study on people with type 1 diabetes."

In this randomized, double-blind, double-dummy, three period cross-over study, 36 subjects with type 2 diabetes will receive three consecutive daily individualized doses of each treatment: BioChaperone<sup>®</sup> Combo, Humalog<sup>®</sup> Mix25<sup>™</sup> and the simultaneous separate injections of Lantus<sup>®</sup> and Humalog<sup>®</sup>. The main objective of this study is to compare the post-meal glycemic control obtained on day 2 and day 3 with BioChaperone<sup>®</sup> Combo vs. Humalog Mix25<sup>™</sup> when administered immediately before the meal. Secondary objectives

include the evaluation of post-meal glycemic control obtained with BioChaperone<sup>®</sup> Combo vs. the separate injections of Lantus<sup>®</sup> and Humalog<sup>®</sup>, as well as an assessment of safety and tolerability of BioChaperone<sup>®</sup> Combo in these subjects. This study will be performed by Profil in Germany.

This trial (EUDRACT 2016-002515-18) is registered and will appear on 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 insulin formulation portfolio, featuring four clinical-stage products and one preclinical product, is among the largest and most differentiated in the industry.

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 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 insulin glargine and a rapid-acting insulin analog (BioChaperone Combo). Adocia is also developing an aqueous formulation of human glucagon (BioChaperone Glucagon), two combinations of insulin glargine with GLP-1s (BioChaperone Glargine Dulaglutide and BioChaperone Glargine Liraglutide) and a concentrated, rapid-acting formulation of human insulin (HinsBet U500), all of which are in preclinical development.

In December 2014, Adocia signed a partnership with Eli Lilly for the development and commercialization of the BioChaperone Lispro projects.

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

To learn more about Adocia, please visit us at <u>www.adocia.com</u>



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