Adocia initiates a clinical study on the post-meal effect of ultra-rapid BioChaperone Lispro insulin formulation

- This single-dose Phase Ib clinical trial in patients with type 1 diabetes is designed to evaluate any change in post-meal glycemic control after injection of BioChaperone Lispro, as compared to Humalog, at the time of the meal.

- This trial, led by Adocia, is the first study in the clinical development plan established as part of the Adocia-Lilly partnership.

Lyon, France, January 20, 2015 – Adocia (Euronext Paris : FR0011184241 – ADOC) announces today the initiation of a Phase Ib clinical trial evaluation for BioChaperone Lispro, an ultra-rapid formulation of insulin lispro licensed to Eli Lilly and Company. This formulation uses Adocia’s proprietary technology BioChaperone, which is believed to enable the acceleration of insulin absorption.

This is the first study to be initiated as part of the Adocia-Lilly partnership. The study aims to measure the effect of BioChaperone Lispro, injected at the time of a standardized meal, on post-meal glycemic control in type 1 diabetes patients and compare this effect to that of Humalog® (insulin lispro rDNA origin). Commercialized fast-acting insulin analogs are usually injected before the meal. An ultra-rapid insulin, meanwhile, aims to allow injection at the time of the meal, or even after the start of a meal, with the goal of reducing the magnitude of glycemic excursions. This study will be sponsored by Adocia, and performed by Profil in Germany.

“We are very pleased to announce the first clinical trial in collaboration with Lilly just a month after the signature of the agreement between our companies,” says Olivier Soula, Adocia’s R&D Director and Deputy General Manager. “This trial is the first step in testing the possible medical benefit of our ultra-rapid insulin formulation for diabetes patients.”

In this crossover, randomized, double-blind study, 36 type 1 diabetes patients will receive one dose of BioChaperone Lispro and one dose of Humalog when taking a standardized meal. The main objective of this study is to compare post-meal glycemic control obtained
after the injection of either BioChaperone Lispro or Humalog. The pharmacokinetic profiles of both products will also be monitored.

“At the end of 2014, we received the initial $50 million up-front payment written under the contract,” adds Gérard Soula, Chief Executive Officer of Adocia. “Based on our strong cash position, we will actively pursue the development of our other innovative projects.”

This trial (2014-005028-92) is registered and will appear on clinicaltrials.gov.

About Adocia:

To be a global leader in the innovative delivery of insulins and therapeutic proteins
ADOCIA is a clinical stage biotechnology company that specializes in the development of innovative formulations of already approved therapeutic proteins. It has a particularly strong expertise in the field of insulins. ADOCIA’s proprietary BioChaperone® technological platform is designed to enhance the effectiveness and safety of therapeutic proteins and their ease of use for patients.

In December 2014, ADOCIA signed a partnership with the company Eli Lilly for the development and commercialization of its new formulation of insulin lispro, BioChaperone Lispro, previously tested successfully in two phase Ib/IIa studies.

ADOCIA will continue to develop its fast-acting human insulin formulation internally. The phase IIa clinical results are expected for the first quarter 2015.

ADOCIA is also actively continuing the development of its BioChaperone Combo, a unique combination of insulin glargine, the gold-standard of basal insulin and insulin lispro, a fast-acting insulin analog. A dose-response clinical study (Phase IIa) is scheduled for Q1 2015.

In August 2014, ADOCIA also launched a phase III clinical study in India on its product based on PDGF-BB for treatment of the diabetic foot ulcer (BioChaperone PDGF-BB).

ADOCIA has extended its activities to the formulation of monoclonal antibodies, which are gold-standard biologics for the treatment of various chronic pathologies (cancer, inflammation, etc.). ADOCIA is engaged in collaborative programs with two major pharmaceutical companies in this field.

Fighting cancer with targeted treatments
DriveIn® is a nanotechnology which is intended to significantly improve delivery of active compounds into cancer cells. This new proprietary platform constitutes an exceptional opportunity to enter the oncology market by improving the efficacy of both already approved treatments and novel proprietary molecules.

« Innovative medicine for everyone, everywhere »
ADOCIA’s therapeutic innovations aim to provide solutions in a profoundly changing global pharmaceutical and economic context, characterized by (i) an increased prevalence and impact of the targeted pathologies, (ii) a growing and ageing population, (iii) a need to control public health expenditures and (iv) an increasing demand from emerging countries.

ADOCIA is listed on the regulated market of Euronext Paris (ISIN: FR0011184241; Reuters/Bloomberg ticker: ADOC, ADOC.PA, ADOC.FP) and is included in the Next Biotech index.
American Depositary Receipts representing ADOCIA common stock are traded on the US OTC market under the ticker symbol ADOCY.
For more information, visit: www.adocia.com

Contact ADOCIA
Gérard Soula - contactinvestisseurs@adocia.com
Chairman and CEO of ADOCIA
Tel.: +33 4 72 610 610
Press Relations
ALIZE RP
Caroline Carmagnol
caroline@alizerp.com
adocia@alizerp.com
Tel.: +33 1 44 54 36 61

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