Adocia Initiates a Dose-Response Phase IIa Clinical Study of Ultra-fast Acting BioChaperone® Lispro

- Current dose-response study in type 1 diabetics will guide design of pivotal Phase III trials
- In a previous Phase IIa trial, BioChaperone Lispro showed an excellent “faster-in” (faster appearance in the blood) / “faster-out” (faster blood clearance) profile, as well as an earlier onset of action and a stronger early metabolic effect compared to Humalog®
- This ultra-fast insulin analog formulation is designed to improve glycemic control, insulin’s core medical benefit


Based on the excellent results announced in April this year from the first Phase IIa clinical study of BioChaperone Lispro vs. Humalog (Eli Lilly’s insulin lispro product) in type 1 diabetics, Adocia is laying the groundwork for pivotal clinical trials. The objective of this second Phase IIa clinical trial is to measure the dose-response relationship for BioChaperone Lispro and to further confirm the improvement in performance relative to Humalog.

“Launching this phase 2a within one month after the release of the clinical data of the previous trial reflects our commitment to rapidly deliver to patients what we believe could be a superior treatment compared to currently available prandial insulins.” said Olivier Soula, R&D director and Deputy General Manager of Adocia.

In this double-blind, randomized, four-period cross-over study, 36 type 1 diabetic patients under euglycemic clamp will be dosed with three increasing doses of BioChaperone Lispro and one dose of Humalog. The primary objective is to investigate BioChaperone Lispro’s dose-response and dose-exposure relationships. The secondary objective is to confirm previous results by comparing the pharmacokinetics and the glucodynamic action of BioChaperone Lispro with Humalog at the same dose.
Adocia recently reported positive clinical data for its first phase IIa trial on BioChaperone Lispro. In this study, BioChaperone Lispro showed a "faster-in" (i.e. faster appearance in the blood) and "faster-out" (i.e. faster clearance) profile than Humalog. This translated into a 30% more rapid onset of action of BioChaperone Lispro and a 69% greater early metabolic effect compared to Humalog. By more closely mimicking the way insulin is secreted in healthy individuals after a meal, the use of BioChaperone Lispro should enable improved post-prandial glucose control in patients, as well as a more convenient dosing of insulin during or after a meal.

With the present dose-response study, Adocia intends to consolidate its clinical proof-of-concept package before initiating Phase III trials, in line with the accelerated development path established by Novo Nordisk for its ultra-fast formulation of insulin aspart (FiAsp). Adocia intends to meet with both the FDA and the EMA this year in order to obtain further guidance on a mutually acceptable clinical development plan.

Results from the new study are expected in Q4 2014.

About diabetes

Diabetes is a chronic condition in which the person has high blood glucose (hyperglycemia), either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. Over time, chronic hyperglycemia contributes to disease progression and results in macrovascular and microvascular complications. Worldwide, more than 382 million individuals are currently suffering from diabetes, with a forecast of 592 million individuals by 2035, i.e. an average increase of 55%, and an increase of as much as 70% in emerging countries. (Source: International Diabetes Federation, 2013).

About Adocia:

To be a global leader in the delivery of insulins and therapeutic proteins

Adocia is 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.

Adocia has successfully completed two Phase I and II studies of a fast-acting human insulin formulation, two Phase I and II studies of an ultra-fast-acting insulin lispro and a Phase I/II of a unique combination of insulin glargine, the gold-standard of basal insulin and insulin lispro, a fast-acting insulin analog. Dose-escalation Phase IIa studies of all three products are scheduled for 2014.

The company has also obtained positive results in a Phase I/II study of a diabetic-foot-ulcer-healing product based on PDGF-BB (Platelet-Derived Growth-Factor BB). A phase III clinical trial dossier has been filed with Indian regulatory authorities, and the trial is expected to start in 2014.

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 remarkably efficient in delivering active compounds into cancer cells. This new 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 at providing 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 its share price is included in the Next Biotech index. For more information, visit [www.adocia.com](http://www.adocia.com)

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**Contact**

Gerard Soula - contactinvestisseurs@adocia.com  
Chairman and CEO, Adocia  
Tel.: +33 4 72 610 610

**Press Relations**

ALIZE RP  
Caroline Carmagnol / Sayuli Nishioka  
[caroline@alizerp.com](mailto:caroline@alizerp.com) – [sayuli@alizerp.com](mailto:sayuli@alizerp.com)  
Tel.: +33 170 225 390

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