



## PRESS RELEASE

## Adocia Announces Positive Preclinical Results for a Concentrated Ultra-Fast insulin, BioChaperone<sup>®</sup> Lispro U300

- **BioChaperone Lispro U300 could be the first concentrated formulation of an insulin analog to be ultra-fast acting**
- **New, proprietary insulin formulation could meet the requirements of diabetic patients prescribed large insulin doses**
- **BioChaperone Lispro U300 is the fourth insulin-based product developed by Adocia**

**Lyon, France, June 10<sup>th</sup>, 2014** - Adocia (Euronext Paris: FR0011184241 – ADOC) announced today positive preclinical results for its concentrated formulation of insulin lispro, BioChaperone Lispro U300. The study showed that BioChaperone Lispro U300 had a faster onset of action than Humalog<sup>®</sup> (Eli Lilly) at 100 IU/mL. Adocia's concentrated formulation uses the proprietary technology BioChaperone<sup>®</sup> which succeeds in accelerating the absorption of prandial insulins and which has already been used in two products currently in clinical development (BioChaperone Lispro and HinsBet<sup>®</sup>).

Prandial insulin is administered to ensure a better glycemic control in patients following meals. This control is critical in order to avoid hyperglycemic events which are the main cause of diabetes-related complications. A growing number of overweight patients and patients with severe insulin resistance require higher insulin dosage. For these patients, there is a need to develop concentrated insulin solutions, in order to inject higher doses at constant volume. However, preserving efficacy of concentrated prandial insulins is a challenge, since increasing insulin concentration is known to slow its absorption kinetics and hamper its fast action. The preclinical data show BioChaperone Lispro U300 has an ultra-fast action compared to Humalog U100, equivalent to the one obtained with BioChaperone Lispro U100.

"We are very excited to have demonstrated that our technology improves prandial insulin analogs medical performance at high concentration" commented Olivier Soula, General Deputy Manager and Director of R&D at Adocia. "To our knowledge, BioChaperone Lispro U300 is the first concentrated formulation of an insulin analog to be ultra-fast acting. The goal with BioChaperone Lispro U300, just like BioChaperone Lispro U100, is to get closer to the endogenous insulin secretion observed in healthy subjects following meals."

In this preclinical cross-over study, BioChaperone Lispro U300 was compared to Humalog in a model established and correlated to human. This correlation was based on the phase 2 BioChaperone Lispro clinical results. The comparison of the pharmacodynamics and pharmacokinetics of BioChaperone Lispro

U300 and Humalog demonstrated a faster action for BioChaperone Lispro U300, despite the increased concentration.

“BioChaperone Lispro U300, our fourth insulin based product, reinforces our portfolio of insulin formulations, which is one of the most complete in the field. This concentrated formulation of insulin lispro has the potential to differentiate Adocia from other insulin players. Furthermore, this extension of our product portfolio underscores our motivation to innovate in the insulin therapy field in order to significantly improve the lives of patients”, said Gérard Soula, CEO of Adocia.

A phase 1/2 clinical study with BioChaperone Lispro U300 is scheduled for the first half of 2015. The BioChaperone technology for prandial insulin is protected by six families of patents valid for some of them until 2033.

### About ultra-concentrated prandial insulin

More and more patients are requiring larger quantities of prandial insulin to correct glucose levels following meals. This is due on the one hand to the evolution of the illness which leads to insulin resistance, and on the other hand to the weight gain of a significant group of type 2 diabetic patients, which creates a limit to the absorption of insulin subcutaneously. These two factors contribute to the increase in the insulin dose injections for the same patient over the years.

Currently, the only concentrated prandial insulin on the market is the human insulin at 500 IU/mL (Humulin® R500, Eli Lilly) whose acting time is significantly slower than those of modern prandial insulins at 100 IU/mL such as Humalog, NovoLog® (Novo Nordisk) and Apidra® (Sanofi).

The formulation of the insulin Lispro at 300 IU/mL with BioChaperone could have an action time comparable to the ultra-fast BioChaperone Lispro U100 currently in clinical development with very promising phase 2 results.

### 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 the third and the fourth quarter 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 at the beginning of the third quarter 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.

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

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