

# PRESS RELEASE

Adocia Announces Approval to Start a Phase IIa Clinical Study of HinsBet<sup>®</sup>, its Fast-acting Human Insulin, in Type 1 Diabetes

- HinsBet's objective is to improve human insulin performance in a cost-effective way
- Phase II a study will compare HinsBet to a fast-acting insulin analog and a regular human insulin in type 1 diabetic patients
- First Patient In planned for the first week of August

**Lyon, France, July 9<sup>th</sup>, 2014 -** Adocia (Euronext Paris: FR0011184241 – ADOC) announced today that BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte*), the German regulatory agency for **drugs and medical devices**, has approved the initiation of a Phase IIa clinical study of HinsBet<sup>®</sup>, a fast-acting formulation of human insulin. HinsBet is a new type of prandial insulin, developed using the Company's proprietary BioChaperone<sup>®</sup> technology, that has been designed to reconcile the performance of insulin analogs with the cost-effectiveness of human insulin.

The aim of this Phase IIa clinical trial is to demonstrate that HinsBet acts faster than Humulin<sup>®</sup> (human insulin, Eli Lilly) and as fast as Humalog<sup>®</sup> (insulin lispro, Eli Lilly), allowing patients who use human insulin to achieve a better glycemic control after a meal. In this double-blind, randomized, 3 arm, crossover study, the pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of HinsBet will be compared to those of Humulin and Humalog. 36 patients with type 1 diabetes will receive single 0.2 U/kg doses of HinsBet, Humulin and Humalog under automated euglycemic clamp conditions. Adocia plans to dose the first patient during the first week of August. Results are expected in Q1 2015.

Many insulin-dependent diabetic patients rely on prandial insulin to control their glycemia after a meal. These treatments aim to replicate the quasi-immediate secretion of insulin observed in healthy people when having a meal. Two main prandial insulin options are available, human insulin and fast-acting insulin analogs. About 80% of diabetic patients, *i.e.* more than 300 million, live in low- and middle-income countries <sup>(1)</sup>. In those countries, human insulin remains the prandial insulin treatment of choice due to its greater affordability and accessibility. However, human insulin acts more slowly than insulin analogs, requiring patients to inject 30 minutes before the meal instead of 15 minutes with insulin analogs. This additional delay represents a real obstacle for patients to control their glycaemia and puts them at risk of hyper- and hypo-glycaemia.

"Diabetic patients have the same medical needs, wherever they may live," commented Gérard Soula, CEO of Adocia "With HinsBet, our objective is to make improved insulin treatment accessible to the largest

population of patients, by offering a product that combines the efficacy of insulin analogs with the lower price of human insulin".

The accelerated action of human insulin observed with HinsBet has been enabled by the proprietary BioChaperone technology, as demonstrated in two previous clinical studies. In addition, this technology has already proven to be safe and to also accelerate the action of another insulin, insulin lispro, in a phase IIa clinical study on type 1 diabetic patients.

"We are excited to launch this new study with HinsBet after the successful phase IIa study with BioChaperone Lispro U100" stated Olivier Soula, General Deputy Manager and Director of R&D at Adocia. "The BioChaperone technology accelerates the action of all prandial insulins, as reflected by our prandial insulin portfolio: HinsBet, BioChaperone Lispro, currently being tested in a Phase II, dose-response study and BioChaperone Lispro U300 for which we are preparing a clinical study."

(1) Source: International Federation of Diabetes, 2013

# About HinsBet

HinsBet is an innovative, fast-acting formulation of human insulin using the proprietary BioChaperone technology that was designed to combine the performance of prandial insulin analogs with the low cost of human insulin. A previous formulation of HinsBet was successfully tested in a Phase I/II clinical study in 2012. Since then, Adocia has developed an optimized formulation of HinsBet. This new formulation showed an even stronger performance, relative to human insulin and insulin lispro, in Adocia's preclinical pig model, which has shown to be correlated with humans. This is the formulation that is going to be clinically tested in the present study.

Adocia's insulin portfolio is protected by 17 patents application families across the world, some of them being in force until 2030.

### 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 Human Insulin

Human insulin represented in 2013 a global market of \$3.5 bn (Source: Annual reports of main companies) and remains the insulin of choice in the non-western world, due to its lower cost and higher accessibility. Low- and middle-income countries also witness the fastest growth of the diabetes pandemic (Source: International Federation of Diabetes, 2013). To answer the resulting increasing demand, significant investments have been made in recent years both by global and local actors to build new human insulin facilities throughout Asia and the Middle East.

### About Adocia

# To be a global leader in the innovative 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<sup>®</sup> 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 IIa 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. A dose-escalation Phase IIa study of BioChaperone Lispro U100 is ongoing, and a dose-escalation Phase IIa study of BioChaperone Combo is scheduled for 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

Drive *In*<sup>®</sup> 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 <u>www.adocia.com</u>

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