

**ADOCIA**

innovative medicine  
for everyone, everywhere



## PRESS RELEASE

### **Adocia initiates two clinical studies on its combination of long-acting insulin glargine and fast-acting insulin lispro, BioChaperone<sup>®</sup> Combo**

- **The first 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 Combo, as compared to HumalogMix<sup>®</sup>, at the time of the meal.**
- **The second single-dose Phase Ib clinical trial in patients with type 2 diabetes is designed to compare the pharmacodynamics profile of BioChaperone Combo to that of HumalogMix and of a double injection of Lantus<sup>®</sup> and Humalog<sup>®</sup>.**

**Lyon, France, July 10, 2015** – Adocia (Euronext Paris: FR0011184241 – ADOC) announces today the initiation of two Phase Ib clinical trials evaluating its innovative formulation combining insulin glargine (Lantus, Sanofi), the gold-standard of long acting insulin, to a fast-acting insulin analog, insulin lispro (Humalog, Eli Lilly and company). This unique combination is made possible thanks to the BioChaperone technology developed by Adocia, which makes insulin glargine compatible with fast-acting insulin analogs.

Insulin treatment intensification for type 2 diabetic patients usually requires the addition of a fast-acting insulin to a long-acting insulin when patients are not reaching glycemic treatment goals on long-acting insulin alone. Today, patients requiring intensive insulin therapy have two treatment options: either a premix insulin, which is a formulation of a single insulin with both fast and long actions, or an association of two distinct products, a long-acting insulin and a fast-acting insulin. This second option, basal/bolus regimen, is not always a realistic option for a large number of patients because of the treatment complexity and the large number of daily injections, up to 4.

Premix insulins, such as NovoMix (Novo Nordisk) and HumalogMix (Lilly), ease everyday life for diabetic patients, who can manage their glycaemia using only one product injected twice daily. Premix insulin analogs have been commercialized for more than ten years and are estimated to generate annual revenues of more than \$2 billion, with significant growth in

emerging markets. However, premix insulins do not offer ideal medical performance because of a delayed prandial action, a basal action profile shorter than 24 hours and an elevated risk of hypoglycemia.

“We are very excited to have received the approval from the German regulatory agency for these two studies to pursue the clinical development on one of our key insulin products,” says Olivier Soula, Adocia’s R&D Director and Deputy General Manager. “We are expecting to further demonstrate the potential of BioChaperone Combo to answer the need for simple but yet efficient insulin treatments.”

The first study aims to measure the effect of BioChaperone Combo, 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 HumalogMix, based on insulin lispro (Lilly). In this double-blind, randomized crossover study, 28 subjects with type 1 diabetes will receive one individualized dose of BioChaperone Combo and one individualized dose of HumalogMix at the beginning of a standardized mixed meal. Commercialized premix insulin analogs are known to have a delayed onset of action compared to fast-acting insulins and hence, do not properly control the glycemic increase associated with the meal.

The second clinical trial is an euglycemic clamp study in type 2 diabetes patients to compare the pharmacodynamic profile of BioChaperone Combo to that of HumalogMix and of the double injection of Lantus and Humalog. In this double-blind, randomized crossover study, 24 subjects with type 2 diabetes will receive one dose of BioChaperone Combo (0.8 IU/kg), versus one dose of HumalogMix (0.8 IU/kg), versus simultaneous doses of Lantus (0.6 IU/kg) and Humalog (0.2 IU/kg) injected at the same time. These two clinical studies are performed by Profil GmbH in Germany.

“The post-meal glycemic control study clearly aims at generating clinically relevant data for demonstrating the potential medical benefit of the product,” says Simon Bruce, MD, Adocia’s Chief Medical Officer. “The clinical study in type 2 diabetes patients is also very interesting to establish the proof of concept in the population of patients for which BioChaperone Combo is first intended.”

## 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 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. Two clinical studies are planned over 2015, a post-meal glucose control study with HinsBet U100 and a PK/PD study with HinsBet U500. 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 third clinical study, a dose-response in type 1 diabetic patients, is also scheduled for the fourth quarter of 2015.

In addition, Adocia 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) in August 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<sup>®</sup> 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 in Paris (ISIN: FR0011184241; Reuters/Bloomberg ticker: ADOC, ADOC.PA, ADOC.FP) and is included in the Next Biotech, Tech 40 and SBF 120 indexes.

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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### **For more information please contact:**

<b>Adocia</b> G�rard Soula Chairman and CEO of Adocia <a href="mailto:contactinvestisseurs@adocia.com">contactinvestisseurs@adocia.com</a> Tel.: +33 4 72 610 610	<b>Adocia Press Relations</b> <b>ALIZE RP</b> Caroline Carmagnol <a href="mailto:caroline@alizerp.com">caroline@alizerp.com</a> <a href="mailto:adocia@alizerp.com">adocia@alizerp.com</a> Tel.: + 33 1 44 54 36 61
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