

**ADOCIA**

innovative medicine  
for everyone, everywhere



## PRESS RELEASE

### **Adocia Initiates a Phase 1/2 Clinical Trial on the Post-Meal Effect of Rapid-Acting Human Insulin, HinsBet® U100**

**Lyon, France, April 11 , 2016** – Adocia (Euronext Paris: FR0011184241 - ADOC), announced today the initiation of a Phase 1b clinical trial to evaluate the post meal effects of HinsBet U100 in subjects with type 1 diabetes. HinsBet is a rapid-acting formulation of recombinant human insulin using Adocia’s proprietary technology BioChaperone, which is designed to accelerate insulin absorption. Another application of this technology, to accelerate insulin analogs such as insulin lispro, was licensed to Eli Lilly in December 2014. BioChaperone Lispro has shown an ultra-rapid profile, relative to Humalog® (insulin lispro, Lilly), in four Phase 1/2 clinical studies.

The trial aims to assess the effect of HinsBet, injected at the start of a standardized mixed meal, on post-meal glycemic control in patients with type 1 diabetes in comparison with the effect exhibited by Humalog® (insulin lispro, Lilly) and Humulin® (regular human insulin, Lilly). Prandial insulins aim to control blood glucose during and after the meal. Whereas regular human insulin is recommended to be injected 30 minutes before a meal to achieve optimal control, prandial insulin analogs have an accelerated profile allowing for injection just 15 minutes before the meal. This difference is important to reduce post-meal hyperglycemia, a primary cause of the long term complications of diabetes.

HinsBet is designed to act as rapidly as a prandial insulin analog while taking advantage of the lower cost of human insulin to facilitate easy access for patients worldwide.

“This study builds on the positive results obtained from a previously completed euglycemic clamp study in which HinsBet displayed a 70% percent earlier onset of action as well as a doubling of early metabolic effect, when compared to Humulin,” said Simon Bruce, Chief Medical Officer of Adocia. “Investigating the effect of HinsBet’s prandial glycemic control following an actual meal serves as a critical step towards demonstrating the potential medical benefit of this product for patients with diabetes.”

The Phase 1b trial is a randomized, double-blind, three-treatment, three-period cross-over trial in 36 patients with type 1 diabetes. Subjects enrolled in the trial will receive individualized

single doses of rapid-acting human insulin (HinsBet), insulin lispro (Humalog) and regular human insulin (Humulin) immediately prior to ingesting a standardized mixed meal. The main objective of this study is to compare post-meal glycemic control obtained with HinsBet or Humulin relative to a standardized meal. Secondary objectives include the comparison of post-meal glycemic control obtained after administering an injection of HinsBet or Humalog, as well as comparisons between the post-meal pharmacokinetic profiles of the three products and the assessment of their safety and tolerability.

The trial is registered and will appear on [clinicaltrials.gov](http://clinicaltrials.gov).

#### About ADOCIA

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins. Adocia's insulin formulation portfolio, featuring four clinical-stage programs and one preclinical program, is among the largest and most differentiated in the industry.

The proprietary BioChaperone® technological platform is designed to enhance the effectiveness and/or safety of therapeutic proteins while making them easier for patients to use. Adocia customizes BioChaperone to each protein for a given application in order to address specific patient needs.

Adocia's clinical pipeline includes a unique formulation of PDGF-BB for the treatment of diabetic foot ulcer and four novel insulin formulations for the treatment of diabetes: two ultra-rapid formulations of insulin analogs (BioChaperone Lispro U100 and U200), a rapid-acting formulation of human insulin (HinsBet U100) and a combination of insulin glargine and a rapid-acting insulin analog (BioChaperone Combo). Adocia is also developing a concentrated, rapid-acting formulation of human insulin (HinsBet U500). In December 2014, Adocia signed a partnership with Eli Lilly for the development and commercialization of the BioChaperone Lispro programs.

Adocia's extended, early-stage programs include innovative monoclonal antibody formulations, featuring two ongoing collaborations programs with major pharmaceutical companies in the field, and the delivery of anticancer drugs using the proprietary DriveIn® nanotechnology platform.

*Adocia aims to deliver "Innovative medicine for everyone, everywhere."*

To learn more about Adocia, please visit us at [www.adocia.com](http://www.adocia.com)



#### For more information please contact:

<p><b>Adocia</b> Gérard Soula Chairman and CEO <a href="mailto:contactinvestisseurs@adocia.com">contactinvestisseurs@adocia.com</a> Tél. : +33 4 72 610 610</p>	<p><b>Adocia Press Relations France</b> <b>ALIZE RP</b> Caroline Carmagnol and Florence Portejoie <a href="mailto:caroline@alizerp.com">caroline@alizerp.com</a> <a href="mailto:adocia@alizerp.com">adocia@alizerp.com</a> Tél. : + 33 1 44 54 36 61</p>	<p><b>Adocia Press Relations Europe</b> <b>MC Services AG</b> Raimund Gabriel <a href="mailto:raimund.gabriel@mc-services.eu">raimund.gabriel@mc-services.eu</a> <a href="mailto:adocia@mc-services.eu">adocia@mc-services.eu</a> Tél. : +49 89 210 228 0</p>
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