Adocia Announces Positive Topline Results from a Phase 1b Clinical Trial Measuring the Post-Meal Effect of Rapid-Acting Human Insulin, HinsBet® U100

- The clinical trial met its primary endpoint, demonstrating superiority of HinsBet® over Humulin® in postprandial blood glucose control one hour post-meal
- HinsBet also showed a similar effect to that of Humalog® on postprandial blood glucose control over the first hour post-meal
- Future development options are under evaluation

Lyon, France, October 27, 2016 – Adocia (Euronext Paris: FR0011184241 - ADOC), a clinical stage biopharmaceutical company focused on diabetes treatment with innovative formulations of approved proteins, announced today positive topline results from a Phase 1b clinical trial evaluating 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®, designed to accelerate insulin absorption.

The goal of the current study was to compare the effects of HinsBet, Humulin® (regular human insulin; Eli Lilly and Co), and Humalog® (insulin lispro; Eli Lilly and Co) when injected at the start of a standardized mixed meal, on post-meal glycemic control in patients with type 1 diabetes. Regular human insulin is currently indicated for administration 30 minutes before a meal in order to compensate for a delay in its onset of action.

“We are excited that this meal tolerance test study confirms a faster onset of action for HinsBet compared to regular human insulin and a similar onset of action compared to Humalog,” said Simon Bruce, Chief Medical Officer of Adocia. “An early effect of insulin is
especially important to limit postprandial hyperglycemia, which has been shown to result in long-term complications for people with diabetes.”

The randomized, double-blind, three-treatment, three-period cross-over Phase 1b trial enrolled 36 people with type 1 diabetes. Subjects received individualized single doses of rapid-acting human insulin (HinsBet), regular human insulin (Humulin) and rapid-acting analog insulin lispro (Humalog) immediately before ingesting a standardized mixed meal. The primary endpoint of this study was to compare the effect of HinsBet and Humulin on the post-meal glycemic control one hour after the meal. This study successfully met its primary endpoint, as HinsBet treatment resulted in lower blood glucose one hour after the meal compared to Humulin treatment (BG1h=228 mg/dL with HinsBet vs. 253 mg/dL with Humulin, LSM ratio 0.9, 95% CI, p=0.0002).

Secondary endpoints included the comparison of post-meal glycemic control over the first hour after the meal obtained with HinsBet and Humalog, as well as comparisons between the post-meal pharmacokinetic profiles of the three products and the assessment of their safety and tolerability. There was no significant difference found between HinsBet and Humalog on their effect on postprandial glucose excursion over the first hour after the meal (AUCBG0-1h=174 h*mg/dL with HinsBet vs. 172 h*mg/dL with Humalog, LSM ratio 1.0, 90% CI, p=0.5373). Conversely, HinsBet significantly reduced postprandial glucose excursion over the first hour compared to Humulin (AUCBG0-1h=174 h*mg/dL with HinsBet vs. 192 h*mg/dL with Humulin, LSM ratio 0.9, 95% CI, p=0.0002).

HinsBet, Humulin and Humalog were similarly well tolerated. No new or unexpected safety findings were observed.

Adocia intends to submit these results for presentation at a major diabetes-related conference. Until such time, detailed results for this trial will remain under embargo.

“We see a significant need for a cost-effective prandial insulin, especially in emerging markets. Based on these positive results, we are envisaging further development of HinsBet for these regions, as well as other development options” commented Gérard Soula, Chief Executive Officer and President of Adocia.

**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 products and one preclinical product, 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 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 basal insulin glargine and rapid-acting insulin lispro (BioChaperone Combo).

Adocia is also developing an aqueous formulation of human glucagon (BioChaperone Human Glucagon), two combinations of insulin glargine with GLP-1s (BioChaperone Glarginine Dulaglutide and BioChaperone Glarginine Laraglutide) and a concentrated, rapid-acting formulation of human insulin (HinsBet U500), all of which are in preclinical development.

In December 2014, Adocia signed a partnership with Eli Lilly for the development and commercialization of the BioChaperone Lispro projects.

*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)
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