



PRESS RELEASE

Adocia announces positive topline study results comparing ultra-rapid insulin BioChaperone[®] Lispro with Novolog[®] and Fiasp[®] in people with type 1 diabetes

- **In this study using insulin pumps, BioChaperone Lispro U100 displayed faster-on and faster-off metabolic effects compared to Novolog[®], confirming previous findings in studies versus Humalog[®]**
- **BioChaperone[®] Lispro U100 showed a significantly faster-off effect compared to Fiasp[®] and similar ultra-rapid onset of action**

Lyon, France, December 6, 2017 – 6 pm CET – Adocia (Euronext Paris: FR0011184241-ADOC), the clinical biopharmaceutical company focused on developing innovative formulations of approved proteins for the treatment of diabetes, announced today positive topline results of a clinical study evaluating BioChaperone[®] Lispro, an ultra-rapid formulation of insulin lispro, compared to Novolog[®] (insulin aspart, Novo Nordisk), a rapid-acting insulin analog, and Fiasp[®] (faster-acting insulin aspart, Novo Nordisk), the only EMA-approved (European Medical Agency) and FDA-approved (Federal Drug Administration, USA) “ultra-rapid acting” insulin formulation.

This Phase 1 study in insulin pumps is the first head-to-head comparison of two “ultra-rapid acting” insulin formulations. In this double-blind, randomized, three-period crossover study, 42 participants with type 1 diabetes received single doses (0.15 U/kg), under a euglycemic clamp procedure, of BioChaperone Lispro U100, Fiasp and Novolog, administered by an insulin pump (Medtronic MiniMed Paradigm[®] Veo) on three separate dosing visits. Objectives of the study included the comparison of the glucodynamic effects and the pharmacokinetic profiles obtained with the three agents. Safety and tolerability assessments were also performed.

“The compelling performance of BioChaperone Lispro in a pump setting establishes our product as a strong contender in the emerging ultra-rapid insulin class, across a full array of injection devices.” commented Olivier Soula, Deputy General Manager and R&D Director of Adocia. *“With major diabetes players actively pursuing an integrated model to exploit synergies between therapeutics, smart devices and connected care, we are convinced that ultra-rapid insulin will be a critical component in delivering better outcomes for people with diabetes.”*

BioChaperone Lispro met the primary objective of the study by demonstrating a statistically significant 63% increase in metabolic effect during the first hour vs. Novolog (LS- Mean AUC_{GIR 0_1h} = 162 mg/kg vs. 99 mg/kg; $p < 0.0001$), confirming the ultra-rapid profile observed in previous studies vs. Humalog® (insulin lispro, Eli Lilly).

Additionally, BioChaperone Lispro displayed a statistically significant faster-off metabolic profile vs. both other products, reaching late half-T_{max} 18 minutes before Fiasp and 22 minutes before Novolog (Late Time to 50% of GIR_{max} = 210 min for BioChaperone Lispro vs. 228 min for Fiasp; $p = 0.0017$ and 232 min for Novolog, $p = 0.002$). BioChaperone Lispro also demonstrated a similar early metabolic effect as Fiasp during the first hour (LS- Mean AUC_{GIR 0_1h} = 162 mg/kg vs. 154 mg/kg; NS). All three treatments lead to similar total effects.

"This study confirmed not only BioChaperone Lispro's ultra-rapid action profile, but also its best-in-class pharmacodynamic performance in an insulin pump, a setting in which the most impressive results of Fiasp to date have been reported. Interestingly, in all our BioChaperone Lispro studies, our product has shown extremely consistent performance across devices and patient populations." commented Dr. Stanislav Glezer, Adocia's Chief Medical Officer. *"These data support the potential of BioChaperone Lispro to become the most precise insulin tool for achieving glycemic control, which is a daily struggle for many people living with diabetes."*

Dr. Bruce Bode, M.D, FACE, Clinical Associate Professor at Emory University (USA), added *"Insulin pumps are currently used by approximately 40% of people with type 1 diabetes in the United States. For these people, the emergence of hybrid closed-loop delivery systems is a great stride towards better glycemic control and improved quality of life. In addition to the rapid onset of action, the faster-off effect observed with BioChaperone® Lispro in this study could be critical to potentiate the effect of the algorithms used in these systems. As such, it brings tremendous hope for better diabetes management solutions in the near future."*

BioChaperone Lispro, Novolog and Fiasp were all similarly well tolerated. No new or unexpected safety findings were reported and no local reactions were seen on the site of administration for any treatment.

Detailed results for this study will be submitted for presentation at a major diabetes conference in 2018.

About BioChaperone® Lispro

BioChaperone® Lispro incorporates Adocia's proprietary technology, BioChaperone®, which is designed to enable the acceleration of insulin absorption. BioChaperone Lispro had previously demonstrated an accelerated insulin action profile across multiple Phase 1/2 studies in people with type 1 and type 2 diabetes compared to that of insulin analog lispro (Humalog®, Eli Lilly), when injected with insulin syringes and insulin pumps. BioChaperone Lispro is ready to enter phase 3 clinical studies.

About Adocia

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins. Adocia's portfolio of injectable treatments for diabetes, featuring four clinical-stage products and six preclinical products, is among the largest and most differentiated of 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). An aqueous formulation of human glucagon (BioChaperone Human Glucagon) successfully completed a Phase 1 trial. Adocia also develops two combinations of insulin glargine with GLP-1s (BioChaperone Glargine Dulaglutide and BioChaperone Glargine Liraglutide), two combinations of insulin lispro with synergistic prandial hormones (BioChaperone Lispro Pramlintide and BioChaperone Lispro Exenatide), and a concentrated, rapid-acting formulation of human insulin (HinsBet U500), all of which are in preclinical development.

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

To learn more about Adocia, please visit us at www.adocia.com



For more information please contact:

Adocia Gérard Soula Chairman and CEO contactinvestisseurs@adocia.com Ph. : +33 4 72 610 610	Adocia Press Relations Europe MC Services AG Raimund Gabriel adocia@mc-services.eu Ph.: +49 89 210 228 0	Adocia Investor Relations USA The Ruth Group Tram Bui t.bui@theruthgroup.com Ph. : +1 646 536 7035
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