



PRESS RELEASE

Adocia Initiates a Phase 1b Clinical Study on the Dose-Proportionality of BioChaperone® Combo in People with Type 2 Diabetes

Lyon, France, June 7th 2017 - 6 pm CEST – Adocia (Euronext Paris: FR0011184241- ADOC), the clinical biopharmaceutical company focused on developing innovative formulations of approved proteins for the treatment of diabetes, announced today the initiation of a Phase 1b clinical trial evaluating the dose-linearity of BioChaperone® Combo 75/25 at three different doses in people with type 2 diabetes. BioChaperone Combo is a proprietary formulation combining the long-acting insulin analog glargine (Lantus®, Sanofi) and the fast-acting insulin analog lispro (Humalog®, Eli Lilly and Company). BioChaperone® technology enables this combination by solubilizing insulin glargine at neutral pH, at which it is compatible with fast-acting insulin analogs.

This study aims to document the dose exposure of BioChaperone Combo across three different doses in people with type 2 diabetes in order to assess dose-proportionality.

"We are very pleased to initiate this new study on BioChaperone Combo which is designed to answer an important regulatory requirement." commented Olivier Soula, Deputy General Manager and R&D Director of Adocia. *"Together with the positive topline results announced yesterday, this study should serve to strengthen the body of evidence supporting the improved performance of our combination vs. premix in people with type 2 diabetes."*

In this double-blinded, randomized, four-period crossover trial, using automated 30-hour euglycemic clamp, 32 participants with type 2 diabetes mellitus will be randomly allocated to a sequence of four treatments, i.e. one of three single doses of BioChaperone Combo 75/25 (0.6 U/kg, 0.8 U/kg or 1.0 U/kg) or one single dose of Humalog® Mix25™ at 0.8 U/kg, on four separate dosing visits.

The primary endpoint is assessment of dose-proportionality for the total insulin exposure across the three doses of BioChaperone Combo. Secondary endpoints include documentation of the dose-response relationship for the total metabolic effect of the three doses of BioChaperone Combo and the comparison of the pharmacodynamic and pharmacokinetic profiles of BioChaperone Combo (0.8 U/kg) with those of Humalog Mix25™ (0.8 U/kg). Objectives also include the assessment of safety and tolerability of both treatments in these participants.

Study results are expected in Q4 2017.

This study will be sponsored by Adocia and performed by Profil Neuss in Germany.

The trial is registered (NCT03180710) and will appear on 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 portfolio of injectable treatments for diabetes, featuring five clinical-stage products and five 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). Additionally, an aqueous formulation of human glucagon (BioChaperone Human Glucagon) has recently entered clinical testing. Adocia is also developing 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



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For more information please contact:

Adocia G�rard 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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Disclaimer

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