PRESS RELEASE

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Adocia Announces Positive Clinical Results Confirming the Ultra-Rapid Profile of a BioChaperone® Lispro Formulation Containing Insulin from Partner Tonghua Dongbao

- In this study, the BioChaperone Lispro formulation containing insulin lispro from Tonghua Dongbao demonstrated similar ultra-rapid pharmacokinetic, pharmacodynamic, and safety profiles when compared to a BioChaperone Lispro formulation containing insulin lispro Humalog®
- In nine previous studies, a BC Lispro formulation using insulin lispro (Humalog®) demonstrated an Ultra-Rapid profile which significantly improved glycemic control compared to Humalog®, Novolog® and Fiasp®
- Results from this study complete the dossier for BioChaperone Lispro, employing insulin lispro from Tonghua Dongbao, required for initiation of Phase 3 studies in China, Europe, and the US
- This study confirms the performance of the insulin lispro drug substance supplied by our strategic partner, Tonghua Dongbao

6pm CET- Adocia (Euronext Paris: FR0011184241 – ADOC, the "Company"), the biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, announced today positive results from a clinical pharmacology study comparing BioChaperone (BC) Lispro formulations employing insulin lispro from two different sources, a biosimilar from Tonghua Dongbao (THDB) and the brand, Humalog®, from Eli Lilly.

"*We are pleased with the clinical results Adocia has obtained using our insulin lispro. These results are quite valuable for both companies, as they may serve to advance the launch of Phase 3 studies of BC Lispro in 2021 in China*", comments Dr Chunsheng Leng, the Tonghua Dongbao CEO.

This randomized, cross-over, double-blind, euglycemic clamp study was conducted on 30 people with type 1 diabetes. The study aimed to assess and compare the pharmacodynamic and pharmacokinetic properties as well as the safety of the four following formulations:

- BC Lispro (Adocia) composed of BioChaperone® and Tonghua Dongbao 's insulin lispro
- BC Lispro (Adocia) composed of BioChaperone® and the insulin lispro, Humalog®
- Humalog® (Eli Lilly) approved in the USA
- Humalog® (Eli Lilly) approved in Europe

The BC Lispro (THDB) formulation demonstrated similar pharmacodynamic and pharmacokinetic properties to BC Lispro formulated with Humalog®, the formulation previously assessed in nine clinical trials.

Specifically, the BC Lispro (THDB) formulation demonstrated a significantly faster absorption profile than the two commercial formulations of Humalog® (insulin lispro exposure over the first hour after injection $AUC_{Lispro\_0\text{-}1h}$: 550 pmol*h/L for BC Lispro (THDB), 379 pmol*h/L for Humalog® Europe ($p<0.0001$ v BC Lispro (THDB)) and 366 pmol*h/L for Humalog US ($p<0.0001$ vs BC Lispro (THDB)); and a faster-on effect (area under the glucose infusion rate curve for the first hour $AUC_{GIR\_0\text{-}1h}$: 200 mg/kg for BC Lispro (THDB) ; 95 mg/kg for Humalog® Europe ($p=0.0027$) and 83 mg/kg for Humalog® US ($p=0.0002$)).

Conversely, BC Lispro (THDB) displayed fast-out/fast-off characteristics since the late exposure and late effect of BC Lispro (THDB) are lower than those of both Humalog formulations (insulin lispro exposure over 2-6h post-dosing $AUC_{Lispro\_2\text{-}6h}$: 802 pmol*h/L for BC Lispro (THDB), 953 pmol*h/L for EU-Humalog ($p<0.0001$ vs BC Lispro (THDB)) and 1014 pmol*h/L for US-Humalog ($p<0.0001$ vs BC Lispro (THDB); area under the glucose infusion rate curve over 4-8h post-dosing $AUC_{GIR\_4\text{-}8h}$: 175 mg/kg for BC Lispro (THDB), 268 mg/kg for EU-Humalog ($p=0.0003$ vs BC Lispro (THDB)) and 277 mg/kg for US-Humalog ($p=0.0001$ vs BC Lispro THDB)).

All four interventions were safe and well tolerated.

These results confirm the ultra-rapid insulin action profile of BC Lispro, and a safety profile similar to that of Humalog®. This study was approved by the German Health Authority on the 24th of July 2020, as well as by the FDA on the 29th of July 2020 as part of an IND study.

"*This is a very important step for Adocia as we now feature a product ready for Phase 3 studies worldwide. Moreover, it is a product supported by a global supply agreement for high quality lispro drug substance from our partner Tonghua Dongbao. Our priority remains to find a partner to lead the Phase 3 program for Europe and the United States*", comments Olivier Soula, the Deputy CEO and Director of R&D at Adocia.

About BioChaperone® Lispro

BioChaperone® Lispro (BC Lispro) is an ultra-rapid prandial insulin formulation containing insulin lispro and the proprietary technology BioChaperone®. The BioChaperone® excipient ensures a faster absorption of insulin. BC Lispro has demonstrated a faster action profile compared to insulin analog lispro (Humalog®, Eli Lilly) and insulin analog aspart (Novolog®, Novo Nordisk), in nine Phase 1/2 studies in people with type 1 and type 2 diabetes, administered either by syringes or insulin pumps. Also, BC Lispro significantly improved insulin performance compared to Humalog® in six clinical studies.

In 2018, Adocia and partner Tonghua Dongbao (China) signed a strategic alliance to develop and commercialize BC Lispro in China and in other Asian and Middle East territories. Tonghua Dongbao also supplies insulin lispro and insulin glargine to Adocia for the entire world (except China). This supply allows Adocia to progress its own BC Lispro and BC Combo programs and expand its partnership opportunities. Adocia retains development rights for BC Lispro in the US, Europe, Japan and Latin America. BC Lispro is ready for out-licensing in these key territories.

For more information on BC Lispro, visit our website: https://www.adocia.com/products/biochaperone-ultra-fast-analog-insulin/

About Adocia

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of therapeutic proteins and peptides for the treatment of diabetes and metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring four clinical-stage products. 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.

Adocia's clinical pipeline includes four novel insulin formulations for prandial treatment of diabetes: two ultra-rapid formulations of insulin analog lispro (BioChaperone® Lispro U100 and U200), a combination of basal insulin glargine and rapid acting insulin lispro (BioChaperone® Combo) and one combination of a prandial insulin with amylin analog pramlintide M1Pram (ADO09). The clinical pipeline also includes an aqueous formulation of human glucagon (BioChaperone® Glucagon) for the treatment of hypoglycemia.

Adocia preclinical pipeline includes three products: a combination of rapid human insulin analogues and Pramlintide (BioChaperone LisPram), a combination of insulin glargine with GLP-1 receptor agonists (BioChaperone® Glargine GLP-1) for the treatment of diabetes and a ready-to-use combination of glucagon and a GLP-1 receptor agonist (BioChaperone® Glucagon GLP1) for the treatment of obesity.

Adocia recently added a fourth program, a preclinical stage cell therapy initiative focused on development of a hydrogel scaffold for use in people with type 1 diabetes. The first patent application supporting this program has been filed.

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innovative medicine
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