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PRESS RELEASE

Adocia initiates a 3-week Phase 1b study of ADO09, a co-formulation of pramlintide and mealtime insulin, in people with type 1 diabetes

- **ADO09 is the first co-formulation of pramlintide and the prandial A21G human insulin analog, the main metabolite of insulin glargine**
- **This study will document the safety and efficacy of ADO09 over a 24-day period of repeat administration, including an outpatient portion, aiming to inform further clinical development**
- **The primary endpoint is the effect of ADO09, compared to prandial insulin Novolog®, on postprandial glycemic control at the end of a 24-day treatment period**
- **Study completion is expected in Q4 2019**

Lyon, France, June 6th, 2019 – 6:00 pm CET - Adocia (Euronext Paris: FR0011184241 – ADOC) the biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, announces today the initiation of a Phase 1b study of ADO09, a ready-to-use, fixed ratio co-formulation of pramlintide (Symlin®, AstraZeneca), the only FDA-approved analog of amylin, and A21G human insulin analog ("A21G human insulin"), a rapid-acting insulin that is known to be the main circulating metabolite of insulin glargine (Lantus®, Sanofi). ADO09 is intended to improve post-meal glucose control and long-term outcomes for people who otherwise require prandial insulin treatment by enabling the combination of these two complementary hormones which, in normal physiology, are co-secreted by the beta cells and act synergistically to control glycemic excursions at mealtime.

This study aims to assess safety and efficacy of ADO09 compared to prandial insulin analog Novolog® (insulin aspart, Novo Nordisk) in subjects with type 1 diabetes using a multiple daily injection regimen over a 24-day period of treatment, including 4 in-clinic days and 20 outpatient days.

Adocia previously announced positive first-in-human topline clinical data for ADO09 in April 2019.

"Since the first clinical results with ADO09 were highly similar to the results obtained with the separate injections of prandial insulin and pramlintide, we were encouraged to rapidly advance the program into multiple daily dosing,

including the outpatient setting , which will help to lay the foundation for later-stage development." said Dr. Olivier Soula, Adocia's Deputy General Manager and Director of R&D.

In this randomized, double-blind, active-controlled, 2 period cross-over clinical trial, 24 subjects with type 1 diabetes will receive multiple daily doses of ADO09 and Novolog® over two periods of 24 days each (including 4 days in the clinic and 20 outpatient days), following a run-in period to optimize basal insulin regimen. Subjects will receive a continuous glucose monitoring (CGM) system for glucose monitoring and control, which will be used for safety and efficacy assessment throughout trial participation. The primary endpoint is to compare post-meal glucose profiles after bolus injections of ADO09 and Novolog®, injected immediately before a standardized mixed meal, at the end of a 24-day multiple daily injection treatment period. Additionally, the study will document the safety and efficacy of ADO09 in an outpatient setting, as well as plasma glucose control as assessed by CGM at Days 1-3 and Days 21-23 and pharmacokinetic, pharmacodynamic and gastric emptying profiles of both treatments at the beginning and end of the study.

Adocia is the sponsor of this study, which will be performed by Profil Neuss in Germany. Results of this study are expected in Q4 2019.

This trial is registered and will appear on ClinicalTrials.gov.

About ADO09

In people without diabetes, insulin and amylin are hormones co-secreted by pancreatic beta cells and act in synergy to control blood glucose. While insulin controls glucose disposal, amylin modulates glucose appearance in the blood by suppressing liver glycogenolysis through glucagon inhibition and by slowing gastric emptying. Amylin also decreases food intake by inducing satiety. As diabetes progresses, and beta cell mass declines, the secretion of both insulin and amylin is diminished and, eventually, absent.

Adocia's proprietary ADO09 formulation enables the fixed-ratio combination of the FDA-approved amylin analogue pramlintide and A21G human insulin analog ("A21G human insulin"). A21G human insulin is the main metabolite of FDA-approved insulin glargine[1]. A21G human insulin has pharmacokinetic and pharmacodynamic profiles similar to that of human insulin. Through the use of glargine, millions of people with diabetes worldwide have been exposed to A21G human insulin, which is considered to be safe[1]. Adocia has filed an international patent application on ADO09.

Pramlintide is approved in the USA for both type 1 and type 2 diabetes as an adjunct therapy to mealtime insulin treatment. The Phase 3 trials leading to pramlintide approval showed that, when added to an existing insulin regimen, pramlintide significantly improves post-prandial glucose control by flattening postprandial glucose excursions. After 6 months of use, pramlintide as an adjunct to insulin therapy resulted in improved HbA1c, reduced prandial insulin consumption, and resulted in weight loss compared to the use of insulin alone in both people with type 1[2] and with type 2[3] diabetes. Like amylin, pramlintide delays the timing and reduces the magnitude of postprandial blood glucose spikes. As intensified insulin therapy requires multiple daily injections and frequent glucose monitoring, however, the addition of daily mealtime injections of pramlintide has proved a challenge to patient adherence, compliance, and persistency.

[1] Bolli *et al.* Diabetes Care. 2012 Dec; 35(12): 2626–2630. & Lucidi *et al.* Diabetes Care. 2012 Dec; 35(12): 2647–2649; Lantus® label, Section 12.3.
[2] Whitehouse F, et al. Diabetes Care. 2002;25(4):724-730; Ratner RE, et al. Diabet Med. 2004;21(11):1204-1212.
[3] Hollander PA, et al. Diabetes Care. 2003;26(3):784-790.

By combining two synergistic agents, ADO09 is designed to deliver superior postprandial glycemic control for people with diabetes without the burden of separate administration of two different products and additional injections.

About Adocia

Adocia is a clinical-stage biotechnology company that specializes in the development of innovative formulations of already-approved therapeutic proteins and peptides for the treatment of diabetes and other metabolic diseases. In the diabetes field, Adocia's portfolio of injectable treatments is among the largest and most differentiated of the industry, featuring seven clinical-stage products. Additionally, Adocia expanded its portfolio to include the development of treatments of obesity and short bowel syndrome.

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 six novel insulin formulations for the 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), a rapid-acting formulation of human insulin (HinsBet® U100), and two combinations of a prandial insulin with amylin analog pramlintide (ADO09 and BioChaperone® Pramlintide Insulin). It also includes an aqueous formulation of human glucagon (BioChaperone® Glucagon) for the treatment of hypoglycemia. Adocia preclinical pipeline includes combinations of insulin glargine with GLP-1 receptor agonists (BioChaperone® Glargine GLP-1) for the treatment of diabetes, a ready-to-use combination of glucagon and a GLP-1 receptor agonist (BioChaperone® Glucagon GLP1) for the treatment of obesity and a ready-to-use aqueous formulation of teduglutide (BioChaperone® Teduglutide) for the treatment of short bowel syndrome.

In 2018, Adocia and Chinese insulin leader Tonghua Dongbao entered into a strategic alliance. In April 2018, Adocia granted Tonghua Dongbao licenses to develop and commercialize BioChaperone Lispro and BioChaperone Combo in China and other Asian and Middle-Eastern territories. The licensing included 50 million dollars upfront and up to 85 million dollars development milestones, plus double-digit royalties on sales. In June 2018, Tonghua Dongbao agreed to manufacture and supply active pharmaceutical ingredients insulin lispro and insulin glargine to Adocia globally, excluding China, to support Adocia's portfolio development in these territories.

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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