



PRESS RELEASE

Adocia Announces Oral Presentation Covering ADO09, its pramlintide insulin coformulation, at the 55th Annual Meeting of the European Association for the Study of Diabetes (EASD)

Lyon, France, September 10, 2019 – 6:00 pm CEST - Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical stage biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, today announced that it will deliver an oral presentation covering its ADO09 (pramlintide insulin) product at the [55th Annual Meeting of the European Association for the Study of Diabetes \(EASD\)](#), being held September 16-20, 2019 in Barcelona, Spain.

“We are excited to share, through these promising initial clinical results, the potential of ADO09, our breakthrough coformulation of prandial insulin and pramlintide for the treatment of type 1 diabetes (T1D).” said Olivier Soula, Deputy General Manager and Director of R&D at Adocia. *“With this coformulation, we aim to finally deliver on the promise of pramlintide in T1D, for which this therapeutic agent has demonstrated remarkable medical benefits, including better postprandial glycemic control and a constellation of other benefits that no other commercial treatment offers them today.”*

ADO09 is a ready-to-use, innovative co-formulation at fixed ratio of pramlintide, 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-prandial glucose control and long-term outcomes for people requiring prandial insulin treatment by enabling the synergistic combination of two complementary hormones: the amylin-analog pramlintide and prandial insulin. Indeed, in a person without diabetes, insulin and amylin are co-secreted and act synergistically to control glycemic excursions after a meal. While pramlintide, when added to an existing insulin regimen, is known to improve HbA1c, flatten postprandial glucose and result in weight loss¹, its use has been notably hampered by the need for additional daily mealtime injections of pramlintide on top of insulin therapy.

¹ Whitehouse F, et al. Diabetes Care. 2002;25(4):724-730; Ratner RE, et al. Diabet Med. 2004;21(11):1204-1212. Hollander PA, et al. Diabetes Care. 2003;26(3):784-790.

Details of the accepted abstract are presented below:

- **[Oral Presentation #109: ADO09, a co-formulation of the amylin-analog pramlintide and the A21G human insulin analog, lowers postprandial blood glucose versus insulin lispro in type 1 diabetes](#)**

Presenting Author: Dr. Grégory Meiffren
Session: OP 19 Treating diabetes with peptides from the gut
Date and Time: Wednesday, September 18, 2019 2:30 PM - 4:00 PM CEST
Location: Joslin Hall

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"), at pH 4. A21G human insulin is the main metabolite of FDA-approved insulin glargine². 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 safe³.

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 1⁴ and with type 2⁵ 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.

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.

About the EASD Annual Meeting

The EASD Annual Meeting is one of the biggest European meetings dedicated to the latest developments and insights in diabetology. The meeting attracts key opinion leaders, company executives, scientists, physicians, researchers, nurses and students interested in diabetes and related subjects. The goal of the EASD Annual Meeting is to encourage excellence in diabetes care through advances in research and education.

² 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.

³ Lantus® label, Section 12.3.

⁴ Whitehouse F, *et al.* Diabetes Care. 2002;25(4):724-730; Ratner RE, *et al.* Diabet Med. 2004;21(11):1204-1212.

⁵ Hollander PA, *et al.* Diabetes Care. 2003;26(3):784-790.

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 six 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 five 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 a combination of a prandial insulin with amylin analog pramlintide (ADO09). 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 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 agreement 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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Disclaimer

This press release contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the "Risk Factors" section of the Reference Document filed with the French Autorité des marchés financiers on April 12, 2019 (a copy of which is available at www.adocia.com) and to the development of economic conditions, financial markets and the markets in which Adocia operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Adocia to be materially different from such forward-looking statements.

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