

PRESS RELEASE

Lyon, December 12, 2024

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## ADOCIA and Tonghua Dongbao Announce the Final Dosing in a Phase 3 Clinical Study of BioChaperone<sup>®</sup> Lispro, Milestone Associated with a \$10 Million Payment

- Final dosing of the last patient concludes the Phase 3 study in people with Type 2 diabetes, event associated with a \$10 million payment from Tonghua Dongbao to Adocia
- Phase 3 topline results are expected in H1 2025
- Granting of the Marketing Authorization will trigger an additional \$20 million milestone payment, followed by double-digit royalties on sales

6:00 pm CET - Adocia (Euronext Paris: FR0011184241 - ADOC, the "Company"), a clinical-stage biopharmaceutical company focused on the research and development of innovative therapeutic solutions for the treatment of diabetes and obesity, today announced the completion of the final dosing of the last Type 2 diabetes patient in a Phase 3 clinical trial evaluating BioChaperone<sup>®</sup> Lispro, the Company's novel ultra-rapid insulin.

This clinical trial is being conducted in China by Adocia's partner, Tonghua Dongbao Pharmaceutical (Shanghai Stock Exchange: 600867), in people with Type 2 Diabetes. The final dosing of the last Type 2 diabetes patient is associated with a milestone payment of \$10 million to Adocia. This payment will be received in the second quarter of 2025 as per the payment terms of the Licensing Agreement.

A second study in people with Type 1 diabetes is nearing the end of treatment, which is expected to be in early 2025. Both Phase 3 topline results, in people with Type 1 and Type 2 diabetes, are expected in H1 2025.

Tonghua Dongbao is expected to submit the Marketing Authorization Application to the Chinese Centre for Drug Evaluation (CDE) in 2025. The grant of the Marketing Authorization would lead to an additional milestone payment of \$20 million and double-digit royalties on sales to Adocia.

**Mr. Jiahong Li**, Chairman of Tonghua Dongbao, said: "We are delighted to be working with Adocia on this innovative insulin. With the development of BioChaperone® Lispro, Tonghua Dongbao joins the very select group of companies that are innovating in the field of insulin. We look forward to making this novel product available to patients in Asia in the near future".

**Olivier Soula**, CEO and Co-Founder of Adocia, added: "Knowing the challenges to develop an innovative insulin, we are very pleased to see this large Phase 3 study completed. This additional revenue generated from a license on our BioChaperone® technology confirms our business model and will strengthen our financial situation."

**The Phase 3 clinical program**, conducted by Tonghua Dongbao, involves over 1,500 people with Type 1 and Type 2 Diabetes in 100 clinical centres across China. The aim of both pivotal trials is to demonstrate the safety and efficacy of BioChaperone® Lispro compared to standard of care Humalog® (Eli Lilly). The primary efficacy endpoint is the change in HbA1c (glycosylated haemoglobin) from baseline to 26 weeks of treatment, with a non-inferiority objective. The secondary efficacy endpoints are 1-hour and 2-hour Postprandial Glucose (PPG) excursions at week 26.

**BioChaperone® Lispro was licensed to Tonghua Dongbao** in 2018, as part of a Licensing Agreement covering China and other Asian countries<sup>1</sup>.

This region is experiencing a sharp rise in the prevalence of diabetes, with nearly 200 million people affected by the disease and an estimated 20 million people using insulin every day.

Over one in four diabetic patients in the world is in China<sup>2</sup>. Tonghua Dongbao is one of the leading insulin providers in Asia, generating over 70% of its revenues from the insulin market, highlighting its strategic commitment to the development and commercialization of BioChaperone® Lispro in China and its region.

This \$10 million milestone payment to Adocia will add up to the \$15 million already received from previous upfront and milestone payments for BioChaperone® Lispro. The Licensing Agreement also provides for a further \$20 million milestone payment upon granting of Marketing Authorization, plus double-digit royalties on future sales.

## About BioChaperone® Lispro

BioChaperone® Lispro is an Ultra-Rapid Insulin, belonging to the latest generation of prandial insulins. It combines Adocia's proprietary BioChaperone® technology with insulin lispro, the active ingredient in the standard of care, Humalog® (Eli Lilly).

This innovative formulation acts significantly faster than earlier insulin generations, effectively reducing post-meal hyperglycemia, which is a key contributor to long-term complications such as retinopathy, diabetic foot ulcers, or kidney failure. Additionally, its rapid elimination minimizes the risk of hypoglycemia, often caused when insulin level remains high after post-meal glucose levels have normalized.

The faster action profile of BioChaperone® Lispro enhances its compatibility with modern diabetes management systems, particularly insulin pump systems, and provides better integration into advanced treatment algorithms.

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<sup>1</sup> Press Release, Apr. 26, 2018: Adocia and Tonghua Dongbao Announce a Strategic Alliance for BioChaperone® Combo and BioChaperone® Lispro in China

<sup>2</sup> International Diabetes Federation, 10<sup>th</sup> Atlas, 2021

Beyond its clinical advantages, the quick onset of BioChaperone® Lispro improves quality of life by offering greater flexibility in dose timing. Patients can administer insulin at mealtime, or even right-after-mealtime, allowing for more accurate dosing based on known meal timing and content. This reduces the risks of overdosing or underdosing, which can lead to hypo- or hyperglycemia and their associated complications. The simplified dosing process eases the psychological burden on patients and caregivers, significantly alleviating the stress associated with diabetes management.

## About Tonghua Dongbao

Tonghua Dongbao Pharmaceutical Co. Ltd (SHSE: 600867), is a pharmaceutical company based in Jilin province, China, specializing in the R&D, manufacturing and marketing of insulins and other diabetes treatments. Tonghua Dongbao currently employs over 3,000 people and has sales of around \$400 million. It has been listed on the Shanghai Stock Exchange since 1994, with a market capitalization of about \$3 billion.

## About Adocia

Adocia is a biotechnology company specializing in the discovery and development of therapeutic solutions in the field of metabolic diseases, primarily diabetes and obesity.

The Company has a broad portfolio of drug candidates based on four proprietary technology platforms: 1) The BioChaperone® technology for the development of new generation insulins and products combining different hormones; 2) AdOral®, an oral peptide delivery technology; 3) AdoShell®, an immunoprotective biomaterial for cell transplantation, with an initial application in pancreatic cells transplantation; and 4) AdoGel®, a long-acting drug delivery platform.

Adocia holds more than 25 patent families. Based in Lyon, the company has about 80 employees. Adocia is listed on the regulated market of Euronext™ Paris (Euronext: ADOC; ISIN: FR0011184241).

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for everyone, everywhere



# 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 as being reasonable. However, there can be no guarantee that the estimates contained in such forward-looking statements will be achieved, as such estimates are subject to numerous risks including those set forth in the “Risk Factors” section of the universal registration document that was filed with the French Autorité des marchés financiers on April 29, 2024, as updated in the Company’s 2024 Half-year financial statements, published on September 19, 2024, both available at [www.adocia.com](http://www.adocia.com). Those risks include uncertainties inherent in Adocia’s short- or medium-term working capital requirements (the Company’s*

*current cash runway being into Q3 2025), in research and development, future clinical data, analyses and the evolution of economic conditions, the financial markets and the markets in which Adocia operates, which could impact the Company’s short-term financing requirements and its ability to raise additional funds.*

*The forward-looking statements contained in this press release are also subject to risks not yet known to Adocia or not considered as material by Adocia at this time. The occurrence of all or part of such risks could cause the actual results, financial conditions, performances, or achievements of Adocia be materially different from those mentioned in the forward-looking statements.*