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## ADOCIA and Tonghua Dongbao Announce Positive Topline Results of Phase 3 Clinical Trial on Ultra-Rapid Insulin BioChaperone<sup>®</sup> Lispro (THDB0206 injection) in people with T1D

- This Phase 3 clinical trial on BioChaperone<sup>®</sup> Lispro (THDB0206 injection) conducted in China in people with Type 1 Diabetes, successfully demonstrated, in comparison with standard of care Humalog<sup>®</sup>:
  - Non inferior HbA1c reduction at 26 weeks (primary endpoint)
  - Significant reduction of the rise of blood glucose after a test meal (key secondary endpoint)
- Blood glucose level, monitored by 10-point self-monitoring blood glucose (SMBG), was statistically decreased 1 hour after each meal in comparison with Humalog<sup>®</sup>
- These results complete and confirm the positive outcomes previously obtained with THDB0206 injection in people with Type 2 Diabetes

8:45 am CEST - 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, announces that its partner Tonghua Dongbao releases today positive topline results on the second Phase 3 clinical trial on BioChaperone<sup>®</sup> Lispro (THDB0206 injection), a novel Ultra-Rapid Insulin formulation.

Conducted by Tonghua Dongbao, this Phase 3 study was approved by the Chinese Regulatory Authorities (CDE<sup>1</sup>). The randomized, open, multicenter study evaluated the safety and efficacy of THDB0206 injection compared to Humalog<sup>®</sup> in adults with Type 1 Diabetes.

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<sup>1</sup> CDE: Center for Drug Evaluation of the National Medical Products Administration

**Mr Li**, President of Tonghua Dongbao, said: *"We are delighted with the positive results from this Phase 3 clinical trial, which confirm the benefits of THDB0206 injection for improving blood glucose control of adults with Type 1 Diabetes. Tonghua Dongbao is committed to continue to innovate in the treatment of diabetes and obesity."*

*"We are extremely proud of the Phase 3 results achieved in both Type 1 and Type 2 diabetes: for both populations, we succeeded in improving postprandial blood glucose control after each meal compared to the standard of care. BioChaperone® Lispro is the only one of the three ultra-fast insulins to achieve this level of performance across all meals of the day,"* declared **Olivier Soula**, CEO and Co-Founder of Adocia. *"This achievement positions Adocia among the few innovators in the field of insulin. The challenges related to the development of metabolic peptides such as insulin, GLP-1, amylin, GIP, and glucagon are comparable. Adocia intends to capitalize on its team's expertise and its rich portfolio of peptide delivery technologies to become a leader in the development of next-generation treatments for diabetes and obesity."*

## Results

A total of 550 Chinese adults with Type 1 diabetes with inadequate glycemic control and using daily multiple injections of insulin were randomized.

After 26 weeks of treatment, HbA1c decreased significantly in both groups compared to the baseline. The reduction in the THDB0206 injection group was comparable to that of the Humalog® group, meeting the primary endpoint.

The first key secondary endpoint was also demonstrated, with a statistically significant lower rise of blood glucose after a standard meal for the THDB0206 injection group, compared to the Humalog® group. In addition, the study shows a significant trend of blood glucose improvement 2 hours after a standard meal for the THDB0206 injection group, compared to the Humalog® group.

The 10-point self-monitoring blood glucose (SMBG) of patients at week 26, an important supportive endpoint of the trial, confirmed the advantage of this product in controlling postprandial blood glucose, with a statistical improvement 1 hour after each meal (breakfast, lunch, dinner).

In addition, the safety and tolerability of THDB0206 injection were good. Most of the adverse events were mild or moderate, and the incidence of adverse events and hypoglycemic events were similar to those of Humalog®.

Those results confirm the positive results obtained with THDB0206 injection in people with Type 2 Diabetes, as communicated in July 2025<sup>2</sup>.

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<sup>2</sup> Press Release, July 25th, 2025 : ADOCIA and Tonghua Dongbao Announce Positive Topline Results of Phase 3 Clinical Trial on Ultra-Rapid Insulin BioChaperone® Lispro (THDB0206 injection) in people with T2D

## About BioChaperone® Lispro

BioChaperone® Lispro was licensed to Tonghua Dongbao in 2018, as part of a Licensing Agreement covering China and other Asian countries<sup>3</sup>. Adocia retains the rights to develop and license BioChaperone® Lispro in worldwide markets outside of the territories covered by this agreement.

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 associated to an excellent local tolerance enhances its compatibility with modern diabetes management systems, particularly insulin pump systems, and provides better integration into advanced treatment algorithms.

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.

The contract with Tonghua Dongbao includes a milestone payment of US\$20 million, which would be triggered upon obtaining marketing authorization in China, and subsequent double-digit royalties on sales to Adocia. The marketing authorization application is under Tonghua Dongbao's responsibility.

## 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 commercialization of insulins and other diabetes treatments. Tonghua Dongbao currently employs over 3,000 people and has sales of around \$280 million. It has been listed on the Shanghai Stock Exchange since 1994, with a market capitalization of about \$2.3 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.

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<sup>3</sup> Press Release, Apr. 26, 2018: Adocia and Tonghua Dongbao Announce a Strategic Alliance for BioChaperone® Combo and BioChaperone® Lispro in China

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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## 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, 2025, as updated in the Company's 2025 Half-year financial statements, published on September 25, 2025, 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, 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.*