

## PRESS RELEASE

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**ADOCIA**

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# ADOCIA's Partner Tonghua Dongbao Announces Positive Results of Three Clinical Trials on BioChaperone® Combo

- Three clinical trials on BioChaperone® Combo (THDB0207) were conducted in Germany on subjects with type 1 diabetes, type 2 diabetes and on healthy volunteers with Chinese origin
- In comparison with premixed standard of care (Humalog® Mix25), trials successfully demonstrated:
  - Good safety and tolerability profile
  - Faster effect, that could be translated in reduced post-prandial hyperglycemia
  - Improved basal control
  - Reduced over-exposure that could limit hypoglycemia
- Data generated will be submitted to the CDE to support the application for the next clinical development phase

9:00 a.m. CEST - Adocia (Euronext Paris: FR0011184241 – ADOC), a clinical-stage biopharmaceutical company focused on the research and development of innovative therapeutic solutions for the treatment of diabetes and other metabolic diseases, announces that its partner Tonghua Dongbao releases today positive results on the three clinical studies conducted on BioChaperone® Combo THDB0207 ("BC Combo") formulation containing insulin glargine and insulin lispro from Tonghua Dongbao.

Conducted by Adocia in Germany, these studies were fully funded by Tonghua Dongbao, the Chinese insulin leader to whom BC Combo was licensed in 2018. These studies were approved by the German Health Authority (BfArM<sup>1</sup>), as well as by the Chinese Regulatory Authorities (CDE<sup>2</sup>), as part of a Chinese IND<sup>3</sup>. As per these interactions, the data generated on the three studies will be submitted to the CDE and used to support the application to enter the next clinical development phase.

<sup>1</sup> BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte, Federal Institute for Drugs and Medical Devices

<sup>2</sup> CDE: Center for Drug Evaluation of the National Medical Products Administration

<sup>3</sup> IND: Investigational New Drug

*"Our sales in insulin analogues have been recording an impressive growth in recent years, and we are extremely pleased about the prospect of soon adding BioChaperone® Combo to our portfolio of innovative insulins," says Dr Chunsheng Leng, Chairman and CEO of Tonghua Dongbao. "These three successful studies bring the product one step closer to being available to Chinese people suffering from diabetes".*

*"I would like to express our gratitude to Tonghua Dongbao for entrusting us with the conduct of these studies," says Olivier Soula, Chief Executive Officer of Adocia. "I am particularly pleased with the results of these clinical studies, which underline the potential of BC Combo to bring additional medical value to people with diabetes, seeking once- or twice-daily insulin injections, ensuring the basal and prandial glycemic control. Tonghua Dongbao can count on our full support to continue the successful development of BC Combo."*

## Results

The following trials were conducted and all three were positives:

- A Trial Investigating the Dose Linearity and Safety of BioChaperone® Combo THDB0207 in Subjects with Type 2 Diabetes (NCT05373212)
- A Trial Investigating the Pharmacodynamics of BioChaperone® Combo THDB0207 Compared with Humalog® Mix25 and Simultaneous Injections of Humalog® and Lantus® in Healthy Chinese Volunteers (NCT05373186)
- A Trial Comparing the Pharmacodynamics and Pharmacokinetics of BioChaperone® Combo THDB0207 and Lantus® and Humalog® in Subjects with Type 1 Diabetes (NCT05373199)

These three trials demonstrated that BC Combo is effective, with typical characteristics of a combination of long-acting and rapid-acting insulins, and can thus ensure glycemic control during postprandial and fasting phases.

Trials were conducted in comparison to Humalog® Mix, Humalog® and Lantus®, in people with type 1 diabetes, type 2 diabetes or on healthy volunteers with Chinese origin.

Compared with Humalog® Mix, BC Combo has a faster effect, that could be translated in reduced post-prandial hyperglycemia. BC Combo has a potential for enhanced fasting glucose control, with an improved 24-hour basal control. It also demonstrated a reduced over-exposure that could limit hypoglycemia.

Those data support the goal of effective once or twice daily dosing.

BC Combo was safe and well tolerated; no new or unexpected safety findings were reported during the trials.

The overall assessment showed that BC Combo had a good benefit/risk ratio, supporting its clinical development into the next phase.

## About BioChaperone® Combo

BioChaperone® Combo THDB0207 (BC Combo) is a fixed combination of two gold standard insulins: long-acting insulin glargine (as contained in the commercial product Lantus®) and rapid-acting insulin lispro (as contained in Humalog®). Many patients worldwide prefer to use fixed combinations of long and rapid acting insulins rather than two separate products (simplicity, reduced number of daily injections).

BioChaperone® Combo targets the premixed insulin market, which accounts for 65% of insulin volumes in China, a country with 140 million diabetic patients.

The different clinical studies conducted confirm the potential of BC Combo to reduce postprandial hyperglycemia and the risk of hypoglycemia, while providing 24-hour basal control.

## About Tonghua Dongbao

Tonghua Dongbao Pharmaceutical Co. Ltd, is a pharmaceutical company in Jilin Province, China, specializing in the R&D, manufacturing and commercialization of insulins as well as other diabetes treatment products. Currently Tonghua Dongbao has more than 3,000 employees and a turnover of approximately US\$400 million. It has been listed on the Shanghai Stock Exchange since 1994, with a market capitalization of US\$3 billion.

Tonghua Dongbao acquired development and commercialization rights on BioChaperone® Combo and BioChaperone® Lispro in 2018 for Asia and other Middle East territories.

## 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 insulins with other classes of hormones; 2) AdOral®, an oral peptide delivery technology; 3) AdoShell®, an immunoprotective biomaterial for cell transplantation, with a first application in pancreatic cells transplantation; 4) AdoGel®, a long-acting drug delivery platform.

Adocia holds more than 25 patent families. Based in Lyon, the company has about 100 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 which are set forth in the "Risk Factors" section of the universal registration document that was filed with the French Autorité des marchés financiers on April 26, 2023 updated by the amendment of 26 July 2023 (D.23-0346-A01) and amendment of 13 September 2023 (D.23-0346-A02), available at [www.adocia.com](http://www.adocia.com),*

*in particular uncertainties that are linked to research and development, future clinical data, analyses, and the evolution of the economic context, the 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 considered as material by Adocia as of this day. The occurrence of all or part of such risks could cause that actual results, financial conditions, performances, or achievements of Adocia be materially different from those mentioned in the forward-looking statements.*