

## PRESS RELEASE

Lyon, September 7<sup>th</sup>, 2022

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**ADOCIA**

innovative medicine  
for everyone, everywhere

# ADOCIA Announces First Cell Therapy Preclinical Proof of Concept of AdoShell<sup>®</sup> Islets for the Treatment of Type 1 Diabetes

- AdoShell Islets regulated glycemic control in immunocompetent diabetic animals in a 132-day trial without the use of insulin or immunosuppression.
- These results will be presented at the upcoming cell therapy session of the PODD 2022 conference held in Boston in October.
- A new series of diabetic rats, being treated with AdoShell Islets, confirm these promising results with 80 days normoglycemia.
- AdoShell Islets will be evaluated in diabetic pigs in the 4<sup>th</sup> quarter of 2022.

7.30am 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 the establishment of a first proof of concept for its' AdoShell Islets implant by achieving glycemic control without insulin injections in immunocompetent diabetic rats during the 132-day study.

*"Adocia's results are remarkable, having successfully performed the first islet transplantation without the use of immunosuppressants in immunocompetent animals. We are delighted to be actively involved in these unprecedented results."* said Dr. Karim Bouzakri, Director of CEED (European Center for the Study of Diabetes).

AdoShell Islets is an immuno-protective synthetic biomaterial containing islets of Langerhans. After implantation in diabetic animals, the islets encapsulated in AdoShell secrete insulin in response to blood glucose levels. The physical barrier formed by the AdoShell biomaterial allows the implanted cells to be invisible to the host's immune system while allowing the necessary physiological exchanges to occur for the survival and function of the islets.

This study consisted of implanting islets from allogeneic rats (Wistar) - encapsulated in AdoShell - into immunocompetent diabetic rats (Lewis). The insulin secreted by the transplanted islets was measured for 132 days and no slowing of secretion was observed during the duration of the study.

At the end of the study the graft was removed, which resulted in an observable drop of insulin secretion and rise in blood sugar levels, the animals rapidly returned to its diabetic state. At the same time, the animals in the control group (diabetic rats that did not receive AdoShell Islets) were unable to control their blood sugar levels.

Additional ongoing studies in diabetic rats, with the aim to optimize the AdoShell technology, confirm these initial results, producing insulin and normalizing the glycemia in 4 diabetic rats for 80 days (study still on-going). The weight gain of the studied rats - which is also an important clinical indicator of healthy test subjects - shows that the AdoShell Islets are performing as expected. In parallel the rats in the control group are not gaining weight as expected in diabetic rats.

These results will be presented at the upcoming cell therapy session of the PODD 2022 conference held in Boston in October.

*"This first proof of concept in diabetic rats validates our AdoShell technology. Our purely physico-chemical approach is unique and being not biological it gives us confidence that these remarkable results can be translated from one species to another,"* said Olivier Soula, Deputy-CEO and Director of R&D at Adocia.

## **OUR PRIORITY, TREATING LIFE THREATENING CASES WITH CELLS FROM DONORS**

More than 40 million people worldwide suffer from type 1 diabetes<sup>1</sup>, also known as insulin-dependent diabetes: In these patients, the beta cells of the islets of Langerhans, cells that secrete insulin, are destroyed by an autoimmune mechanism. As a result, the patient survival depends on daily injections of insulin.

Despite the use of insulin, some patients have intensely unstable diabetes characterized by extreme glycemic variability, responsible for iterative and/or severe unfelt hypoglycemia, altering the quality of life and increasing morbidity and mortality. The prognosis of this so-called "brittle" diabetes is poor, with a mortality rate between 20 to 50% over 5 years, depending on the study<sup>2</sup>. Brittle diabetes affects about 3 out of 1000 people with insulin-dependent diabetes, which represents 1000 patients in France and nearly 75 000 worldwide.

Cell therapy techniques by replacing cells that have been destroyed exist and consist in injecting the patient with islets of Langerhans taken from pancreas of donors. These techniques are practiced in many countries and in 2020 the French High Authority for Health (the HAS) gave a favorable opinion on the registration of islets transplantation on the list of procedures that can be reimbursed by the public Health Insurance. However, this technique has a major pitfall because - like any allograft - islet transplantation as practiced to date requires the concomitant use of heavy immunosuppressive treatments to avoid rejection of the transplanted cells. These immunosuppressive protocols, whose undesirable effects are widely documented (hematological anomalies, infections, and neoplasia), limit the use of transplantation techniques to patients already under immunosuppressive treatment because they are also undergoing kidney transplantation.

The first application of AdoShell Islets concerns the improvement of these techniques performed with donor pancreases and is precisely aimed at these so-called "brittle" patients so that they can benefit from them.

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1 International Diabetes Federation, "around 10% of all people with diabetes"

2 HAS – juillet 2020 [https://www.has-sante.fr/jcms/p\\_3195137/en/transplantation-d-ilots-pancreatiques-rapport-d-evaluation-technologique](https://www.has-sante.fr/jcms/p_3195137/en/transplantation-d-ilots-pancreatiques-rapport-d-evaluation-technologique)

"Our approach is first and foremost very pragmatic: to use donor cells already used in current therapeutics and to fit into existing protocols. In this way, we hope to make a first treatment available to the most severe patients as soon as possible" said Gérard Soula, Chairman and CEO of Adocia.

## **A TECHNOLOGY APPLICABLE TO OTHER CELLULAR SOURCES WITH THE OBJECTIVE OF TREATING THE GREATEST NUMBER OF PEOPLE**

In parallel with the development of AdoShell Islets from donor pancreases, Adocia also aims to develop its technology from stem cells, which would ultimately make this technology possible to free itself from the limit of the number of donors and thus treat a much larger number of patients.

"We are currently working on setting up collaborations with companies that develop stem cells with an ambitious vision: to offer the best curative treatment for diabetes without requiring immunosuppressants," concluded Gérard Soula, Chairman and CEO of Adocia.

During the virtual conference held on September 20th to release the financial results of the first half of 2022, we will present the AdoShell Islets program in detail to investors and shareholders, along with the company's entire program portfolio.

## **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 three 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 for patients with "brittle" diabetes.

Adocia holds more than 25 patent families.

Based in Lyon, the company has approximately 115 employees. Adocia is listed on the Euronext™ Paris market (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 21, 2022 (a copy of which is 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.