ADOCIA

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for everyone, everywhere

PRESS RELEASE

# Adocia Presents First Half 2019 Financial Results

- **Cash position of nearly 21 million euros end of June 2019**
- **Revenue of 1.7 million euros resulting from services performed within the licensing agreement with Tonghua Dongbao**

**Lyon, France July 17th, 2019** – 6:00 pm CEST – Adocia (Euronext Paris: FR0011184241 – ADOC), the clinical-stage biopharmaceutical company focused on the treatment of diabetes and other metabolic diseases with innovative formulations of proteins and peptides, announces today its financial results for the first six months ended June 30, 2019.

Half-year consolidated financial statements, expressed according to IFRS, underwent limited review by the statutory auditors and subsequently approved at the Board of Director's meeting held today.

"*We continue to actively develop our product portfolio while maintaining prudent cash management.*" said Gérard Soula, Adocia's Chairman and Chief Executive Officer. "*This half year was particularly active, with a very satisfactory progression of our collaboration with Tonghua Dongbao on BioChaperone Lispro and BioChaperone Combo, as well as the release of excellent first clinical results of ADO09, our combination of prandial insulin and pramlintide. This in turn led to the rapid launch of a 3-week study on ADO09. Of note, we expect to receive during this quarter the decision on the second phase of the ongoing arbitration with Eli Lilly.*"

## Key financial results

The table below summarizes the condensed consolidated interim financial statements prepared for the six-month periods ended June 30, 2019 and June 30, 2018, respectively:

| *In (€) thousands, Consolidated financial statements, IAS/IFRS* | 06/30/2019 (6 months) | 06/30/2018 (6 months) |
|---|---|---|
| Revenue | 1 710 | 32 801 |
| Grants, research tax credits and others | 3 044 | 3 303 |
| **Operating revenue** | **4 754** | **36 105** |
| **Operating expenses** | **(18 142)** | **(21 784)** |
| **OPERATING INCOME** | **(13 388)** | **14 321** |
| **FINANCIAL INCOME (LOSS)** | **404** | **453** |
| Tax expense | (9) | (4 135) |
| **NET INCOME** | **(12 994)** | **10 639** |

The financial results of the Company at June 30, 2019 are characterized by:

- **Revenue of 1.7 million euros**, mostly deriving from the licensing agreements signed with Tonghua Dongbao (THDB) in April 2018 for the development, manufacturing and commercialization of BioChaperone® Lispro and BioChaperone® Combo in China and other territories.

  The non-refundable upfront payment in the amount of 50 million dollars, or 41.1 million euros, was partially recognized as revenue, for 32.8 million euros at the end of June 2018. The remaining non-amortized amount of the initial payment is being recognized upon provision of research and development services by Adocia related to the transfer and development of the products. Adocia recognized 1.7 million euros in revenue over the first semester of 2019.

- **Operating expenses** for the first six months of 2019 amount to 18.1 million euros, a decrease of 3.6 million euros compared to the first six months of 2018. The decrease is explained by lower legal expenses (2.1 million euros) related to the ongoing legal procedures against Eli Lilly & co ("Lilly") and by lower staff expenses (1.4 million euros). In 2018 staff expenses were impacted by performance bonuses granted to employees as a result of the signature of the partnership with Tonghua Dongbao.

- **A net loss before tax** of 13 million euros.

- **A cash position of 20.7 million euros:** The Company has a cash position close to 21 million euros as of 30 June 2019, compared to 39.8 million euros as of 1 January 2019, a decrease of 19.2 million euros.

  Excluding the cash payment received from Tonghua Dongbao and legal fees, the net cash flow over the six first months of 2019 amounted to 15.7 million euros, compared to 13.5 million euros over the first six months of 2018. The increase in use of cash was mainly driven by research and development activities, including expenses related to the preparation and conduct of clinical trials, as well as support to our partner Tonghua Dongbao for the development of the licensed programs.

  The cash position as of end of June 2019 does not include the payment due by Lilly following the favorable ruling received by Adocia in the first phase of the arbitration. The payment of the 11.6 million dollars plus accrued interest is expected after a decision regarding the second, final phase of the arbitration.

  Additionally, payment of the research and tax credit ("*Crédit d'Impôt Recherche*") generated from 2018 expenses, in the amount of 6.4 million euros, is expected in the second half 2019.

- **Financial debt** as of 30 June 2019 amount to 8.1 million euros which represents a net increase of 1 million euros compared to the beginning of the year. This increase resulted from 1.2 million euros debt financing of renovation expenses for the main building. This is partially offset by the payments against the loans to finance the acquisition and renovation of that same building acquired in 2016.

*"Our financial results for the first half of the 2019 are in line with our forecast and reflect our continued investments in our portfolio, especially in clinical developments,"* said Valérie Danaguezian, Chief Financial Officer of Adocia "*Pending the decision on the second phase of the arbitration, we shall maintain our rigorous expense management policy and we have the means to finance our operational plan."*

## Key events for the first half 2019

The first semester of 2019 was marked by important technical and clinical advances on two of Adocia's key programs: BioChaperone Lispro, the ultra-rapid insulin, and ADO09, the combination of prandial insulin and pramlintide.

In **January 2019**, Adocia announced the initiation of a Phase 1 clinical trial evaluating BioChaperone Lispro and two prandial insulin analogs in the iLet™ automated insulin delivery system (commonly called the "bionic pancreas") from BetaBionics. This randomized, cross-over study performed in the United States of America will recruit up to 30 subjects with type 1 diabetes to compare the pharmacokinetic and pharmacodynamic profiles of insulins lispro, aspart and BioChaperone Lispro in the iLet™ bionic pancreas, on an inter- and intra-subject basis.

**In parallel**, Adocia, and its partner Tonghua Dongbao (THDB), carry on qualification activities for the insulin lispro manufactured by THDB in order to enable the start of Phase 3 trials of BioChaperone Lispro in China and other territories.

In **April 2019**, Adocia announced the first positive topline results of ADO09, a combination of prandial insulin with pramlintide. ADO09 was developed 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 a prandial insulin. Indeed, in a person without diabetes, insulin and amylin are co-secreted and act synergistically to control glycemic excursions after a meal. In this randomized, double-blind, cross-over study, which enrolled 24 participants with type 1 diabetes, treatment with ADO09 resulted in a statistically significant 85% reduction of blood glucose excursions over the first two hours after the meal compared to Humalog® ($p<0.0001$) and in comparable postprandial glycemic control to that of the separate injections of Humulin® and Symlin®. Of note, in December 2018, Adocia had announced positive first-in-human clinical data for BioChaperone® Pramlintide Insulin (BC Pram Ins), a neutral pH co-formulation of pramlintide and human insulin based on Adocia's proprietary BioChaperone® technology. Based on similar clinical results and a development plan considered to be faster for ADO09, Adocia has prioritized development of ADO09.

In the wake of these very encouraging clinical results, Adocia announced, early in **June 2019**, the launch of a 3-week Phase 1b clinical trial of ADO09 in people with type 1 diabetes. This study aims to assess safety and efficacy of ADO09 in subjects with type 1 diabetes using a multiple daily injection regimen over a 24-day period of treatment, including an outpatient period. The primary endpoint is to compare post-meal glucose profiles after bolus injections of ADO09 and Novolog®, injected immediately before a standardized mixed meal, at the end of a 24-day multiple daily injection treatment period. Results from this study are expected during Q4 2019.

Finally, and consistent with the evolution of our portfolio towards more mature stages of development, Adocia recently **strengthened its organization** by recruiting Mr. Marc Vouillamoz for the role of Director of Pharmaceutical Operations. His experience, acquired within large pharmaceutical organizations, in manufacturing processes, quality and regulatory affairs is an asset to support our Company in its evolution.

On the **legal front**, the first phase of the Arbitration procedure initiated by Adocia against Lilly concluded in favor of Adocia in **August 2018**. The Arbitration Tribunal awarded Adocia USD 11.6 million, as well as interest. Adocia's additional claims against Lilly for an amount of USD 1.3 billion and the counterclaims of Lilly for an amount of USD 188 million, remain pending, with a decision of the Tribunal expected in the course of Q3 2019.

Furthermore, in **October 2018**, Lilly filed a civil complaint with the United States District Court of the Southern District of Indiana to seek a declaratory judgment for two of its US patents regarding ultra-rapid insulin formulations (Lilly's United States Patent Nos. 9,901,623 and 9,993,555 entitled "Rapid-acting insulin

compositions"). Lilly contends in its complaint that it filed the action because it refutes Adocia's assertion that the patents reflect an inventive contribution by Adocia. Adocia does not expect the matter to be resolved during this fiscal year.

## 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 combination of a prandial insulin with amylin analog pramlintide (ADO09) and a rapid-acting formulation of human insulin (HinsBet® U100). 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 into 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 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.*

*This press release and the information contained herein do not constitute an offer to sell or the solicitation of an offer to buy Adocia shares in any jurisdiction.*

## APPENDIX: Financial results at June 30, 2019

### Operating revenue

The table below provides details on operating revenue for each period:

| *In (€) thousands* | 06/30/2019 (6 months) | 06/30/2018 (6 months) |
|---|---|---|
| **Revenue (a)** | **1 710** | **32 801** |
| Research and collaborative agreements | 0 | 0 |
| Licensing revenues | 1 710 | 32 801 |
| **Grants, public financing, others (b)** | **3 044** | **3 303** |
| **OPERATING REVENUE (a) + (b)** | **4 754** | **36 105** |

Operating revenue mainly resulted from the licensing and research agreements as well as the public financing of research and development expenses. As of June 30, 2019, they amounted to 4.8 million euros versus 36.1 million euros last year over the same period.

**Revenue of 1.7 million euros**, mostly deriving from the licensing agreements signed with Tonghua Dongbao (THDB) in April 2018 for the development, manufacturing and commercialization of BioChaperone® Lispro and BioChaperone® Combo in China and other territories.

The non-refundable upfront payment in the amount of 50 million dollars, or 41.1 million euros, was partially recognized as revenue, for 32.8 million euros at the end of June 2018. The remaining non-amortized amount of the initial payment is being recognized upon provision of research and development services by Adocia related to the transfer and development of the products. Adocia recognized 1.7 million euros in revenue over the first semester of 2019.

**Other operating income** consisted primarily of the French research and development tax credit amounting to 3 million euros for the first half of 2019, compared to 3.2 million during the first half of 2018. This decrease reflects lower qualifying payroll expenses compared to the same period last year.

### Operating expenses

The table below provides details on operating expenses by function for each period:

| *In (€) thousands* | 06/30/2019 (6 months) | 06/30/2018 (6 months) |
|---|---|---|
| Research and development expenses | (12 322) | (13 134) |
| General and administrative expenses | (5 820) | (8 650) |
| **CURRENT OPERATING EXPENSES** | **(18 142)** | **(21 784)** |

**Research and development costs** mainly include payroll expenses assigned to research and development operations, subcontracting costs (including preclinical and clinical studies), intellectual property rights expenses, purchases of materials (reagents and other consumables), of pharmaceutical products and other

raw materials. These expenditures amounted to 12.3 million euros for the first half of 2019, a decrease of 0.8 million euros compared to the first half of 2018. This is mainly due to a decrease in personal expenses, as the financial accounts as of June 2018 were impacted by the grant of performances bonuses following the signature of the partnership with Tonghua Dongbao. No bonuses have been granted over the first half 2019. These Research and development expenses represent 77% of the total operational expenses (excluding the fees related to the legal procedures) as of end of June 2019.

**General and administrative expenses** primarily include expenses for employees not directly working on research and development, as well as services related to management, legal and business development of the Company and its subsidiary in the US. They amounted to 5.8 million euros at June 30, 2019 versus 8.7 million euros at June 30, 2018. The 2.8 million euros decrease is explained for 2.1 million euros by the decrease of legal expenses supporting the ongoing arbitrations and for 0.5 million euros by the decrease in payroll expenses (2018 performance bonuses).

The table below provides details on operating expenses by nature for each period:

| *In (€) thousands* | 06/30/2019 (6 months) | 06/30/2018 (6 months) |
|---|---|---|
| Purchases used in operations | (786) | (1 122) |
| Payroll expense | (6 235) | (7 668) |
| Share-based payments | (464) | (658) |
| External expenses | (9 985) | (11 477) |
| Taxes and contributions | (123) | (234) |
| Depreciation, amortization & provisions | (548) | (623) |
| **OPERATING EXPENSES** | **(18 142)** | **(21 784)** |

**Purchases used in operations** decreased by nearly 30% to reach 0.8 million euros. This decrease is explained by significant raw material expenses occurred over the six first months of 2018 necessary to the production of clinical batches.

**Payroll expenses** totaled 6.2 million euros at June 30, 2019 compared to 7.7 million euros at June 30, 2018. The average workforce increased by 6%, at 124.2 Full Time Equivalents (FTE) in 2018 and 132.1 FTE in 2019. The decrease of payroll expense is primarily due to the payment of performance bonuses to employees in June 2018, resulting from the signing of the partnership with Tonghua Dongbao.

**The 0.5 million euros share-based payments** item at June 30, 2019 includes the impact of the plans introduced in previous years as no plan has been granted over the first six months of 2019. The 0.2 million euros decrease is explained by the vesting of several share-based plans in 2018. In accordance with IFRS 2, share-based payments are recognized at the fair value of the equity instruments granted to the executives and employees. These elements had no impact on the Company's corporate financial statements or cash position.

**External charges** mainly included the costs of preclinical studies, clinical trials, subcontracting expenses, intellectual property costs, professional fees and administrative expenses. These expenses amounted to 10 million euros at June 30, 2019, decreasing by 1.5 million euros compared to the same period in 2018. It is primarily explained by the lower amount of legal services incurred for the procedures against Eli Lilly.

**Taxes** totaled 0.1 million euros at June 30, 2019 compared to 0.2 million euros at June 30, 2018.

**Depreciation and amortization** amounted to 0.5 million euros at June 30, 2019 compared to 0.6 million euros at June 30, 2018.

## Balance sheet items

| *In (€) thousands, Consolidated financial statements, IAS/IFRS* | 06/30/2019 | 12/31/2018 |
|---|---|---|
| **Net cash and cash equivalents** | **20 690** | **39 841** |
| **Total assets** | **55 705** | **70 043** |
| **Equity** | **32 806** | **45 848** |
| **Financial debts** | **8 089** | **7 117** |

The amount of cash and cash equivalents held by the Company was close to 21 million euros at June 30, 2019 compared to 39.8 million euros at January 1, 2019.

Consolidated shareholder's equity decreased from 45.8 million euros at January 1, 2019 to 32.8 million euros at June 30, 2019. The decrease reflects the negative result at the end of June 2019.

Financial liabilities amount to 8.1 million euros at June 30, 2019 which represents a net increase of 1 million euros compared to the beginning of the year. This increase resulted from the 1.2 million euros debt financing of renovation expenses conducted this year on the main building. This is partially offset by the payments of the loans contracted to finance the acquisition and renovation of that building, bought in 2016.