Kiadis Pharma announces Financial Results for the six months ended June 30, 2018 and Company update

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**June 30, 2018 and Company update**

**Amsterdam, The Netherlands, August 31, 2018 - Kiadis Pharma N.V. ("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS**), a clinical-stage biopharmaceutical company, today announces its unaudited interim Financial Results for the six months ended June 30, 2018, which have been prepared in accordance with IAS 34 as adopted by the European Union.

**Arthur Lahr, CEO of Kiadis Pharma, commented:** *"We have made tremendous progress in the last six months: ATIR101 is now very close to potential CHMP opinion in 2018, we are on track with our Phase 3 trial, and obtained further confirmatory data from our Phase 2 trials. To allow us to ramp up our Phase 3 trial and prepare for commercialization in the EU we also raised substantial equity and debt facilities that extended our cash runway into the third quarter of 2019, and, upon positive CHMP opinion, potentially into the first quarter of 2020.* *We have also significantly strengthened our organization in medical, operations, commercial and finance functions. Kiadis is in great shape and well positioned to deliver on the promise of ATIR101."*

**Operating highlights - ATIR101 (including post reporting period)**

* European marketing authorization application for ATIR101:
  + Responses to the Day 120 List of Questions submitted in March 2018;
  + Day 180 List of Issues received in May 2018 and responses submitted in August 2018;
  + On track to obtain CHMP opinion from the European Medicines Agency in the fourth quarter of 2018.
* Phase 3 trial CR-AIR-009, comparing ATIR101 against the post-transplant cyclophosphamide (PTCy) or 'Baltimore' protocol:
  + Progress in line with internal plans: 14 clinical sites are currently open for recruitment, 16 patients have been enrolled;
  + Protocol amendment submitted to regulatory authorities: number of patients increased to 250 to further increase power [80% power to detect 16% Graft-versus-host-disease-free and Relapse-Free Survival (GRFS) difference]; interim analysis to occur after 2/3 of GRFS events to increase chance of positive read out, now expected in the second half of 2020; conditioning regimens harmonized between the two treatment arms to reduce heterogeneity.
* Phase 2 trial CR-AIR-008 ('008'): The last patient received a single dose of ATIR101 in January 2018.
* Pooled analysis: Further analysis of 1-year Phase 2 pooled data [Intention-To-Treat (ITT), 37 patients] from studies CR-AIR-007 and single dose CR-AIR-008 shows GRFS 53% [95% confidence interval (CI), 39%-72%]; Overall Survival (OS) 58% (95% CI, 44%-77%), in line with Phase 2 CR-AIR-007 trial. For the PTCy/Baltimore protocol, single site data from Johns Hopkins (McCurdy et al. 2017) and Atlanta (Solh et al, 2016) show a disease-risk index (DRI) normalized 1-year GRFS value of 40% and 30%, respectively.

**Operating highlights - Organization (including post reporting period)**

* Mr. Robbert van Heekeren resigned as Chief Financial Officer and as member of the Management Board.
* Mr. Scott A. Holmes appointed as new Chief Financial Officer.
* Organization strengthened across all functions, comprises 73 employees, up from 51 a year ago. Key new appointments include head of Medical US (former Iovance/ Dendreon), head of Medical EU (former Genzyme/ AstraZeneca), head of market access EU (former Genzyme/ Novo Nordisk), head of pharmacovigilance (former Astellas), head of facilities (former Merck/ Douwe Egberts).
* Dr. Otto Schwarz, former Chief Operating Officer of Actelion and Mr. Subhanu Saxena, former Chief Executive Officer of Cipla and former member of the senior executive team of Novartis, were appointed as Supervisory Board members of the Company at the Annual General Meeting of shareholders in June 2018. Mr. Stuart Chapman resigned from the Supervisory Board following the shareholders' meeting.

**Financial highlights (including post reporting period)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FINANCIAL SUMMARY** | | **For the six months ended** | |  |
| **(Amounts in EUR million, except per share data)** | | **June 30,** **2018** | **June 30,** **2017** | **Change** |
|  |  |  |  |  |
| **Total revenue and other income** | | **-** | **-** | **-** |
| **Total operating expenses** | | **(11.1)** | **(8.2)** | **(2.9)** |
|  | Research and development | (7.7) | (5.9) | (1.8) |
|  | General and administrative | (3.4) | (2.3) | (1.1) |
| **Operating result** | | **(11.1)** | **(8.2)** | **(2.9)** |
| **Net financial result** | | **(3.0)** | **(0.4)** | **(2.6)** |
| **Net result** | | **(14.1)** | **(8.5)** | **(5.6)** |
|  |  |  |  |  |
| **Net operating cash flow** | | **(10.6)** | **(7.6)** | **(3.0)** |
|  |  |  |  |  |
| **Cash position at end of period** | | **41.7** | **10.7** | **31.0** |
|  |  |  |  |  |
| **Equity** | | **25.3** | **3.5** | **21.8** |
|  |  |  |  |  |
| **Earnings per share before dilution (EUR)** | | **(0.74)** | **(0.61)** | **(0.13)** |

* In the first six months of 2018, the Company did not generate any revenues. Total operating expenses increased by EUR2.9 million from EUR8.2 million in the first six months of 2017 to EUR11.1 million in the same period of 2018. This increase was primarily caused by a further expansion of the workforce in all areas of the organization, the move to a larger building which includes a commercial manufacturing facility, laboratories and office space, and consultancy expenses for business development and market access.
* In the first six months of 2018, net financial result came in at EUR3.0 million compared to EUR0.4 million for the same period of 2017. Higher finance costs were mainly the result of higher interest expenses on loans and borrowings, and a net foreign exchange loss in the first six months of 2018 compared to a net foreign exchange gain in 2017.
* The net loss for the six months ended June 30, 2018 came at a level of EUR14.1 million compared to a loss of EUR8.5 million for the six months ended June 30, 2017. Operating expenses and net result for the first six months of 2018 were in line with management expectations.
* The Company ended the first six months of 2018 with EUR41.7 million in cash and cash equivalents. In March 2018, the Company issued 2.6 million shares and raised EUR23.4 million in gross proceeds.
* On July 31, 2018, the Company received a new debt facility from Kreos Capital V (UK) Ltd providing the Company with up to EUR20 million of additional financing.

A full financial report for the six months ended June 30, 2018 is available on Kiadis Pharma's website at [www.kiadis.com/financial-news/](http://www.kiadis.com/financial-news/)

**For more information, please contact:**

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| **Kiadis Pharma:** Karl Hård, Head of IR & Communications Tel. +31 611 096 298 [k.hard@kiadis.com](mailto:k.hard@kiadis.com) | **Optimum Strategic Communications:** Mary Clark, Supriya Mathur, Hollie Vile Tel: +44 203 714 1787 [kiadis@optimumcomms.com](mailto:kiadis@optimumcomms.com) |

**About Kiadis Pharma**  
Kiadis Pharma is initially developing its lead product candidate, ATIR101, for use in conjunction with haploidentical HSCT for adult blood cancers to address key limitations of haploidentical HSCT, without prophylactic immunosuppression and its associated morbidity and mortality. Based on the positive results from the single dose Phase II CR-AIR-007 study, the Company submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, in April 2017 for approval of ATIR101 as an adjunctive treatment in haploidentical HSCT for high risk adult hematological malignancies. Kiadis Pharma submitted responses to the EMA's Day 180 List of Issues in August 2018. The Company expects a Committee for Medicinal Products for Human Use, or CHMP, opinion in the fourth quarter of 2018 which, if positive, would enable it to receive a conditional marketing approval from the European Commission as early as in the first quarter of 2019. If then conditionally approved, Kiadis Pharma intends to launch ATIR101 in selected countries in Europe through its own commercial organization starting in the second half of 2019.

In December 2017, Kiadis Pharma commenced an international, multicenter, randomized and controlled Phase III clinical trial of ATIR101 against the Post-Transplant Cyclophosphamide, or PTCy protocol, the main protocol used to perform a haploidentical HSCT. The trial will be performed in 250 patients with acute leukemia and myelodysplastic syndrome, or MDS, at approximately 50 sites in the United States, Canada, Europe and certain additional countries. The trial's primary endpoint is GVHD-Free and Relapse-Free Survival, or GRFS, which is defined as survival without acute GVHD grade III/IV, without chronic GVHD requiring systemic immunosuppression, and without relapse, and is a composite endpoint widely used in HSCT trials that captures survival, quality of life and future prognosis. The first patient was enrolled in December 2017. If successful, the Company intends to use data from this Phase III trial as a basis for the filing of a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA. The Company also plans to use data from the Phase III trial to support the conversion of the anticipated conditional marketing approval of ATIR101 in Europe into a standard marketing approval. ATIR101 received regenerative medicine advanced therapy, or RMAT, designation from the FDA in September 2017, which provides benefits that are materially equivalent to a breakthrough designation from the FDA. In addition, ATIR101 has been granted multiple orphan drug designations both in the European Union and the United States.

The Company's shares are listed on Euronext Amsterdam and Brussels under the ticker KDS.

**Forward Looking Statements**  
*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Kiadis Pharma's or, as appropriate, Kiadis Pharma's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, Kiadis Pharma expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither Kiadis Pharma nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.*