

# KIADIS TO ACQUIRE CYTOSEN THERAPEUTICS, INC.

## 17.APRIL 2019 AT 07:00:00 CET

**Kiadis to Acquire CytoSen Therapeutics, Inc.**

- *Transaction creates leader in cell-based cancer immunotherapy, with complementary T-cell and NK-cell platforms focused initially on hematopoietic stem cell transplants (HSCT)*
- *CytoSen's lead NK-cell therapy candidate, CSDT002-NK, is expected to enter clinical development in 2020 building on successful clinical proof-of-concept studies in 25 patients at the MD Anderson Cancer Center (MDACC)*
- *The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) to support clinical development in leading US transplant centers*
- *Dr. Carl June, a pioneer in the development of CAR T-cell therapy, to join Kiadis' Scientific Advisory Board*
- *Conference call for analysts and investors today at 3:00pm CEST (9:00am EDT)*

**Amsterdam, The Netherlands, April 17, 2019 - Kiadis Pharma N.V. ("Kiadis" or the "Company") (Euronext Amsterdam and Brussels: KDS)**, a clinical stage biopharmaceutical company, today announced that it has entered a definitive agreement to acquire US-based CytoSen Therapeutics, Inc. ("CytoSen"), subject to Kiadis' shareholder approval and customary closing conditions.

Privately held CytoSen has developed a proprietary natural killer (NK)-cell platform to enable NK-cell therapy with broad anti-cancer potential. It was founded on technology exclusively licensed from the University of Central Florida (UCF) and further developed at Nationwide Children's Hospital (NCH). The company's founders, including Dean Lee, Stefan Ciurea and Robert Igarashi, are leading physicians and scientists at NCH, MDACC and UCF, respectively. Following the transaction, Dr. Carl June, a pioneer in the development of CAR T-cell therapy and current scientific advisor to CytoSen, will join Kiadis' Scientific Advisory Board.

The transaction creates a leader in cell-based cancer immunotherapy. The combined company has a complementary development pipeline focused on improving outcomes for patients undergoing hematopoietic stem cell transplants (HSCT). Kiadis' lead T-cell product ATIR101 is in EU registration and a global Phase 3 clinical trial; CytoSen's lead NK-cell product candidate, CSDT002-NK, building on promising clinical proof-of-concept studies in 25 patients carried out at MD Anderson Cancer Center, is expected to enter the clinic in the US in 2020. The unique combination of proprietary and synergistic NK-cell and T-cell therapy platforms has the potential to revolutionize HSCT and enables Kiadis to create a pipeline with novel cancer treatments.

**Arthur Lahr, CEO of Kiadis commented:** *"Our vision is to leverage the strengths of the human immune system to help patients with life-threatening diseases. With the addition of CytoSen, we can create cell therapy treatments that combine the innate and adaptive arms of the immune system. The ATIR T-cell and CSDT002-NK-cell programs each have the potential to make transplants safer and more effective. In combination, they have the potential to revolutionize HSCT, making it suitable for an even wider group of patients. This transaction will transform Kiadis into a unique company with two synergistic proprietary cell-based immunotherapy platforms and the opportunity to create a pipeline of innovative treatments for cancer patients."*

**Carl H. June, MD, Richard W. Vague Professor in Immunotherapy in the Department of Pathology and Laboratory Medicine at the University of Pennsylvania, commented:** *"NK-cell therapy could significantly advance the field of immuno-oncology. Also, I believe the fields of NK-cells*

*and T-cells are enormously synergistic and the combination could potentially help patients with devastating diseases. I am pleased to be joining the Scientific Advisory Board of Kiadis."*

**Dean A. Lee, MD, PhD, co-founder of CytoSen and director of the Cellular Therapy and Cancer Immunology Program at Nationwide Children's Hospital (NCH), commented:** *"CytoSen has the most advanced NK-cell technology to enable NK-cell therapy with broad anti-cancer potential. The strong experience, infrastructure, and competencies of Kiadis in cell therapy will accelerate our delivery of NK-cells to patients, and the new opportunities for exploring NK-cell and T-cell synergies will enable disruptive innovation in the cell therapy space. I am excited to collaborate with Kiadis to bring this innovation to patients."*

NK-cells are one of the body's first lines of immunological defense with an innate ability to rapidly and selectively destroy abnormal cells, such as cancer or virally-infected cells. Advancing research into the biology of NK-cells, as well as emerging early-stage clinical evidence, has increasingly shown that NK-cell immunotherapy has the potential to be at the forefront of cancer immunotherapy. CytoSen's patented nanoparticle processing technology enables improved *ex vivo* expansion and activation of NK-cells supporting multiple high dose infusions with potent anti-cancer cytotoxicity.

CytoSen's lead program, CSTD002-NK in HSCT, is built on proof-of-concept studies in 25 patients carried out at MDACC. First results of these studies demonstrated a relapse rate of 8% and progression-free survival (PFS) of 66% (published in [Blood](#), with follow up data presented at the American Society of Hematology (ASH) annual meeting in 2018). The upcoming clinical study with CSDT002-NK, expected to start in 2020, has been designed with and will be supported by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The study will enroll high-risk acute myeloid leukemia (AML) patients undergoing a haploidentical HSCT at a consortium of leading US transplant centers in the BMT CTN network. Additionally, CytoSen's NK-cell therapy will be investigated for other cancer treatments based on an 8-patient proof-of-concept study conducted at MDACC in refractory AML.

#### ***Transaction Details:***

At closing, CytoSen shareholders will receive upfront consideration of 1.94 million shares of Kiadis stock. The upfront consideration constitutes approximately 7.4% of Kiadis' shares outstanding after the transaction. In addition, CytoSen shareholders are eligible to receive potential future consideration of up to 5.82 million additional shares of Kiadis stock upon the achievement of six clinical development and regulatory milestones, with the final milestone being first FDA approval of an NK-cell product based on CytoSen's technology. The majority of the Kiadis shares issued to the CytoSen shareholders, including to its Executive Chairman and founders, will be subject to a lock-up for a period of two years from closing. At signing, CytoSen held approximately USD 6 million in net cash, which will remain in the combined company. Saola Healthcare Partners acted as financial advisor to Kiadis in the transaction.

#### ***Shareholder Approval:***

The transaction is subject to the approval of Kiadis' shareholders. The Company has called an extraordinary meeting of shareholders (EGM) to be held on Wednesday, May 29, 2019, at which the proposal supporting the transaction will be voted upon. Kiadis' two largest shareholders (funds represented by and/or affiliated with Life Sciences Partners and Draper Esprit), together representing 31.5% of Kiadis stock, have executed voting agreements in favor of the transaction. In the event that the transaction does not complete because the General Meeting withholds its approval, CytoSen is entitled to a USD 1 million break fee to be paid in cash or Kiadis shares.

#### ***Kiadis Business Update:***

- Kiadis previously submitted a marketing authorization application (MAA) to the EMA for ATIR101 which is currently under review. The Company plans to respond to the day 180 outstanding issues by the end of May 2019, allowing for potential EU approval and launch by the end of 2019.
- The global Phase 3 trial for ATIR101, CR-AIR-009, will compare ATIR101 to the post-transplant cyclophosphamide (PTCy) or 'Baltimore' protocol. Completion of enrollment and an interim analysis of the primary endpoint is expected in 2021.

- Kiadis' cash position was EUR 60.3 million as of December 31, 2018 and EUR 49.0 million as of March 31, 2019.

**Conference Call / Webcast Information:**

Kiadis' management will host a webcast / conference call for analysts and investors today, April 17, 2019 at 3:00pm CEST / 2:00pm BST / 9:00am EDT. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement of the call:

**Confirmation Code:** 5737097

**Participant dial-ins:**

Location	Phone Number
Belgium	+32 (0)2 400 6926
Norway	+47 2350 0296
Finland	+358 (0)9 7479 0404
Sweden	+46 (0)8 5065 3942
France	+33 (0)1 76 77 22 57
Switzerland	+41 (0)22 567 5750
Germany	+49 (0)69 2222 2018
United Kingdom	+44 (0)330 336 9411
Netherlands	+31 (0)20 703 8261
United States	+1 323-794-2093

**Webcast:** <https://webcasts.eqs.com/osc20190417>

A question and answer session will follow the presentation. The presentation may be accessed by visiting <http://www.kiadis.com/financial-news>.

**About CytoSen Therapeutics, Inc.**

CytoSen is a private biopharmaceutical company on the front line of advancing development of next generation NK-cells with the first scalable, therapeutic platform for high dose, cancer-killing NK-cells calibrated to each cancer target while reinforcing immune defenses. Born from the intersection of cellular immunotherapy and nanotechnology, CytoSen's NK-cell therapy harnesses the power of the immune system to treat cancer.

**About the BMT CTN**

The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) conducts multi-institutional clinical trials of high scientific merit, focused on improving survival for patients undergoing hematopoietic cell transplantation (HCT) and/or receiving cellular therapies. The BMT CTN is funded by the National Heart, Lung, and Blood Institute and National Cancer Institute at the National Institutes of Health (NIH) and is a collaborative effort of 20 Core Transplant Centers/Consortia, The Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP)/Be The Match and Emmes, a clinical research organization. CIBMTR is a research collaboration between the NMDP/Be The Match and the Medical College of Wisconsin. More information about the BMT CTN can be found at [www.bmtctn.net](http://www.bmtctn.net).

**About Kiadis Pharma**

Kiadis is 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 to the European Medicines Agency in April 2017 for approval of ATIR101 as an adjunctive treatment in haploidentical HSCT for high risk adult hematological malignancies. If the product is conditionally approved, Kiadis intends to launch ATIR101 in Europe through its own commercial organization by year end 2019.

In December 2017, Kiadis 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 at approximately 50 sites in the United States, Canada, Europe and certain additional countries. ATIR101 received regenerative medicine advanced therapy 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.

**Kiadis Contacts:**

**Kiadis:**

Amy Sullivan, SVP, Corporate Affairs

[a.sullivan@kiadis.com](mailto:a.sullivan@kiadis.com)

Maryann Cimino, Manager, Corporate Affairs

Tel. +1 617 710 7305

[m.cimino@kiadis.com](mailto:m.cimino@kiadis.com)

**Optimum Strategic Communications:**

Mary Clark, Supriya Mathur, Hollie Vile

Tel: +44 203 950 9144

David Brilleslijper (Amsterdam)

Tel: +31 610 942 514

[kiadis@optimumcomms.com](mailto:kiadis@optimumcomms.com)

**Forward Looking Statements**

*"Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Kiadis' or, as appropriate, Kiadis' 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, or our ability to develop and successfully integrate new assets and product programs into our business, can all 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 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 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 release."*