



PRESS RELEASE

## Servier and Pfizer announce FDA clearance of IND application for UCART19 in Adult Relapsed/Refractory Acute Lymphoblastic Leukemia

**9 March 2017** – Servier, together with Pfizer Inc. (NYSE:PFE) and Cellecctis (Alternext: ALCLS; Nasdaq: CLLS), announced today that the U.S. Food and Drug Administration (FDA) has granted Servier with an Investigational New Drug (IND) clearance to proceed in the U.S. with the clinical development of UCART19, an allogeneic, gene-edited cellular therapy candidate to treat relapsed/refractory acute lymphoblastic leukemia.

Servier is sponsoring the CALM Phase 1 study on UCART 19. In 2015, Servier acquired exclusive rights from Cellecctis for UCART19, which is being co-developed by Servier and Pfizer.

The CALM study was initiated in the UK in August 2016. CALM is an open label, dose-escalation study designed to evaluate safety, tolerability and antileukemic activity of UCART19 in patients with relapsed or refractory CD19-positive B-cell acute lymphoblastic leukemia (B-ALL).

The allogeneic UCART19 candidate and CALM protocol were reviewed at the National Institutes of Health's Recombinant DNA Advisory Committee (RAC) meeting on December 14, 2016. Servier submitted an IND application on February 1, 2017, with Pfizer's support. With this IND clearance, the CALM study will be expanded to include several centers in the U.S., including the MD Anderson Cancer Center in Houston (Texas).

"We are very pleased that Servier's first IND approval has been granted for such an innovative approach as allogeneic CAR T therapy", said Dr Patrick Thérasse, Director of Clinical Development Oncology at Servier. "B-ALL is a devastating disease and this study is key to gaining greater insight into the efficacy and safety profile of this new immune-oncology approach in patients with B-ALL."

"Pfizer is excited by the potential of this investigational CAR T approach to treating ALL and other B-Cell malignancies," said Barbara Sasu, Vice President, CAR T Research at Pfizer. "We are looking forward to having the opportunity to investigate this approach in the U.S."

### About UCART19

UCART19 is an allogeneic CAR T-cell product candidate being developed for treatment of CD19-expressing hematological malignancies, gene edited with TALEN®. UCART19 is initially being developed in acute lymphoblastic leukemia (ALL) and is currently in Phase I. The current approach with UCART19 is based on the preliminary positive results from clinical trials using autologous products based on the CAR technology. UCART19 has the potential to overcome the limitation of the current autologous approach by providing an allogeneic, frozen, "off-the-shelf" T cell based medicinal product.

In November 2015, Servier acquired the exclusive rights to UCART19 from Cellecctis. Following further agreements, Servier and Pfizer began collaborating on a joint clinical development program for this cancer immunotherapy. Pfizer has been granted exclusive rights by Servier to develop and commercialize UCART19 in the United States, while Servier retains exclusive rights for all other countries.



### **About Servier**

Servier is an international pharmaceutical company governed by a non-profit foundation with its headquarters in Suresnes (France). With a strong international presence in 148 countries and a turnover of 4 billion euros in 2016, Servier employs 21 000 people worldwide. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular diseases, diabetes, cancers, immune-inflammatory diseases, and neurodegenerative diseases, as well as by its activities in high-quality generic drugs. Being completely independent, the Group reinvests 25% of turnover (excluding generics) in research and development and uses all its profits for growth.

Becoming a key player in oncology is part of Servier's long-term strategy. Currently, there are nine molecular entities in clinical development in this area, targeting gastric and lung cancers and other solid tumors, as well as various leukemias and lymphomas. This portfolio of innovative cancer treatments is being developed with partners worldwide, and covers different cancer hallmarks and modalities, including cytotoxics, proapoptotics, targeted, immune and cellular therapies, to deliver life-changing medicines to patients.

More information: [www.servier.com](http://www.servier.com)

### **Pfizer Inc.: Working together for a healthier world®**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

### **Pfizer Disclosure Notice**

*The information contained in this release is as of 9 March 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about a product candidate, UCART19, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet clinical study commencement and completion dates as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when drug applications may be filed for UCART19 in any jurisdiction; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of UCART19; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*

### **About Collectis**

Collectis is a biopharmaceutical company focused on developing immunotherapies based on gene-edited CAR T-cells (UCART). The company's mission is to develop a new generation of cancer therapies based on engineered T-cells. Collectis capitalizes on its 17 years of expertise in genome engineering - based on its flagship TALEN® products and meganucleases as well as its pioneering electroporation PulseAgile technology - to create a new generation of immunotherapies. CAR technologies are designed to target surface antigens expressed on cells.



Using its life-science-focused, pioneering genome-engineering technologies, Collectis' goal is to create innovative products in multiple fields and with various target markets. Collectis is listed on the Nasdaq market (ticker: CLLS) and on the NYSE Alternext market (ticker: ALCLS).

To find out more about us, visit our website: [www.collectis.com](http://www.collectis.com)

Talking about gene editing? We do it. TALEN® is a registered trademark owned by the Collectis Group.

**Contact Servier**

Karine Bousseau  
Servier External Communications  
Tel: +33 1 5572 6037  
Email: [media@servier.com](mailto:media@servier.com)

**Contact Pfizer Inc**

Sally Beatty  
Media Relations  
+1 (212) 733-6566  
Ryan Crowe  
Investor Relations  
+1 (212) 733-8160