Preliminary Data from Servier and Pfizer’s UCART19 Product Candidate Shows High Complete Remission Rate Across Two Phase I Adult and Pediatric Acute Lymphoblastic Leukemia Trials

12 December 2017 – Servier, Pfizer Inc. (NYSE: PFE) and Cellectis (Euronext Growth: ALCLS - Nasdaq: CLLS) presented at the 59th American Society of Hematology (ASH) Annual Meeting and Exposition in Atlanta preliminary results from two phase 1 studies of UCART19, an investigational allogeneic anti-CD19 CAR T-cell product, in adult and pediatric patients with relapsed or refractory (R/R) CD19-positive B-cell acute lymphoblastic leukemia (B-ALL). These first-in-human data demonstrated the safety and tolerability of UCART19, resulting in an 83% complete remission rate across the adult and pediatric patient population.

Results from the CALM (UCART19 in Advanced Lymphoid Malignancies) Trial

The CALM study (UCART19 in Advanced Lymphoid Malignancies) is an open label, dose-escalation study designed to evaluate the safety, tolerability and anti-leukemic activity of UCART19 in adult patients with R/R B-ALL. Five out seven patients treated achieved molecular remission at Day 28 post UCAR19. Molecular remission is defined by negative minimal residual disease (MRD). MRD is a measurement of the number of residual leukemic cells that remain after treatment.

“These early results for UCART19 are very encouraging both in terms of manageable safety and the impressive complete molecular remission rate in these hard-to-treat adult patients with R/R B-ALL,” said Reuben Benjamin, Principal Investigator of the CALM Study and Consultant Hematologist at King’s College Hospital, United Kingdom. “This first cohort explored a lower dose of UCART19 that is approximately one tenth of that used in most autologous CAR-T trials. These results support additional evaluation of UCART19 at varying doses.”

Only one Grade 1 cutaneous acute graft versus host disease (GvHD) occurred. No severe neurotoxicity was observed. Cytokine release syndromes (CRS) were mild and manageable except in one patient treated with UCART19 at the first dose level, who developed CRS Grade 4 and neutropenic sepsis leading to death at Day 15.

Results from the PALL (Pediatric Acute Lymphoblastic Leukemia) Trial

The PALL (Pediatric Acute Lymphoblastic Leukemia) study is a phase 1, open label study designed to evaluate the safety and ability of UCART19 to induce molecular remission defined by MRD negativity at Day 28 to enable allogeneic stem cell transplantation in pediatric patients with high-risk R/R B-ALL. Results showed all five children achieved MRD negativity, enabling them to proceed to allogeneic stem cell transplant. Only one Grade 1 cutaneous acute GvHD occurred. No severe neurotoxicity was observed. Cytokine release syndromes were mild in the majority of cases and were all manageable.
Servier is the sponsor of both studies that are active in Europe and the United States.

“We are proud to present the first clinical trial data with UCART19 in patients with heavily pretreated R/R ALL,” said Patrick Therasse, MD, PhD, Head of Research and Development-Oncology for Servier. “We believe this innovative, allogeneic CAR T-cell approach could be disruptive to the patient community.”

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 adult and pediatric ALL and is currently in Phase I. 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 Cellectis. 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 France (Suresnes). With a strong international presence in 148 countries and a turnover of 4 billion euros in 2016, Servier employs 21,000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generic drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier’s constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancers and diabetes, as well as by its activities in high-quality generic drugs.

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: https://servier.com.

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PFIZER DISCLOSURE NOTICE
The information contained in this release is as of December 12, 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 anticipated 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; risks associated with preliminary data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; 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, and, if approved, whether UCART19 will be commercially successful; 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 and www.pfizer.com.

About Cellectis
Cellectis is a clinical-stage biopharmaceutical company focused on developing a new generation of cancer immunotherapies based on gene-edited T-cells (UCART). By capitalizing on its 17 years of expertise in gene editing – built on its flagship TALEN® technology and pioneering electroporation system PulseAgile – Cellectis uses the power of the immune system to target and eradicate cancer cells. Using its life-science-focused, pioneering genome engineering technologies, Cellectis’ goal is to create innovative products in multiple fields and with various target markets. Cellectis 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.cellectis.com. Talking about gene editing? We do it. TALEN® is a registered trademark owned by the Cellectis Group.

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This press release contains “forward-looking” statements that are based on our management’s current expectations and assumptions and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or
achievements expressed or implied by the forward-looking statements. Further information on the risks factors that may affect company business and financial performance, is included in filings Cellectis makes with the Security Exchange Commission from time to time and its financial reports. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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