PRESS RELEASE

# PIXUVRI® (pixantrone) receives positive CHMP opinion to convert conditional approval into standard marketing authorization in patients with aggressive non-Hodgkin B-cell lymphoma

## Pixantrone has been available to patients since 2012 following a conditional approval from the European Medicines Agency

9 April 2019 – Servier today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for PIXUVRI® (pixantrone) to convert its conditional approval into a standard marketing authorization as a single agent for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma. The CHMP's opinion will now be sent to the European Commission (EC) for the adoption of the decision.

In 2012, in recognition of the lack of standard of care and the poor prognosis for patients with aggressive non-Hodgkin B-cell lymphoma, the EMA gave a conditional marketing authorization for PIXUVRI® as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma.[1] Conditional marketing authorizations are granted in the EU to speed access to products that address unmet medical needs and where availability would result in a significant public health benefit.

"Patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma have limited treatment options," said Prof Pier Luigi Zinzani from the University of Bologna Institute of Hematology and Medical Oncology in Bologna, Italy. "In this patient population, PIXUVRI® offers a treatment option in later lines."

The positive opinion from the CHMP is based on data from the global clinical development of PIXUVRI®.

The pivotal study, PIX301 was an open-label, randomized, Phase III study comparing PIXUVRI® monotherapy with physician's choice of treatment in 140 patients with relapsed or refractory aggressive non-Hodgkin lymphoma, 50% of whom had been previously treated with rituximab. PIXUVRI® was shown to be beneficial in these patients: 20% of patients responded completely to PIXUVRI® compared with 5.7% of patients receiving other agents (p=0.021).[2,3]

To satisfy requirements of the conditional authorization, a further Phase III clinical study, PIX306, was completed to provide additional efficacy data to confirm the benefit of

PIXUVRI® in patients that had received prior treatment with rituximab. In the study PIX306, all patients were previously treated with rituximab, and the treatment was possible as a second line. While the superiority of PIXUVRI® over comparator was not met, both PFS and OS results in patients with ≥ 2 prior treatment lines are comparable, when indirectly compared to the PIXUVRI® treated population in the pivotal study PIX301.[3,4]

The most common side effects with PIXUVRI® are neutropenia, leukopenia, lymphopenia, anemia, thrombocytopenia, nausea, vomiting, skin discolouration, alopecia, chromaturia and asthenia.[2]

“Aggressive non-Hodgkin B-cell lymphoma is a devastating disease for which treatment options are limited. Servier is committed to providing PIXUVRI® to these patients so we are very pleased with today’s announcement,” said Patrick Therasse, Head of Servier Research and Development Oncology Department. “At Servier, oncology is one of our priorities. We will continue to work hard to get new therapeutic options to people affected by cancer.”

**#ENDS#**

**About non-Hodgkin lymphoma (NHL)**

NHL is a blood cancer that affects the lymphatic system, which is defined as a network of vessels and glands that run throughout the body.[5] The lymphatic system is a key component of the immune system, as it plays a role in destroying old or abnormal cells and fighting bacteria and other infections.[6]

NHL can occur in different parts of the body from the lymph nodes in the neck to the liver or spleen, but also in other organs such as the stomach, small bowel, bones, brain, testicles or skin.[7] Around 168,000 new cases of NHL are diagnosed in the United States and Europe every year.

**About PIXUVRI® (pixantrone)**

PIXUVRI® is indicated in the European Union as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma.[8] PIXUVRI® is a cytotoxic medicine that works by interfering with the DNA within cells and preventing them from making more copies of DNA. This means that the cancer cells cannot divide and eventually die.[1]

PIXUVRI® is mentioned in the ESMO guidelines as an anthracycline-like drug with reduced cardiotoxicity, which demonstrated some efficacy in heavily treated patients.[9]

More detail is available in the summary of the European public assessment report (EPAR) on the EMA website at www.ema.europa.eu.

Servier commercializes PIXUVRI® under a license from CTI BioPharma.

## 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 149 countries and a turnover of 4.2 billion euros in 2018, Servier employs 22,000 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (excluding generics) 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 neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.

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

More information: www.servier.com

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