PRESS RELEASE

Servier announces European Commission decision to convert conditional approval into standard marketing authorization in patients with aggressive non-Hodgkin B-cell lymphoma for PIXUVRI® (pixantrone)

Pixantrone has been available to patients since 2012 following a conditional approval in Europe

13 June 2019 – Servier today announced that the European Commission (EC) has approved the conversion of the conditional approval of PIXUVRI® (pixantrone) 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.

“There are limited treatment options for multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma,” said Prof Pier Luigi Zinzani from the University of Bologna Institute of Hematology and Medical Oncology in Bologna, Italy. “PIXUVRI has demonstrated efficacy in late stage disease and the EC approval confirms PIXUVRI as a treatment option for these patients.”

The EC approval 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 ($p=0.021$).[1,2]

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 regimens containing rituximab. In the study PIX306, all patients were previously treated with rituximab. While the superiority of PIXUVRI with rituximab compared to gemcitabine with rituximab was not met, both progression-free survival and overall survival results in patients with ≥ 2 prior treatment lines were similar, when indirectly compared to the PIXUVRI treated population in the pivotal study PIX301.[2,3]

“At Servier, we work diligently to develop and deliver medicines that address critical unmet medical needs in diseases such as multiply relapsed or refractory aggressive non-Hodgkin lymphoma,” said Patrick Therasse, Head of Servier Research and Development Oncology. “PIXUVRI has been benefitting patients since its conditional approval in 2012 but today’s

decision brings reassurance to patients and clinicians that this medicine remains a relevant treatment option in this indication."

The most common side effects with PIXUVRI are neutropenia, leukopenia, lymphopenia, anemia, thrombocytopenia, nausea, vomiting, skin discolouration, alopecia, chromaturia and asthenia.[1]

#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.[4] 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.[5]

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.[6] 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.[7] 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.[8]

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 twelve 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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