

## Servier submits NDA for pegaspargase (Oncaspar®) for the registration upon EAEU decentralized procedure

**Moscow, 27 March 2020 —** Servier pharmaceutical company announces the submission of NDA for Pegaspargase (Oncaspar®), lyophilisate for solution for injection, to the Ministry of Health of the Russian Federation, the reference country. Registration and approval of medical use will be carried out according to the decentralized procedure of the EAEU. Over the next three weeks, the registration dossier will be submitted to the authorized bodies of the states of recognition. It is expected that after registration in Russia and subsequent recognition by other countries, the medicine will be available to patients of the five EAEU countries, including Russia.

Pegaspargase is an antitumor cytostatic agent intended for the treatment of acute lymphoblastic leukemia (ALL) in combination with other cytostatics. The use of a new dosage form of the original pegaspargase (lyophilisate for solution for intramuscular and intravenous injection) is due to the cessation of production of the previously used dosage form (solution for intramuscular and intravenous injection).

Acute lymphoblastic leukemia is a malignant tumor of the hematopoietic system. ALL accounts for 75-80% of all tumor diseases of the hematopoietic system in children (3-4 cases per 100 thousand children per year), being the most common cancer in children. Most often, ALL is diagnosed before the age of 14; peak childhood incidence occurs at the age of 2-5 years. In 2018 in Russia 1840 people had acute lymphoblastic leukemia diagnosed, 1032 of them aged 0-19 years<sup>1</sup>.

Pegaspargase is included into the so-called Moscow-Berlin treatment protocol, which has been used for many years to treat children with acute lymphoblastic leukemia.

*«In the current challenging conditions, we have taken the necessary steps to provide the authorized bodies of the registration dossier of Oncaspar (INN pegaspargase) as soon as possible. Our goal is to ensure the availability of pegaspargase in Russia and other EAEU countries»,—* commented Natalya Chukreeva, Pharmaceutical Affairs Director for Russia and EAEU, Servier.

Servier acquired the Shire oncology portfolio, including exclusive rights to the pegaspargase drug (Oncaspar) and related processes, back in 2018. The previously existing marketing authorisation of pegaspargase (solution for intramuscular and intravenous injection) was canceled on August 13, 2019 upon the request of the holder of the corresponding registration certificate "Medak GmbH" (Germany).

### About Servier

Servier is a French pharmaceutical company, founded by a family, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a total revenue of 4.6 billion euros in 2019, Servier employs 22,000 people worldwide. Entirely independent, the Group invests on average 25% of its total revenue (excluding generics) every year in research and development and uses all its profits for its

<sup>1</sup> Collected works edited by A.D. Kaprina, V.V. Starinsky, G.V. Petrova: Malignant neoplasms in Russia in 2018 (morbidity and mortality) - M.: The Herzen Moscow Scientific and Research Oncological Institute, branch of the Federal State Budgetary Institution Scientific Research Center for Radiology of the Ministry of Health of Russia, -2019. -ill. -p. 250.



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.

Nihon Servier has been supplying patients with Servier's ethical drugs for almost 40 years under license agreement with local partners in Japan.

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

#### **About Servier Russia**

Servier has been operating in Russia for almost 20 years remaining one of the leading pharmaceutical companies. In 1999 an R&D center was established in Moscow. In 2007, a full-cycle pharmaceutical plant Servier RUS was launched in Moscow, meeting all international requirements and good manufacturing practice (GMP) standards and producing a wide range of modern original medicines for Russian citizens. In 2012, the first export deliveries of drugs manufactured in Russia to the CIS countries were carried out. In 2016, the Moscow Government assigned the status of Industrial Complex to the Servier RUS pharmaceutical plant. In April 2019, the plant launched contract manufacturing of an innovative drug for the treatment of HIV, and in December 2019 Servier was one of the first companies to successfully launch the Track&Trace system.

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



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