NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

March 23, 2021

MHLW approval of Vidaza® (azacitidine) for the Treatment of Acute Myeloid Leukemia

Kyoto, Japan, March 23, 2021 – Nippon Shinyaku Co., LTD. (Nippon Shinyaku; Headquarters, Kyoto; President, Shigenobu Maekawa) announced today that Nippon Shinyaku which is a marketing authorization holder of Vidaza® 100mg injection in Japan has obtained an expanded approval for the treatment of Acute Myeloid Leukemia (AML) from the Ministry of Health, Labor and Welfare (MHLW).

AML which is one of blood cancers and a serious disease that requires prompt and appropriate treatment. AML results from genetic abnormalities in myeloblasts which are immature blood cells. The unrestricted growth of leukemia cells in the bone marrow prevents from the production of normal blood and results in various symptoms such as infection and bleeding. The number of AML patients in Japan is reported as about 7,000.

Vidaza® is a lyophilized product for injection containing nucleoside derivatives, azacitidine as its active ingredient. It has been reported that Vidaza® is incorporated into RNA or DNA after phosphorylation in cells, inhibits protein synthesis, and shows cytotoxic effects. Moreover, it is reported that Vidaza® inhibits aberrant DNA methylation. In Japan, Vidaza® was launched in March 2011 for the treatment of myelodysplastic syndromes.

We are dedicated to the development and commercialization of therapeutic agents and providing medical information, focusing on the field of hematological malignancies. We hope that the additional indication for this drug will contribute to patients suffering from AML, their families, and healthcare professionals.

About Nippon Shinyaku

Our mission is to help people lead healthier and happier lives. Through creating unique medicines that will bring hope to patients and families struggling with illness, we aim to be an organization trusted by the community. Please visit our website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

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