

August 8, 2023

NS-018, Treatment for Myelofibrosis under development in overseas received Orphan Drug Designation from EC

Kyoto, Japan, August 8, 2023 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the European Commission (EC) has granted Orphan Drug Designation to NS-018 (ilginatinib), an oral selective JAK2 inhibitor which is being developed for myelofibrosis (MF) by NS Pharma, Inc. (Paramus NJ, USA; President, Tsugio Tanaka), a wholly owned subsidiary of Nippon Shinyaku.

The Orphan Drug Designation by EC is issued to drugs which are intended for diseases that affect fewer than 5 in 10,000 people in European Union (EU), and are life-threatening or chronically debilitating. The designation provides for a ten-year marketing exclusivity period. In the US, NS-018 has already been designated as an Orphan Drug by the U.S. Food and Drug Administration (FDA) in December, 2022.

MF is a rare, intractable hematologic cancer with anemia, splenomegaly, and general malaise caused by extensive fibrosis in the bone marrow. The prognosis is poor in the high-risk MF. Since most MF patients are relatively elderly, bone marrow transplantation, the only curative therapy available at the moment, can be applied to a limited number of patients. Therefore, drug therapy will remain as an indispensable option. However, in addition to thrombocytopenia due to the hematopoietic disorder of MF itself, thrombocytopenia can be caused by MF therapeutic agents, and the associated bleeding symptoms are a clinical issue.

NS-018 is a JAK2 inhibitor discovered in-house, and has a characteristic of high selectivity for active JAK2. NS-018 is expected to be effective and safe for MF patients with low platelet counts.

Nippon Shinyaku will continue our best efforts to deliver NS-018 to patients suffering from MF as soon as possible.

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