NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

December 20, 2022

NS-018, Treatment for Myelofibrosis under development in overseas received Orphan Drug Designation from the U.S. FDA

Kyoto, Japan, December 20, 2022 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that the U.S. Food and Drug Administration (FDA) 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 is issued to drugs which are intended for rare diseases that affect fewer than 200,000 patients in the U.S., or that affect more than 200,000 patients but are not expected to recover the costs of developing and marketing a treatment drug. The designation provides for a potential seven-year marketing exclusivity period as well as certain incentives including tax breaks.

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.

Contact

Corporate Communications Dept., Nippon Shinyaku
FAX: +81-75-321-9128