

NEWS RELEASE



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NS-018, an Investigational Treatment for Myelofibrosis, Receives Orphan Drug Designation from the European Commission

NS Pharma, Inc. (NS Pharma; President, Tsugio Tanaka), is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; President, Toru Nakai)

Paramus, NJ: August 8, 2023 – NS Pharma, Inc. announced today that the European Commission (EC) has granted Orphan Drug Designation to NS-018 (ilginatinib) an oral, selective JAK2 inhibitor which is being investigated for the treatment of myelofibrosis (MF).

The EC Orphan Drug Designation is issued to investigational treatments for diseases that affect fewer than 5 in 10,000 people in the European Union and are life-threatening or chronically debilitating. The designation provides for a ten-year marketing exclusivity period. In the US, NS-018 received Orphan Drug Designation by the U.S. Food and Drug Administration in December 2022.

MF is caused by buildup of excessive scar tissue in the bone marrow, which impairs the body's ability to produce blood cells.¹ In addition to impaired blood cell production, MF often leads to enlargement of the spleen (splenomegaly) which can lead to feelings of abdominal pain and pressure.¹ Other common symptoms include fatigue, bone pain, fever, and weight loss.¹ MF can be diagnosed at any age but is most common in men and women 65 years or older.¹ The median survival of patients with MF is approximately six years.¹

Several gene mutations are associated with MF, and the most common mutation is to the Janus kinase 2 (JAK2) gene.² NS-018 is a highly selective and potent inhibitor of JAK2 developed by scientists from Nippon Shinyaku.

About NS Pharma, Inc.

NS Pharma, Inc., is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. For more information, please visit <http://www.nspharma.com>. NS Pharma is a registered trademark of the Nippon Shinyaku group of companies.

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2. Myelofibrosis. Mayo Clinic. Accessed at: <https://www.mayoclinic.org/diseases-conditions/myelofibrosis/symptoms-causes/syc-20355057>