

# NEWS RELEASE



December 20, 2022

## **NS Pharma Announces Receipt of Orphan Drug Designation from the U.S. FDA for NS-018, an Investigational Treatment for Myelofibrosis**

**Paramus, NJ: December 20, 2022** - NS Pharma, Inc. (NS Pharma; President, Tsugio Tanaka), a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; President, Toru Nakai), today announced that the U.S. FDA has granted Orphan Drug Designation to NS-018 (ilginatinib), an investigational treatment for myelofibrosis (MF), a rare and incurable blood cancer.

The FDA issues Orphan Drug Designations to support the development and evaluation of new treatments to prevent, diagnose, or treat a rare disease or condition.

MF is caused by buildup of excessive scar tissue in the bone marrow, which impairs the body's ability to produce blood cells.<sup>1</sup> 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.<sup>1</sup> Other common symptoms include fatigue, bone pain, fever, and weight loss.<sup>1</sup> MF can be diagnosed at any age but is most common in men and women 65 years or older.<sup>1</sup> The median survival of patients with MF is approximately six years.<sup>1</sup>

Several gene mutations are associated with MF, and the most common mutation is to the Janus kinase 2 (JAK2) gene.<sup>2</sup> 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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### References:

1. What is primary myelofibrosis? MPN Research Foundation. Accessed at: <https://www.mpnresearchfoundation.org/primary-myelofibrosis-pmf/>
2. Myelofibrosis. Mayo Clinic. Accessed at: <https://www.mayoclinic.org/diseases-conditions/myelofibrosis/symptoms-causes/syc-20355057>