

# NEWS RELEASE



March 28, 2022

## **Marketing approval of MonoVer for I.V. injection 500mg/1000mg by MHLW for the treatment of iron deficiency anemia**

**Kyoto, Japan, March 28, 2022** - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced as of today that the Ministry of Health, Labour and Welfare (MHLW) has approved marketing authorization of MonoVer for I.V. injection 500mg/1000mg (ferric derisomaltose/NS-32) for the treatment of iron deficiency anemia.

Iron deficiency anemia (IDA) is the anemia caused by iron deficiency and reduction of hemoglobin synthesis associated with heavy uterine bleeding, post-partum hemorrhage, gastrointestinal bleeding, poor absorption of iron through gastrointestinal tract and other relevant diseases. Typical symptoms including palpitation, shortness of breath, fatigue, and other symptoms such as concave nails (koilonychia) caused by iron deficiency are recognized. To treat IDA, it is fundamental to treat the underlying cause of IDA and replenish iron stores. Regarding iron replenishment, oral iron can be the first choice, and intravenous iron can be selected when oral iron preparations are insufficient due to iron loss caused by massive bleeding, inappropriate to be used due to side effects or poor absorption.

MonoVer is an intravenous iron preparation that contains ferric derisomaltose, a high-stability matrix structure binding with iron and low immunogenicity linear oligosaccharide (derisomaltose), as API. MonoVer is considered to be a choice for the IDA treatment as the maximum single dose 1000mg enables full iron correction in a short period with few times of infusion.

Nippon Shinyaku licensed in the product from Pharmacosmos A/S (Headquarters, Holbaek, Denmark; President & CEO, Lars Christensen) in December, 2016. This marketing approval is based on the results from three Japanese Phase 3 trials for IDA with heavy uterine bleeding, gastrointestinal bleeding, and post-partum hemorrhage. The product has been approved in more than 46 countries.

Nippon Shinyaku aims to contribute to the treatment of iron deficiency anemia by appropriately delivering MonoVer to patients.

### Summary of MonoVer

Product Name	MonoVer for I.V. injection 500mg/1000mg
JAN	Ferric derisomaltose
Dosage Forms and Strengths	MonoVer for I.V. Injection 500 mg: Aqueous injection containing ferric derisomaltose as ferric iron (500 mg) in 1 vial (5 mL) MonoVer for I.V. Injection 1000 mg: Aqueous injection containing ferric derisomaltose as ferric iron (1000 mg) in 1 vial (10 mL)
Indications and Usages	Iron deficiency anemia
Dosage and Administrations	Generally, in adults with BW $\geq$ 50 kg, the single dose should be up to 1000 mg iron once a week intravenous drip infusion, or up to 500 mg iron up to twice a week slow intravenous bolus injections. Generally, in adults with BW < 50 kg, the single dose should be up to 20 mg/kg iron once a week intravenous drip infusion, or up to 500 mg iron up to twice a week slow intravenous bolus injections. While the total iron dose varies by patient's Hb and body weight, the maximum total dose is 2000 mg iron (or 1000 mg iron in adults with BW < 50 kg).

### ABOUT PHARMACOSMOS A/S

Pharmacosmos Group, headquartered in Holbaek, Denmark, and founded in 1965, is a highly specialised company focused on carbohydrate chemistry and a global leader in the development of innovative treatments for patients suffering from iron deficiency and iron deficiency anaemia. With companies in the UK, Nordics, Germany, the USA, and China, as well as through partners, Pharmacosmos markets its products across the world. With a strong and ongoing commitment to R&D, Pharmacosmos is able to leverage a unique carbohydrate production platform along with deep expertise in the synthesis of iron-carbohydrate complexes.

### ABOUT NIPPON SHINYAKU CO., LTD.

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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