

Launch of “Zanosar IV Infusion 1 g” for Treatment of Cancer (Gastroenteropancreatic Neuroendocrine Tumors)

Nobelpharma Co., Ltd. (Headquarters: Tokyo, President: Jin Shiomura) today announces the launch of "Zanosar IV Infusion 1g" (generic name: streptozocin or STZ), a drug for the treatment of gastroenteropancreatic neuroendocrine tumor as of February 23.

Since the approval in the U.S. obtained by an American company, Upjohn (currently Pfizer), in 1982 for the indication of symptomatic or progressive metastatic pancreatic islet cell cancer, STZ has been used for a long time for the treatment of gastroenteropancreatic neuroendocrine tumor ("GEP NET") as a monotherapy or in combination with doxorubicin (DOX) or fluorouracil (5-FU).

In Japan, upon the request from the Ministry of Health, Labour and Welfare as a result of "Evaluation Committee on Unapproved or Off-label Drugs with High Medical Needs," Nobelpharma started the development and conducted Phase I/II study of Zanosar in patients with unresectable or metastatic GEP NET.

Zanosar was designated as an orphan drug for the indication of GEP NET on November 16, 2011 and was approved for marketing under the brand name of "Zanosar IV Infusion 1g" on September 26, 2014. Zanosar is manufactured, distributed and marketed nationwide by Nobelpharma Co., Ltd.

Zanosar is the first cytotoxic anti-cancer drug for treatment of GEP NET in Japan, leading to an expansion of the treatment options for patients with unresectable or metastatic GEP NET. Nobelpharma is committed to address the issues of rare disease treatments through Zanosar continuing to contribute to society by providing drugs for unmet medical needs.

Nobelpharma will conduct postmarketing surveillance on all patients receiving Zanosar to collect safety and efficacy data for certain period of time from its launch.

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[Product Profile]

Brand Name: Zanosar IV Infusion 1g

Generic Name: streptozocin

Indication: gastroenteropancreatic neuroendocrine tumor

Package: 1 vial

Dosage and Administration: Either as a weekly treatment (once a week) or as a daily treatment for 5 consecutive days every 6 weeks

NHI Drug Price: 42,531 yen

Manufacturer: Nobelpharma Co., Ltd.

Product Website: <http://nobelpark.jp/>

* GEP NET is a relatively rare tumor with the annual incidence of 3 to 5 per 100,000 people, and 2015 estimation of the number of candidates for drug therapy is about 3,600.



About Nobelpharma

Nobelpharma has been contributing to medical care through R&D of necessary but neglected pharmaceuticals since 2003. Nobelpharma gives priority in developing pharmaceuticals desired strongly by patient groups, the Japan Medical Association, and other organizations with the intent to fill the unmet medical needs. Focusing mainly on orphan drugs, additional indications for drugs used off-label, and pediatric medicines, Nobelpharma has obtained marketing approvals for 14 products primarily for unmet medical needs, of which 9 are designated as orphan drugs.

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