



For Immediate Release

October 16, 2009

Dainippon Sumitomo Pharma Co., Ltd.

Therapeutic agent for hepatocellular carcinoma “MIRIPLA®” obtained manufacturing and marketing approval

Dainippon Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; President: Masayo Tada) announces that the Company has obtained a manufacturing and marketing approval for “MIRIPLA® for intra-arterial injection 70 mg” (generic name: miriplatin hydrate), a therapeutic agent for hepatocellular carcinoma in Japan as of October 16, 2009 from Ministry of Health, Labor and Welfare.

“MIRIPLA®” is first suspended in an oily lymphographic agent and then administered through hepatic artery into hepatocellular carcinoma. As such an oily lymphographic agent, the Company has “MIRIPLA® suspension vehicle 4 mL” (generic name: iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil), which is approved for suspending MIRIPLA®. The manufacturing and marketing approval for this suspension vehicle was obtained on August 20, 2009 from the competent Ministry.

“Lipiodolization” or “Chemo-lipiodolization” is one of the standard methods for treating hepatocellular carcinoma where an anticancer drug is suspended in an oily lymphographic agent (iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil) and then administered into hepatic artery. The Company has carried out a research program to discover an anticancer drug suitable for this treatment and succeeded in development of a lipophilic platinum complex, miriplatin which has high affinity to iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil.

MIRIPLA® has a high suspensibility in “MIRIPLA® suspension vehicle 4 mL “. Some of the characteristics of MIRIPLA® are: it accumulates and stays in a tumor after the administration into hepatic artery, platinum component is released gradually over a long duration and yet exposure to entire body is minor.

In clinical tests on hepatocellular carcinoma, satisfactory anti-tumor effects were confirmed not only on patients of initial treatment but also on patients who relapsed after treatment such as hepatic resection. Some side effects were observed, but they were regarded as those generally observed under chemo-lipiodolization therapy, and they were thought to be tolerable at medical institutions familiarized with this treatment. There was no adverse event on vessel disorder in hepatic artery related to this drug.

The Company has an intention to launch both “MIRIPLA[®] for intra-arterial injection 70 mg” and “MIRIPLA[®] suspension vehicle 4 mL” after they are listed on the national health insurance drug price standard. As a result of launching of MIRIPLA[®], the Company expects to increase the line-up of products for the liver diseases, which includes Sumiferon[®], a natural interferon-alpha product, and to further contribute to the total care of liver diseases.

[An outline of MIRIPLA[®] is described in the page of “reference”.]

<Reference>

Profile of MIRIPLA[®]

[Brand name]	MIRIPLA [®] for intra-arterial injection 70 mg
[Generic name]	miriplatin hydrate
[Content/Description]	70 mg of miriplatin contained in one vial (equivalent to 71.65 mg of miriplatin hydrate)
[Indication]	Lipiodolization in hepatocellular carcinoma
[Dose and Administration]	70 mg of miriplatin is suspended in 3.5 mL of suspension vehicle for this drug, and administered once a day through catheter inserted into hepatic artery. Administration of miriplatin-suspension ends when tumor vessel is filled with the drug, provided that the upper limit should be 6 mL per administration (equivalent to 120 mg of miriplatin). An observation period of 4 weeks or longer is required in the case of repeated administration.
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma

Profile of “the suspension vehicle”

[Brand name]	MIRIPLA [®] suspension vehicle 4 mL
[Generic name]	iodine addition products of the ethylesters of the fatty acids obtained from poppyseed oil
[Content/ Description]	4 mL of this liquid contained in one ampule
[Indication]	For suspending MIRIPLA [®] for intra-arterial injection 70 mg
[Dosage and Administration]	3.5 mL of this suspension vehicle added to 70 mg of miriplatin
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma