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Dainippon Sumitomo Pharma Co., Ltd.

Dainippon Sumitomo Pharma submits an application for anticancer antibiotic  
amrubicin HCl (Brand name in Japan: CALSED®) in China

Osaka, Japan, September 5, 2012 – Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) announces today that it has submitted an imported drug registration application in China for anticancer antibiotic amrubicin HCl (Generic name, Brand name in Japan: CALSED®) to the State Food and Drug Administration, P.R. China (SFDA) for the treatment of small cell lung cancer as of August 21, 2012.

In Phase 3 studies in China on new (untreated) patients of extensive disease small cell lung cancer, a combination of amrubicin HCl and cisplatin HCl was compared to a combination of cisplatin and etoposide, the standard therapy for small cell lung cancer. As a result, non-inferiority of the amrubicin-cisplatin combination vs the cisplatin-etoposide combination was demonstrated at the primary endpoint of “overall survival”. Receiving these results, DSP submitted an imported drug registration application to the SFDA for amrubicin HCl as a first-line treatment for small cell lung cancer.

By providing a new treatment for small cell lung cancer in China, DSP hopes to contribute to the treatment of Chinese patients with lung cancer.

(Reference)

About amrubicin HCl (Brand name in Japan: CALSED®)

Amrubicin HCl is the world's first totally synthesized anthracycline anticancer antibiotic created by DSP that has demonstrated anti-tumor effects as a potent inhibitor of topoisomerase II. In Japan, DSP received manufacturing and marketing approval for the treatment of small cell lung cancer and non-small cell lung cancer in April 2002, then launched the product in December 2002. Nippon Kayaku Co., Ltd. has marketed the product since 2005.

About small cell lung cancer

Lung cancer can be roughly classified as small cell lung cancer and non-small cell lung cancer. In a survey in 2005, the number of patients with newly diagnosed lung cancer in China was approximately 530,000 with approximately 470,000 deaths. According to the 2010 Statistical Yearbook of Health it is said to be the number one cancer mortality in China.

Small cell lung cancer affects roughly 15-20% of patients who develop lung cancer. Its

characteristics are rapid development and metastasis, a tendency for recurrence, and it is a disease with a poor prognosis. Treatments include surgery, radiation therapy, and chemotherapy using carcinostatics. However, in extensive disease small cell lung cancer where surgery and radiation therapy are not suitable, etoposide-cisplatin combination therapy is the standard treatment.

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