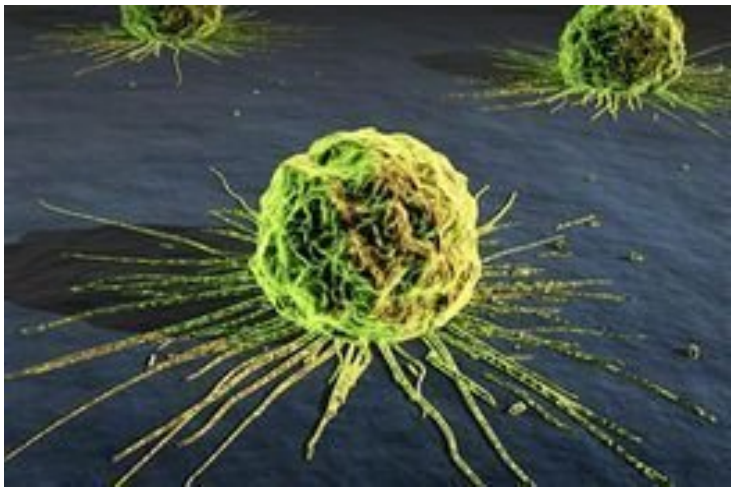
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Taiho seeks Japanese nod for oral cancer agent

February 28, 2013 | News | By BioSpectrum Bureau

Taiho Pjarma seeks Japanese Ministry of Health, Labor and Welfare, nod to manufacture oral cancer agent TAS 102



Singapore: Taiho Pharmaceutical submitted an application for approval of the manufacture and marketing of the novel oral nucleoside antitumor agent TAS-102 (combination of trifluorothymidine (FTD) and tipiracil hydrochloride (TPI)) to the Japanese Ministry of Health, Labor and Welfare, for the indication of unresectable, advanced, recurrent colorectal cancer.

The application for approval is based on the results of a phase II clinical trial (Study 10040030) conducted at 20 facilities throughout Japan. It was a randomized, double-blind comparative study of TAS-102 and a placebo involving 172 patients with unresectable, advanced, recurrent colorectal cancer that was refractory to the standard chemotherapy of at least two or more regimens containing fluoropyrimidine, irinotecan, and oxaliplatin.

The results indicated that the group administered TAS-102 had improved overall survival rates (median overall survival of nine months vs. 6.6 months) and a significantly reduced risk of mortality (HR: 0.56, p=0.0011). The most frequently reported adverse drug reaction with a CTCAE grade of three or higher was neutropenia.

Grade three or higher diarrhea, fatigue, nausea, and other adverse reactions were no more than 10 percent. Taiho Pharmaceutical is currently proceeding with a global phase III clinical trial of TAS-102 in a similar colorectal cancer population (Recourse) with the ultimate goal of global registration and commercialization of the agent. Taiho Pharmaceutical believes that TAS-102 will make a significant contribution to cancer patients and will continue its development efforts to broaden its use.