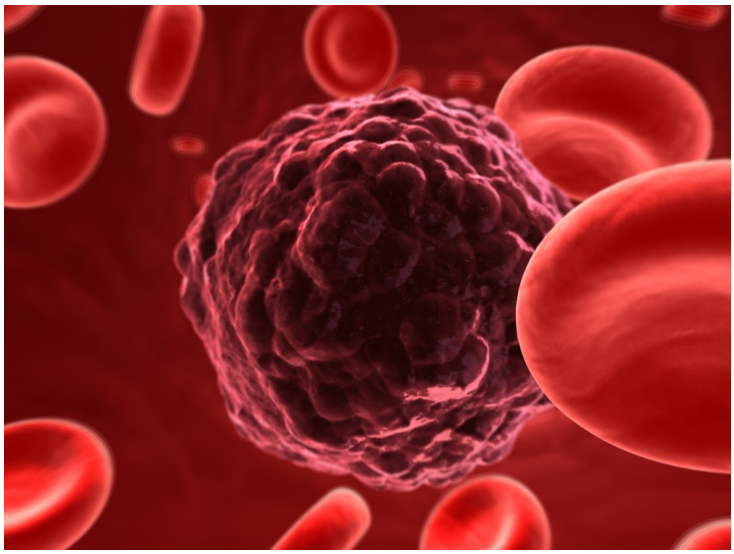
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Taiho to start ph III trial in colorectal cancer

May 31, 2012 | News | By BioSpectrum Bureau

Taiho Pharma to start Ph III clinical trial in colorectal cancer



Singapore: Japan based-Taiho Pharmaceutical is starting global phase III clinical trial (RECOURSE) for the novel combination antimetabolite TAS-102 in June this year.

RECOURSE is a randomized, double-blind, placebo-controlled Phase III trial that compares TAS-102 with best supportive care (BSC) to investigate the efficacy and safety of TAS-102 when administered to patients with advanced recurrent colorectal cancer that is both unresectable and relapsed/refractory to standard chemotherapies. Standard chemotherapies include fluoropyrimidines, irinotecan, oxaliplatin, bevacizumab and, in the case of patients whose tumor harbors the wild-type KRAS gene, an anti-EGFR monoclonal antibody.

The primary endpoint is overall survival. Eight hundred patients around the world will be enrolled into the trial, beginning in Japan in June, followed by North America, Europe and Australia. The principal investigators will be Dr Atsushi Ohtsu, National Cancer Center Hospital East (Kashiwa/Japan), Dr Robert J Mayer, Dana Farber Cancer Institute (Boston/USA), and Dr Eric Van Cutsem, University Hospital Gasthuisberg (Leuven/Belgium).

Taiho Pharmaceutical is proceeding with the global development of TAS-102 so that this drug can be offered as soon as possible to metastatic colorectal cancer patients who have exhausted standard treatment options.