



ゼリア新薬

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February 6th, 2007

PRESS RELEASE

Zeria Pharmaceutical Co., Ltd.
10-11 Nihonbashi-Kobunacho,
Chuo-ku, Tokyo 103-8351

Conclusion of Co-development and Co-marketing Agreement of ASACOL[®] for Inflammatory Bowel Disease, with Kyowa Hakko Kogyo Co., Ltd.

We would like to announce that Zeria and Kyowa Hakko Kogyo Co., Ltd. concluded on January 29, 2007 the agreement for the co-development and co-marketing of the drug for inflammatory bowel disease (IBD), Asacol[®] (development code: Z-206; generic name: mesalazine; Asacol is an oral enteric-coated pharmaceutical formulation of mesalazine). Asacol[®] was exclusively licensed in 2004 from Tillotts Pharma AG in Switzerland to Zeria, and the clinical Phase III trials are underway.

Under this agreement, clinical development for ulcerative colitis (UC) is performed by Zeria alone but that for Crohn's disease (CD) will be conducted jointly. After a marketing approval, Zeria will perform blistering and packaging, and supply to both companies for co-market the product. Distribution, marketing and activities of providing, gathering and transmitting medical information will be conducted in parallel (1 brand, 2 channels).

Asacol[®] is the pharmaceutical formulation of mesalazine with the pH-dependent gastro resistant coating specially designed for targeted release. It is being marketed in 53 countries. Asacol[®]'s global sales occupy over 1/3 of the global IBD market, and it is the leading pharmaceutical product in its therapeutic class.

Since Asacol[®] tablet is designed to release mesalazine starting in the terminal ileum and throughout the colon, lesions especially in the lower gastrointestinal tract can be treated.

Among chronic inflammatory diseases in large and small intestines, UC is the disease causing chronic inflammation or lesions in colon mucosa. In CD, chronic inflammation or lesions are found anywhere in the GI tract but most common in terminal ileum, colon and rectum. Both diseases are chronic, refractory and recurrent, and produce symptoms such as abdominal pain, bleeding and diarrhea. Patient populations of UC and CD are gradually increasing in Japan.

Zeria is focusing on marketing of pharmaceuticals for digestive diseases such as H₂ antagonist Acinon[®] Capsule 75/150, Promac[®] Granule 15%/D Tablet 75 containing zinc for gastric ulcer, Marzulene[®]-S Granule/ES Tablet for gastric ulcer and gastritis, and New Lecicarbon[®] Suppository for constipation.

Furthermore, in the same area, Zeria is developing a colon cleansing agent for colonoscopy (Z-205 or Visiclear[®] Tablet) in Japan, Z-338 for functional dyspepsia in the US, Europe and Japan, and Z-360 for pancreatic cancer in Europe.