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**For Immediate Release**

Company name Otsuka Holdings Co., Ltd.  
Representative Tatsuo Higuchi  
President and Representative Director, CEO  
Code number 4578 First Section , Tokyo Stock Exchange  
Inquiries Takuma Kimura  
Director, Investors Relations Department

**TEYSUNO™ (S-1) RECEIVES EUROPEAN MARKETING AUTHORIZATION  
FOR ADVANCED GASTRIC CANCER**

**Authorization Provides a New Treatment Option for European Gastric Cancer Patients**

Tokyo, 14 March 2011 – Taiho Pharmaceutical Co., Ltd., and its parent company, Otsuka Holdings Co., Ltd., announced today that the European Commission (EC) has granted marketing authorization for Teysuno™ (S-1), a novel oral anti-cancer agent indicated for the treatment of adults with advanced gastric cancer when given in combination with cisplatin. The authorization is applicable to the 27 Member States and the three European Economic Area (EEA) countries of the European Union (EU).

“For European patients living with gastric cancer, the availability of this new treatment option is a timely addition to the therapeutic landscape,” said Alfredo Carrato, MD, Professor and Director of the Medical Oncology Department at Ramon y Cajal University Hospital in Madrid, Spain.

A member of the fluoropyrimidine class of anticancer agents, Teysuno™ is a combination of three pharmacological compounds. The main active substance in Teysuno, tegafur, is a prodrug of a chemical called 5-fluorouracil (5-FU), meaning that it is converted in the body to 5-FU. In the body, 5-FU interferes with the enzymes involved in making DNA. As a result, it can prevent the growth of cancer cells or result in cell death.

The two other active substances in Teysuno™ allow tegafur to be effective at lower doses and with fewer side effects. Specifically, gimeracil prevents the breakdown of 5-FU and oteracil reduces the activity of 5-FU in normal, non-cancerous tissue in the gut.

The EC’s marketing authorization decision was based in part on the results of the First-Line Advanced Gastric Cancer Study (FLAGS), the largest international Phase III trial ever conducted in patients with advanced gastric cancer.

“We are pleased that the European Commission has recognized the importance of the FLAGS study findings, which showed that Teysuno-based combination therapy was as effective as a comparator regimen, with an

acceptable safety profile,” commented Fabio M. Benedetti, MD, Chief Medical Officer of Taiho Pharma U.S.A., Inc.

Teysuno™ will be launched in Europe during the second half of 2011.

### **About Gastric Cancer**

With an estimated 934,000 new cases per year (8.6% of all new cancer cases), gastric cancer is the fourth most common cancer worldwide, following lung, breast, and colorectal cancers. It is the second most common cause of cancer-related death, accounting for an estimated 700,000 to 800,000 deaths annually. Nearly 70% of new cases occur in developing countries; 42% of new cases occur in China alone.

In Europe, gastric cancer is the seventh most common cancer and the sixth most common cause of cancer death, with an estimated annual mortality rate of 118,200. In general, gastric cancer incidence rates are about twice as high among men as in women. The disease is difficult to cure unless it is diagnosed in its early stages. Unfortunately, because early gastric cancer causes few symptoms, the disease is not usually diagnosed until it has reached an advanced stage. In Europe, the five-year survival rate for gastric cancer is roughly 20% in men and 25% in women. Similarly, in the United States, the five-year survival rate for gastric cancer is 24%, though survival rates improve to 61% if the disease is detected early. However, less than one-quarter of gastric cancers are diagnosed at an early stage in the United States. In contrast, the five-year survival rate exceeds 50% in Japan, where early gastric cancer is diagnosed relatively frequently due to mass screening efforts, which have been practiced since the 1960s.

### **About Teysuno**

Teysuno™ was authorized for the treatment of gastric cancer in Japan in 1999. Teysuno™ is also authorized for patients with gastric cancer in South Korea, China, Singapore and Taiwan. To date, Teysuno™ has been used by more than 870,000 patients in Japan and Asia.

### **About Taiho Pharmaceutical Co., Ltd.**

Taiho Pharmaceutical Co., Ltd. (Taiho) is a company engaged in discovery, development, manufacturing and marketing of pharmaceutical products, with headquarters in Tokyo, Japan. Taiho is one of the leading companies focused on oncology. More information is available at the company's website at [www.taiho.co.jp/english/index.html](http://www.taiho.co.jp/english/index.html).

### **About Otsuka Holdings Co., Ltd.**

The Otsuka Group is a global organization of 145 healthcare companies with nearly 39,000 employees. Otsuka Holdings Co., Ltd., is the Group's holding company. The main operating companies are Otsuka Pharmaceutical Co., Ltd.; Otsuka Pharmaceutical Factory, Inc.; Taiho Pharmaceutical Co., Ltd.; Otsuka Warehouse Co., Ltd.; and Otsuka Chemical Co., Ltd. The Group operates in 23 countries and regions, conducting diversified businesses in four segments all connected by a focus on health: pharmaceuticals, nutraceuticals, consumer products, and other product areas. The Group's corporate philosophy of "Otsuka-people creating new products for better health worldwide" is supported by the corporate ethic of "JISSHO (Proof through Execution) and SOZOSEI (Creativity)." The Otsuka Group thus seeks to foster a culture and vitality appropriate to an enterprise involved with human health and to create innovative products that contribute to the health and wellness of people worldwide. For more information, please visit the company's website at [www.otsuka.com/en/](http://www.otsuka.com/en/).

### **Media Contact**

JFK Communications, Inc.  
Megan Faulkner  
609.514.5117  
MFaulkner@JFKHealth.com

