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**ABSTRACT #4514**  
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**S-1, A NOVEL ORAL FLUOROPYRIMIDINE,  
WHEN COMBINED WITH CISPLATIN, DEMONSTRATES SIGNIFICANT  
IMPROVEMENT IN OVERALL SURVIVAL OF ADVANCED GASTRIC CANCER  
PATIENTS OVER S-1 ALONE**

**Positive results of the “SPIRITS” Study Reported in Oral Presentation at ASCO 2007**

**Chicago, IL - June 3, 2007** -- Taiho and sanofi-aventis announced today the results of a phase III trial in advanced gastric cancer, which shows that the combination of the investigational oral fluoropyrimidine S-1 with cisplatin significantly reduces the risk of death by 22.6% (HR: 0.774; 95% CI [0.608-0.985]) over S-1 alone. Findings from the “SPIRITS” study, a Japanese multicenter, randomized, open label phase III trial, were presented today at the 43<sup>rd</sup> Annual Meeting of the American Society of Clinical Oncology in Chicago, IL.

The overall survival with a two-year follow-up was significantly higher in the S-1/cisplatin combination arm over S-1 alone (in median, respectively 13 months versus 11 months,  $p=0.036$ ). The overall Response Rate (RR) is also significantly better among patients treated with S-1 and cisplatin (54% of patients treated with the combination responded to treatment compared with 31.1% with S-1 alone,  $p=0.001$ ).

There were more grade 3/4 hematological and gastro-intestinal (anorexia/nausea) toxicities when cisplatin was combined with S-1, and there were much lower incidences of the same side effects with S-1 alone.

“This study demonstrates that the combination of S-1 and cisplatin brings to the patient with advanced gastric cancer an acceptable benefit/risk ratio,” presented Dr. Hiroyuki Narahara, study investigator. “The results confirm previous data we’ve seen in Japan, where S-1 has been on the market for the treatment of gastric cancer for eight years now.”

**About the “SPIRITS” Study**

The “SPIRITS” study is part of an investigational ongoing program testing S-1 in combination with different anti-cancer drugs in advanced gastric cancer. This study was designed to evaluate the efficacy of S-1 combined with cisplatin compared to S-1 alone in patients with unresectable or recurrent advanced gastric cancer who have never been treated with chemotherapy.

Three hundred and five patients were randomized to receive either oral S-1 twice daily for 28 days followed by a 14-day rest period, or oral S-1 twice daily for 21 days plus IV cisplatin on the eighth day of treatment, followed by the 14-day rest period. The dose of S-1 was the same for both patient groups, 40 mg/m<sup>2</sup> twice daily.

The primary endpoint of the SPIRITS study was overall survival (OS). Secondary endpoints included Response Rate, Time to Treatment Failure (TTF) and toxicity. The trial was designed to have 90% power to detect an improvement in median overall survival from 8 to 12 months.

### **About S-1**

S-1 is a novel oral fluoropyrimidine that combines 3 pharmacological agents: Tegafur, which is a pro-drug of 5 fluorouracil; gimeracil (5-chloro-2,4 dihydropyridine, CDHP) which inhibits dihydropyrimidine dehydrogenase (DPD) enzyme; and oteracil (potassium oxonate, Oxo) a gastrointestinal side effects corrector.

S-1 is currently marketed in Japan for the treatment of gastric, colorectal, head and neck, non-small cell lung, metastatic breast and pancreas cancers. In the United States, Europe and other countries, the product is in phase III clinical development. Taiho commercializes and develops S-1 in Japan and in a few other countries of Asia. Sanofi-aventis collaborates on the current clinical development and is leading the future clinical development and commercialization of the product in the United States, Europe, and other countries in the world, except certain Asian countries.

### **About Gastric Cancer**

Gastric (or stomach) cancer is the fourth most common type of cancer worldwide with more than 934,000 new patients every year. It is also the second most common cause of cancer death worldwide, with more than 700,000 deaths annually. There were about 22,800 new cases of gastric cancer in the United States in 2005. In Europe, this number is over 143,000 patients.

### **About Taiho**

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 sanofi-aventis**

Sanofi-aventis is one of the world's leading pharmaceutical companies, ranking number one in Europe. Backed by a world-class R&D organisation, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine and vaccines. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

### **Forward Looking Statements**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although*

*sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2006. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*