

October 28, 2016

EA Pharma Co., Ltd.  
Kissei Pharmaceutical Co., Ltd.

**Japanese NDA for an ulcerative colitis treatment agent  
(Development code : AJG511) was filed.**

EA Pharma Co., Ltd. (President & CEO, Hajime Shimizu; Headquarters, Chuo-ku, Tokyo)(hereinafter “EA Pharma”), a subsidiary of Eisai Co., Ltd. for gastrointestinal disease area, and Kissei Pharmaceutical Co., Ltd. (Chairman & CEO, Mutsuo Kanzawa; Headquarters, Matsumoto City, Nagano Prefecture)(hereinafter “Kissei”) announce that EA Pharma today filed a NDA for an ulcerative colitis treatment agent (Development code : AJG511) in Japan.

AJG511 is a rectal foam containing budesonide as active ingredient, which EA Pharma in-licensed from Dr. Falk Pharma (Germany) and jointly developed with Kissei, and is the first foam enema in Japan.

Ulcerative colitis is a kind of inflammatory bowel disease. In ulcerative colitis, ulcers develop in the colonic mucosa, and symptoms including abdominal pain, diarrhea and hemorrhagic stool markedly decline QOL (quality of life). In Japan, ulcerative colitis is designated as an intractable disease, and it is said at least 170000 people suffer from the disease in this country.

AJG511 is a locally active steroid and, thus, is expected to reduce steroid-related systemic side effects. Further, since the dosage form is a foam, this foam keeps the drug stay in the rectum and the sigmoid colon once the drug reach there and avoid leakage after administration. EA Pharma and Kissei expect that AJG511 can meet the needs for easy-to-use and safe locally-active treatment and provide a new treatment choice.

EA Pharma and Kissei plan to distribute the product by the respective companies under a same brand name in Japan after having obtained NDA by EA Pharma. The two companies will strive to make a further contribution to increase of QOL of patients by providing new drugs of unprecedented action mechanisms and dosage forms to increase treatment choices.

End

Press Contact	
EA Pharma Co., Ltd. Corporate Planning Dept. TEL : +81(0)3-6280-9802	Kissei Pharmaceutical Co., Ltd. Public Relations TEL : +81(0)263-25-9523

## **More Information**

### **■ About Dr. Falk Pharma**

Dr. Falk Pharma is one of the world's leading pharmaceutical companies, established in 1967. Dr. Falk Pharma globally sells "Salofalk", "Budenofalk", "Ursofalk", "Mucofalk" and other products. More than 200 international symposiums and workshops that Falk Foundation e.V. has supported for 45 years and longer have attendance of opinion leaders from at least 100 countries in the world and contribute to increase of knowledge in treatment of gastrointestinal and liver diseases.

For more details of Dr. Falk Pharma, please see

<http://www.dr.falkpharma.com/start/neu/?L=1>