

October 16, 2024
SEIKAGAKU CORPORATION
(Securities Code: TSE 4548)

Seikagaku Announces Regulatory Approval in China for MucoUp[®], a Submucosal Injection Agent for Endoscopic Surgery, and Conclusion of a Distribution Agreement with Tozai Boeki Kaisha, Ltd.

Seikagaku Corporation (Tokyo, Japan; “Seikagaku”) announced today that it has received the regulatory approval notice for MucoUp[®] (Chinese product name: 莫可阿普[®]; “the Product”), a submucosal injection agent for endoscopic surgery, from the National Medical Products Administration (“NMPA”) of China, dated September 30, 2024. Seikagaku has also concluded a distribution agreement with Tozai Boeki Kaisha, Ltd. (Tokyo, Japan; “Tozai Boeki”), which will be the distributor for the Product in China.

The Product is a medical device, of which the main ingredient is sodium hyaluronate. The Product is a surgical aid used in endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) to resect/dissect tumors. The Product is injected into the submucosal layer of the stomach/colon to improve the operability of EMR/ESD. The Product received a manufacturing and marketing approval in Japan under the name of MucoUp[®] in 2006, and today is widely used as the standard surgical aid in EMR/ESD. Following the China NMPA regulatory approval, Seikagaku will supply this safe, high-quality medical device to the Chinese market.

The population in China is aging fast and this is leading to the increase of patient needs for endoscopic examination and treatment. The Product, by being used widely as a standard surgical aid in EMR/ESD, is expected to contribute to the improvement of endoscopic surgery techniques and also improve the quality of life for patients in China.

Tozai Boeki, the distributor of the Product, is a trading company founded in 1958. Tozai Boeki has a wealth of experience in the medical device business in China and provides an affluent product line and customer support in the field of gastrointestinal endoscopy. Seikagaku, in its role as the Marketing Authorization Holder of the Product, will support Tozai Boeki’s activities through the provision of academic information and other means.

The launch of the Product in China is scheduled for the fiscal year ending March 31, 2026, and therefore there will be limited effect on Seikagaku’s forecast of the consolidated financial results for the fiscal year ending March 31, 2025.

#####