Summary

Phase III Additional Clinical Study of $^{111}$In-Pentetreotide (MP-1727): Diagnosis of Gastrointestinal Hormone Producing Tumors Based on the Presence of Somatostatin Receptors

Tsuneo SAGA1, Nagara TAMAKI3, Keiichi ITO1, Tetsuro YAMAZAKI5, Keigo ENDO6,*, Goro WATANABE7, Hirotao MARUNO8, Rikuo MACHINAMI9, Kiyoshi KOIZUMI10,***, Taro ICHIKAWA11,***, Hiroshi TAKAMI12, Miyuki ISHIBASHI13, Atsushi KUBO14, Kiyoko KUSAKABE15, Yukio HIRATA16, Yuji MURATA17, Yukitaka MIYACHI18, Masahiko TSUBUKI19, Harumi SAKAHARA20,***, Kazuhiro KATADA21, Norihisa TONAMI22, Kazutaka YAMAMOTO23,***, Junji KONISHI1, Masayuki IAMURA2, Ryuichiro DOI2, Akira SHIMATSU24,***, Shinzaburo NOGUCHI25,***, Yoshinao HASEGAWA26, Osamu ISHIKAWA27, Yuji WATANABE28 and Masayuki NAKAO29

*Coordinating Investigator, **Controller, ***Members of Independent Data-Monitoring Committee

1Department of Nuclear Medicine and 2First Department of Surgery, Kyoto University Faculty of Medicine, 3Department of Nuclear Medicine, Hokkaido University School of Medicine, 4Graduate School of Information Sciences and 5Department of Radiology, Tohoku University, 6Department of Nuclear Medicine, Gunma University School of Medicine, 7Department of Gastroenterological Surgery and 8Department of Radiology, Toranomon Hospital, 9Department of Pathology, Kawakita General Hospital, 10Department of Radiology, Tokyo Medical University Hachioji Medical Center, 11Department of Radiology, Nippon Medical School Tamanagayama Hospital, 12Department of Surgery and 13Fourth Department of Internal Medicine, Mizonokuchi Hospital, Teikyo University School of Medicine, 14Department of Radiology, Keio University School of Medicine, 15Department of Radiology, Tokyo Women’s Medical University, 16Department of Clinical and Molecular Endocrinology and 17Department of Radiology, Tokyo Medical and Dental University, 18First Department of Internal Medicine and 19Department of Radiology, Toho University Omori Hospital, 20Department of Radiology, Hamamatsu University School of Medicine, 21Department of Radiology, Fujita Health University School of Medicine, 22Department of Nuclear Medicine, Kanazawa University Faculty of Medicine, 23Medical Division, The Wakasa Wan Energy Research Center, 24Clinical Research Institute, Kyoto National Hospital, 25Department of Surgical Oncology, Osaka University Medical School, 26Department of Nuclear Medicine and 27First Department of Surgery, Osaka Medical Center for Cancer and Cardiovascular Diseases, 28Department of Radiology, Kurashiki Central Hospital, 29Department of Radiology, Faculty of Medicine, Kagoshima University

Additional phase III multicenter clinical study was performed to investigate the efficacy, safety, and usefulness of somatostatin receptor scintigraphy using $^{111}$In-pentetreotide (MP-1727), which binds to somatostatin receptors. Forty patients were included in the study; Group A: 18 patients, gastrointestinal hormone producing tumors had been detected with conventional imaging modalities, Group B: 22 patients, no tumors had been detected with conventional imaging modalities in spite of high serum hormone levels. By comparing the results of the octreotide suppression test, 12/16 cases (75.0%) of Group A and 11/19 cases (57.9%) of Group B were assessed as “effective.” By comparing the results of immunohistological examination, 5/9 cases (55.6%) of Group A and 2/4 cases (50.0%) of Group B were assessed as “effective.” Severe adverse events were not observed in any of the evaluable 35 cases. MP-1727 was judged as clinically useful in 11/16 cases (68.8%) of Group A and 5/19 cases (26.3%) of Group B. These results suggest that MP-1727 scintigraphy is very useful for the diagnosis and decision of the therapeutic strategy of gastrointestinal hormone producing tumors.

Key words: $^{111}$In-pentetreotide, Scintigraphy, Gastroenteropancreatic tumor, Somatostatin receptor, Octreotide suppression test.