

Summary

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

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Additional phase III multicenter clinical study was performed to investigate the efficacy, safety, and usefulness of somatostatin receptor scintigraphy using ¹¹¹In-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: ¹¹¹In-pentetreotide, Scintigraphy, Gastroenteropancreatic tumor, Somatostatin receptor, Octreotide suppression test.