

Mundipharma applies for marketing Remimazolam in Japan

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Mundipharma has submitted an application to the Japanese Pharmaceuticals and Medical Devices Agency to market Remimazolam for general anesthesia in Japan.

Mundipharma prepared this submission after acquiring the exclusive rights to develop and market Remimazolam in Japan from speciality German pharmaceuticals company, PAION AG, in December 2017.

The efficacy and safety of Remimazolam has been demonstrated in Phase II/III clinical trials in Japan. It has been administered to more than 1,700 healthy adults and patients in domestic and international clinical trials and has shown rapid onset and offset of anesthesia and sedation, as well as positive results on its maintenance of circulation dynamics and safety profile.

Remimazolam is an ultra-short-acting intravenous benzodiazepine anesthetic for anesthesia and conscious sedation for minor invasive procedures. It is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways.

“This represents an important milestone as we strive to provide patients and doctors access to Remimazolam in Japan,” said Mundipharma CEO, Raman Singh. “We are pleased to be leading these efforts because we believe that this innovative anesthetic solution can provide a significant difference for patients compared to current treatment options in Japan.” he added.