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Global pharmaceutical firm The Medicines Company and Tokyo-based SymBio Pharmaceuticals Ltd. have signed a strategic partnership agreement for commercialization of lonsys (fentanyl iontophoretic transdermal system) in Japan.

The partnership includes an agreement granting SymBio an exclusive license in Japan to develop and commercialize lonsys. lonsys was approved by the US Food and Drug Administration (FDA) on April 30, 2015, for the short-term management of acute post-operative pain in adult patients requiring opioid analgesia in the hospital.

On September 25, 2015, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending marketing authorization for lonsys. A phase I study for lonsys targeting healthy Japanese patients has been completed.

Financial terms of the agreement, in addition to net sales royalties payable to The Medicines Company, include a \$10 million upfront payment and certain regulatory and commercial milestones.

"This partnership further signals an important commitment of our company to pursue growth opportunities outside the United States through partnerships and to deliver innovation in the management of patients with acute post-operative pain to the Japanese market," said Glenn Sblendorio, President of The Medicines Company. "Through this partnership, lonsys has the potential to become The Medicines Company's first product to reach patients in Japan."

"We are very excited to add lonsys to our product portfolio. This product has the potential to change the management of pain in the hospital," said Fuminori Yoshida, Chief Executive Officer for SymBio. "We hope to take full advantage of an accelerated path to regulatory approval given that lonsys has already completed a phase I study in Japanese patients."

lonsys (fentanyl iontophoretic transdermal system) CII, contains fentanyl, an opioid agonist. Ionsys is indicated for the short-term management of acute postoperative pain in adult patients requiring opioid analgesia in the hospital.