

This material is an English translation of the press release announced on July 1, 2024 in Japanese, and the Japanese release is given priority about the content and the interpretation.

July 1, 2024

**Notification of the results of the Phase II clinical study of HP-6050 in Japan
(a transdermal formulation for sedation)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu, Saga; President: NAKATOMI Kazuhide; hereinafter “Hisamitsu Pharmaceutical”) hereby announces that it has results of the Phase IIa clinical study of a “transdermal formulation for sedation” in Japan (Development code: HP-6050, hereinafter referred to as “the product”).

In the Phase IIa clinical study, the efficacy and safety of administration of the product will be compared with a placebo in patients with delirium, psychomotor agitation and irritability. As a result, the efficacy of the product was shown, and there were no adverse reactions that could cause major concerns in development. Based on the results of this study, in the future, Hisamitsu aims to initiate a Phase IIb clinical study in Japan during FY 2025.

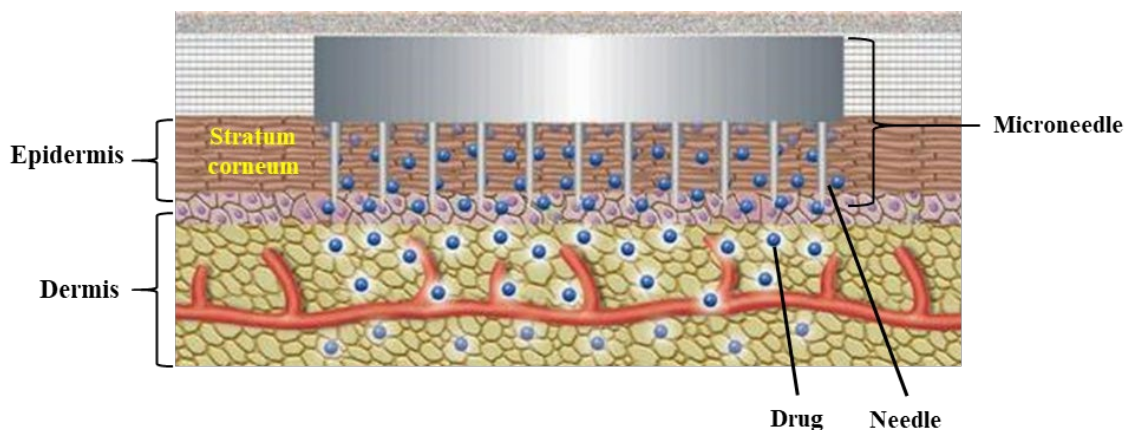
In Japan, there are no products on the market indicated for sedation of delirium^{*1}, psychomotor agitation^{*2} and irritability^{*3}, and the product is expected to provide convenient and safe sedation for patients who present with the above symptoms and require sedation. The product is a formulation that utilizes Hisamitsu's microneedle technology, “HalDisc® Technology”. This technology is a new transdermal drug delivery system that combines a microneedle disc made of biodegradable resin with an applicator for administration, which is applied to the skin to deliver the drug into the body. Microneedles allow drugs that are conventionally used as injectable agents to be administered transdermally because they enable drug administration that is unaffected by the stratum corneum barrier function. And it is expected to produce rapid onset of effects due to the faster rise in blood concentration after administration compared to conventional transdermal drug delivery systems.

^{*1} Delirium: Acute brain dysfunction with diurnal fluctuations, a disorder of the mind and behavior induced by a physical illness, with a variety of psychiatric symptoms such as disorientation, psychomotor agitation, confusion, hallucinations, and delusions.

^{*2} Psychomotor agitation: A state in which the will and desire are hyperactive and reflected in the motor aspect.

^{*3} Irritability: Angry/angry state in response to minor external stimuli.

In the future, Hisamitsu will continue its efforts to advance the clinical development of HP-6050.



[Microneedle Schematic]