

This is the English translation of a Japanese press release published on August 4, 2025. If there are any differences in content or interpretation, the Japanese version shall prevail.

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August 4, 2025

**Notification of the Commencement of the Phase III Clinical Study of HP-6050  
in Japan (Microneedle drug delivery system for treatment of agitation)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu City, Saga Prefecture; President and CEO: NAKATOMI, Kazuhide) is pleased to announce that it has commenced of the Phase III clinical study of a transdermal formulation for sedation in Japan (development code: HP-6050; generic name: dexmedetomidine hydrochloride).

In the Phase III clinical study, the efficacy and safety of this product will be investigated and compared with a placebo in patients with delirium<sup>\*1</sup>, psychomotor agitation<sup>\*2</sup> and irritability<sup>\*3</sup> associated with organic disorders.

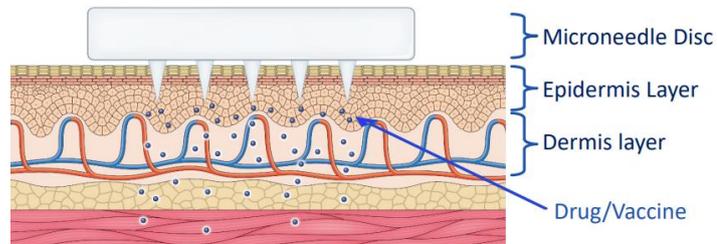
In Japan, there are no approved medications indicated for the treatment of agitation in patients with delirium, psychomotor agitation and irritability associated with organic disorders. If left untreated, patients are at risk of falling down, self-removal of IVs or tubes necessary for treatment, and/or become restless. Therefore, a combination of non-pharmacologic and pharmacological interventions is implemented when patients present with such conditions. However, when these interventions are difficult or ineffective, it is necessary to promptly administer alternative psychotherapy for symptomatic treatment.

This product is a formulation that utilizes our microneedle technology, HalDisc<sup>®</sup> Technology. This technology is a new transdermal drug delivery system that combines a microneedle disc made of biocompatible resin with an applicator for administration, which is applied to the skin to deliver the drug into the body. Microneedles are a new type of drug delivery system that offers advantages not found in conventional injectable or topical medications, enabling safer and more convenient transdermal drug delivery. It is expected to produce rapid onset of action resulting in an increase in drug concentration after administration. It enables simple, safe, and rapid reduction of agitation for patients exhibiting delirium, psychomotor agitation, and irritability, allowing them to proceed with scheduled examinations, procedures, and treatments.

If this product is approved, it will be the first microneedle drug delivery system for medical use in the world. The results of this study will be obtained in FY2027.

- \*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.

**[Microneedle Schematic]**



**[Features of HalDisc® Technology]**

- Drugs of both high and low molecular weight can be efficiently and rapidly transferred into the bloodstream.
- The integration of microneedles and applicators is expected to prevent accidental needle injuries and reduce pain.
- This technology suggests that even formulations requiring cold storage, such as vaccines, may be storable at room temperature, which is expected to simplify transportation and storage.



Device overview