This material is an English translation of the press release announced on September 19, 2023 in Japanese, and the Japanese release is given priority about the content and the interpretation.

September 19, 2023

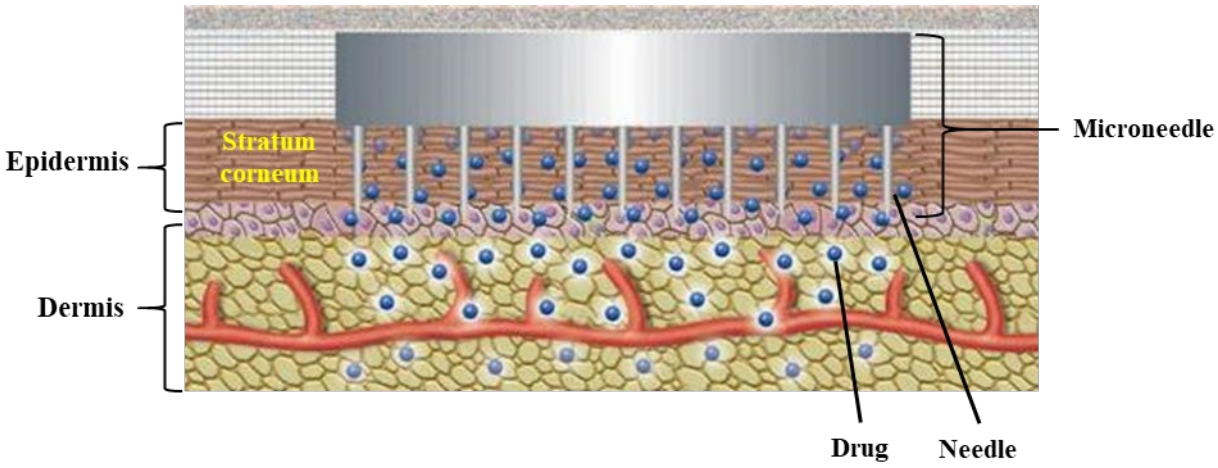
Notification of the commencement of the Phase II clinical study of HP-6050 in Japan (a transdermal formulation for sedation)

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

In the Phase II 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.

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.

The results of this study will be known in FY2024.



[Microneedle Schematic]