

## **Phase 2 clinical trial initiated for the treatment of cutaneous warts, a human papillomavirus infection.**

**- Development of a novel antiviral drug against human papillomavirus -**

**KinoPharma, Inc. (KinoPharma) and IWAKI SEIYAKU CO., LTD. (IWAKI SEIYAKU) have jointly commenced a Phase 2 clinical trial to confirm the efficacy of a drug candidate for the treatment of cutaneous warts ('the Drug') in humans.**

### Development background

KinoPharma and IWAKI SEIYAKU have been jointly developing an ointment since January 2021 based on KinoPharma's novel antiviral agent against human papillomavirus (HPV). This collaboration was further developed and a co-development and commercialization agreement was signed in August 2022 to advance clinical development for the indication of cutaneous warts. After confirming the safety of the Drug in animals and humans, the decision was made jointly to commence a Phase 2 clinical trial to confirm the efficacy of the Drug against cutaneous warts, and a notification of clinical trial (CTN) was submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) today.

### About the Drug

Based on KinoPharma's novel concept of human papillomavirus (HPV) antiviral drugs targeting human host factors, KinoPharma and IWAKI SEIYAKU have collaborated to develop an ointment formulation that is the optimal delivery method for HPV infection on the skin and mucous membranes, and have filed a patent application.

### What is human papillomavirus (HPV)?

It is so named because it forms a raised papilla-like tumor when it infects the skin or other parts of the body. There are more than 100 different types of HPV, some of which may lead to cancer and others to benign neoplasms. HPV infection is known to cause a number of diseases such as skin (cutaneous warts), anogenital (condyloma acuminatum, anal cancer), reproductive organ (cervical cancer) and upper aerodigestive tract (oropharyngeal cancer, etc.) infections.

### What are cutaneous warts?

Cutaneous warts are small proliferative lesions (benign tumors) of the skin caused by infection with the human papillomavirus (HPV). HPV enters the skin through small wounds and infects cells in the basal layer of the epidermis. Infected cells actively divide and form warts. Treatment generally involves cryotherapy using liquid nitrogen, but there are problems such as the need for repeated procedures and pain associated with the treatment. There are no approved antiviral drugs for HPV. Cutaneous warts are relatively common in children, but can

occur in all age groups, with an estimated prevalence of 3.4% (based on data from the 2021 Japan Social Insurance Medical Practice Survey).

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About IWAKI SEIYAKU CO., LTD.

IWAKI SEIYAKU is a pharmaceutical company focused on the manufacture and distribution of the ethical, OTC medicines, and Aesthetic products. The company is especially active in the dermatology market. IWAKI SEIYAKU is expanding its brand and product portfolio in the future and will make every effort to supply this product stably.

About KinoPharma, Inc.

KinoPharma is a biotech engaged in research and development of novel antivirals in collaboration with Kyoto University and other top universities in Japan. It is involved in the development of new concept antiviral drugs that suppress viral replication by targeting host factors.

In addition to HPV-related diseases, KinoPharma is also working on the development of drugs for deadly viral infections and next-generation pandemic viral infections.

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