

About Summary Results of Phase 2 Clinical Study on Verruca Vulgaris conducted by
KinoPharma in collaboration with Iwaki Seiyaku as a Japanese Partner

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KinoPharma, Inc. (Head Office: Chuo-ku, Tokyo; CEO: Masafumi Kuroishi; hereinafter “KinoPharma”) announces that it has obtained the results of the safety and efficacy of a Phase 2 clinical study of an ointment formulation (hereinafter “the Product”) for the indication of verruca vulgaris (also known as “common warts”) being developed in collaboration with Iwaki Seiyaku CO.,LTD. (hereinafter “Iwaki Seiyaku”) (Headquarters: Chuo-ku, Tokyo, Japan; President: Taisuke Nishimura). KinoPharma and Iwaki Seiyaku have jointly developed an ointment containing a novel active ingredient which has anti-HPV action to inhibit HPV genome transcription since 2021, and in order to promote clinical development and commercialization of the Product for the indication of verruca vulgaris, the two companies entered into a joint development and commercialization agreement in August 2022.

This study is a multicenter, randomized, placebo-controlled, double-blind, comparative study conducted in Japan to evaluate the safety and efficacy of three doses of active treatment groups and a placebo group applied twice daily for 12 weeks (total four groups, 39 to 41 patients per group) in 159 patients with typical verruca vulgaris on the upper or lower extremities. The safety of the Product was evaluated by the incidence of adverse events including frequency, severity and causality, while efficacy was evaluated in terms of the reduction rate of verruca area and the rate of verruca disappearance.

In the safety evaluation, erythema and contact dermatitis at the site of administration were observed in one or two subjects in each of active treatment groups as adverse events with undeniable causal relationship to the drug (or adverse reactions), but all were judged as mild severities and no other particular safety problems were observed. In the efficacy evaluation, the reduction rate of verruca area and the verruca disappearance rate were higher in the active treatment groups than in the placebo group, although there was no statistically significant difference for the whole population. On the other hand, the subgroup analysis suggested that several factors such as the verrucae area (or size of warts) at starting time of dosing, may affect the efficacy of the drug, and a significant reduction in verruca area was observed for the population with relatively smaller size of verrucae. We recognize that the results of this study could show the safety of the drug

and demonstrate its efficacy against verruca vulgaris at least in certain subsets of patients. Through the study, we perceive that we could confirm the drug's potential for a new treatment option for verruca vulgaris and also this study was suggestive to consider the drug profile for next stage of development.

Based on the results of this study, we will proceed with further development to establish the dosage and administration of the drug which will demonstrate its solid efficacy with preferable safety profile, and we will strive to bring the drug to patients bothering verruca vulgaris as soon as possible. We have already started to discuss future development plans in collaboration with Iwaki Seiyaku.

About Human Papillomavirus (HPV)

Human Papillomavirus (HPV) is named so because it forms a raised tumor (wart) like a papilla when it infects the skin or other parts of the body. There are more than 100 types of HPV, some of which are cancer-causing (High risk HPV) and some of which are causing benign tumors (Low risk HPV). HPV infection is generally known to cause many diseases of the skin (verruca vulgaris), genital organs (condyloma acuminatum, anal cancer), reproductive organs (cervical cancer), and upper respiratory tract (oropharyngeal cancer, etc.). There are no antiviral drugs approved and marketed to date that are effective against HPV.

About Verruca Vulgaris (Common warts)

Verrucae vulgaris, commonly called “warts”, are small proliferative lesions of the skin caused by HPV infection. HPV enters the skin through small wounds and infects cells in the basal layer of the epidermis. Infected cells become actively dividing and form “warts”. Treatment generally involves cryotherapy using liquid nitrogen, but there are issues such as the need for repeated procedures and the pain associated with treatment. There are no approved drugs with antiviral activity against HPV, the cause of the disease. Verruca vulgaris is relatively common in children, but it can occur in any age group, with an estimated prevalence of about 3.4% (KinoPharma estimates based on data from the 2021 Japan Social Insurance Medical Practice Survey).

About Iwaki Seiyaku

The pharmaceutical and fine chemical businesses of its parent company, Astena HD, are broadly involved in the value chain from research and development to manufacturing and sales of pharmaceutical products to contribute to human health and the pharmaceutical industry. Under the HD organization, Iwaki Seiyaku develops and manufactures topical skin care products for medical use and offers solutions to patients suffering from skin diseases with various product lineup centered on dermatological products.

About KinoPharma

KinoPharma is a university-originated venture company engaged in innovative drug development through strategic collaboration with academia such as Kyoto University and others. KinoPharma is mainly focusing on the development of antiviral drugs based on a new concept of inhibiting viral growth by targeting key essential factors in infected host cells. In addition to developing drugs for various diseases caused by HPV infection such as cervical intraepithelial neoplasia (CIN, a precancerous condition of cervical cancer), verruca vulgaris, and condyloma acuminatum, the company is also developing novel drugs for lethal viral infections and next-generation pandemic viral infections.

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