

December 12, 2023

Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)
Maruishi Pharmaceutical Co., Ltd.

KORSUVA® IV Injection Syringe for Dialysis 17.5µg, 25.0µg and 35.0µg to Launch in Japan for Treatment of Pruritus in Patients Undergoing Hemodialysis

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto, Nagano, Japan; Chairman and CEO: Mutsuo Kanzawa; "Kissei") and Maruishi Pharmaceutical Co., Ltd. (Head Office: Tsurumi, Osaka, Japan; Representative Director and President: Katsuhito Inoue; "Maruishi") announced that KORSUVA® IV Injection Syringe for Dialysis 17.5µg, 25.0µg, and 35.0µg (generic name: difelikefalin acetate "KORSUVA®") for the treatment of pruritus in patients undergoing hemodialysis will launch in Japan on December 13, 2023.

KORSUVA® is a kappa opioid receptor agonist originated and developed by Cara Therapeutics, Inc. (Head Office: USA, President and CEO: Christopher Posner; "Cara"). In April 2013, Maruishi acquired certain rights from Cara, and since March 2017, Maruishi and Kissei have been jointly developing KORSUVA® for the indication of uremic pruritus in Japan. On September 25, 2023, Maruishi obtained manufacturing and marketing authorization of KORSUVA® in Japan for the treatment of pruritus in patients undergoing hemodialysis. The product is manufactured by Maruishi and marketed by Kissei in Japan.

KORSUVA® is provided as a pre-filled syringe formulation to facilitate convenience in the medical environment. Through the supply of KORSUVA® Kissei and Maruishi strive to expand treatment options for uremic pruritus and to improve the QOL (Quality of Life) of patients undergoing hemodialysis.

《 Reference 》

Product Summary of KORSUVA® IV Injection Syringe for Dialysis

Brand Name	KORSUVA® IV Injection Syringe for Dialysis 17.5µg KORSUVA® IV Injection Syringe for Dialysis 25.0µg KORSUVA® IV Injection Syringe for Dialysis 35.0µg										
Generic Name	Difelikefalin acetate (JAN)										
Indications	Improvement of pruritus in hemodialysis patients (limited to cases in which the effects of existing treatments are insufficient)										
Dosage and Administration	Normally, inject difelikefalin with the below table dosage to adults into the venous side of the dialysis circuit during return transfusion at the end of dialysis three times a week. <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Dry weight</th> <th>Dosage</th> </tr> </thead> <tbody> <tr> <td>Under 45 kg</td> <td>17.5 µg</td> </tr> <tr> <td>45 kg or higher but under 65 kg</td> <td>25.0 µg</td> </tr> <tr> <td>65 kg or higher but under 85 kg</td> <td>35.0 µg</td> </tr> <tr> <td>85 kg or higher</td> <td>42.5 µg</td> </tr> </tbody> </table>	Dry weight	Dosage	Under 45 kg	17.5 µg	45 kg or higher but under 65 kg	25.0 µg	65 kg or higher but under 85 kg	35.0 µg	85 kg or higher	42.5 µg
Dry weight	Dosage										
Under 45 kg	17.5 µg										
45 kg or higher but under 65 kg	25.0 µg										
65 kg or higher but under 85 kg	35.0 µg										
85 kg or higher	42.5 µg										
Formulation	Injection (syringe)										
NHI price	KORSUVA® 17.5µg 2,971 JPY per syringe KORSUVA® 25.0µg 3,609 JPY per syringe KORSUVA® 35.0µg 4,341 JPY per syringe										
Manufacturing and Marketing Authorization Holder	Maruishi Pharmaceutical Co., Ltd.										
Distributor	Kissei Pharmaceutical Co., Ltd.										
Date of Marketing Approval in Japan	September 25, 2023										
Date of Drug Price Listing	November 22, 2023										
Date of Launch in Japan	December 13, 2023										

Product photo



About uremic pruritus in dialysis patients

Uremic pruritus is a common itching condition in spite of the absence of obvious skin lesion, which occurs in many patients with end-stage renal disease undergoing hemodialysis.

It is reported that long-lasting and intense distressing itching in these patients make their QOL very low and have negative impacts on psychological and physical health such as poor sleep quality, depression, and an increased risk of death.

It is considered that endogenous opioids are related to pruritus as one of the expression mechanisms of pruritus in dialysis patients. KORSUVA[®] selectively activates kappa opioid receptor which is one of the subtypes of opioid receptors, and exerts its antipruritic action by acting on the kappa opioid receptor.

About Kissei Pharmaceutical Co., Ltd.

Kissei is a Japanese pharmaceutical company based on the management philosophy “contributing to society through high-quality, innovative pharmaceutical products” and “serving society through our employees.” As a strong R&D-oriented corporation, it concentrates on providing innovative pharmaceuticals to patients worldwide in the focus fields of urology, nephrology/dialysis, gynecology and rare/intractable diseases.

For more details about Kissei Pharmaceutical Co., Ltd., please visit <https://www.kissei.co.jp/>.

About Maruishi Pharmaceutical Co., Ltd.

Maruishi is a specialty pharma that has a strong presence in the perioperative and infection control area and is known as a leading producer of Japanese Pharmacopoeia drugs. Making use of the technology, knowledge, and know-how that have been cultivated over 130 years of history, Maruishi continues to contribute to the healthcare and improvement of QOL of the patients.

For more details about Maruishi Pharmaceutical Co., Ltd., please visit <https://www.maruishi-pharm.co.jp/>.

About Cara Therapeutics, Inc.

Cara Therapeutics (Nasdaq: CARA) is a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus.

For more information, visit <https://www.caratherapeutics.com/> and follow the company on X (Twitter), LinkedIn and Instagram.