



#### FOR IMMEDIATE RELEASE

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# JT Files New Drug Application for JTE-061 Cream, Aryl hydrocarbon Receptor (AhR) modulating agent, for the Treatment of Pediatric Atopic Dermatitis in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) announced today that JT has filed a New Drug Application for JTE-061 (generic name: tapinarof) cream 0.5%, a therapeutic aryl hydrocarbon receptor modulating agent, for the treatment of pediatric patients aged 2 to <12 years with atopic dermatitis.

In 2020, JT previously entered into an exclusive license agreement with Dermavant Sciences GmbH (which was later acquired by Organon & Co.) for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. JT also signed an exclusive license agreement with Torii for the co-development and commercialization of tapinarof in Japan. Under this agreement, JT and Torii are jointly developing tapinarof cream 0.5% for pediatric patients with atopic dermatitis, and Torii will be responsible for marketing the product in Japan subsequent to JT's obtaining manufacturing and marketing approval.

In the Phase 3 clinical study conducted in Japan in pediatric patients aged 2 to <12 years with atopic dermatitis, tapinarof cream 0.5% met the primary efficacy endpoint, demonstrating superiority over vehicle. Furthermore, the safety of tapinarof cream 0.5% was confirmed during long-term treatment. JT and Torii expect that tapinarof cream 0.5% will offer a new treatment option for pediatric patients with atopic dermatitis in Japan.

In addition, in June 2024, JT received manufacturing and marketing approval in Japan for tapinaorf cream 1% (VTAMA® Cream 1%) for the treatment of atopic dermatitis in patients aged 12 years and older and plaque psoriasis in adults. VTAMA® Cream 1% has been distributed in Japan by Torii since October 2024.

## **ABOUT Atopic Dermatitis**

Atopic dermatitis is a chronic and pruritic inflammatory skin disease. It is thought to develop through exposure to various irritants or allergens in patients with a

## physiological abnormality of the skin (dry skin and abnormal skin barrier function).

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Japan Tobacco Inc. (JT) is a global company headquartered in Tokyo, Japan. It is listed on the primary section of the Tokyo Stock Exchange (ticker: 2914.T). JT Group has approximately 53,000 employees and 61 factories worldwide, operating in three business segments: tobacco, pharmaceutical, and processed food. Within the tobacco business, the largest segment, products are sold in over 130 markets and its flagship brands include Winston, Camel, MEVIUS, and LD. The Group is committed to investing in Reduced-Risk Products and markets its heated tobacco products under its Ploom brand.

Consumers, shareholders, employees, and society are the four stakeholder groups (4S) at the heart of all of JT Group's activities. Inspired by its "Fulfilling Moments, Enriching Life" purpose, the Group aims to ensure sustainable and valuable contributions to its stakeholders over the long term. In addition to our three business segments, this goal is also supported by D-LAB, the JT Group's corporate R&D initiative, set up to search and create added-value business opportunities. For more information, visit <a href="https://www.it.com/">https://www.it.com/</a>.

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