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Mochida Pharmaceutical Co., Ltd.
Duchesnay Inc.

# Initiation of a Phase III Clinical Study of BON-001 for Nausea and Vomiting of Pregnancy in Japan

Mochida Pharmaceutical Co., Ltd. (Head Office: Shinjuku-ku, Tokyo, Japan; President: Naoyuki Mochida; hereinafter “Mochida”) and Duchesnay Inc. (Head Office: Quebec, Canada; President: Éric Gervais; hereinafter “Duchesnay”) announce the initiation of a Phase III clinical study (the “Study”) of BON-001 (the “Product”) for nausea and vomiting of pregnancy in Japan.

The Study is a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparative study in pregnant women with nausea and vomiting of pregnancy, with the objectives of evaluating the efficacy and confirming the safety of the Product among Japanese women.

Nausea and vomiting of pregnancy (NVP), commonly referred to as morning sickness are symptoms experienced by more than half of pregnant women in Japan*. At present, there is no drug approved in Japan with an indication for nausea and vomiting of pregnancy.

The Product, developed by Duchesnay, is a combination of doxylamine succinate and pyridoxine hydrochloride. The combination is marketed in 45 countries for the treatment of nausea and vomiting of pregnancy, under the brand name Bonjesta® and in several other countries under various brand names. Its efficacy and safety are being evaluated in the Japanese population as part of the BON-001 clinical development program.

As the Product had not been approved in Japan, the Ministry of Health, Labour and Welfare, in response to a request from the Japan Society of Obstetrics and Gynecology, publicly invited companies to develop the Product. In December 2025, Mochida entered into an agreement with Duchesnay for the development and commercialization of the Product in Japan, and is working on its development toward obtaining marketing approval in Japan. The introduction of the Product is also expected to address the issue of “drug loss” in Japan.

"We have long been engaged in the development of products in the field of obstetrics and gynecology, including dienogest, a treatment for endometriosis and other gynecological conditions. We are very pleased to initiate this Phase III clinical study of the Product in collaboration with Duchesnay. This study marks an important milestone in the clinical development of the Product in Japan and a step toward addressing the unmet medical need associated with nausea and vomiting of pregnancy. Together with Duchesnay, we remain committed to advancing the development of the Product in Japan," said Taiji

Hayano, Executive Managing Officer, Development at Mochida.

“At Duchesnay, we are committed to advancing clinical research and ensuring our products meet the highest scientific and regulatory standards globally. By collaborating with our international partners like Mochida, we can effectively navigate and address the complex regulatory and clinical requirements of each country, helping expand access to this treatment for women around the world,” said Michael Gallo, Vice President, Regulatory & Medical Affairs, Duchesnay Pharmaceutical Group (DPG). “We deeply appreciate Mochida’s ongoing efforts to advance scientific knowledge and generate valuable new data that support informed and impactful healthcare decisions.”

Mochida and Duchesnay will continue their collaboration to advance the development of the Product with the aim of providing a new treatment option for women in Japan experiencing nausea and vomiting of pregnancy.

*Japan Society of Obstetrics and Gynecology / Japan Association of Obstetricians and Gynecologists, Guidelines for Obstetrical Practice in Japan, Obstetrics 2026.

About Mochida

Mochida Pharmaceutical Co., Ltd. (https://www.mochida.co.jp), headquartered in Tokyo, Japan, has been committed to research and development of innovative pharmaceutical products since its establishment in 1913, providing distinctive medicines to the medical community. Currently, the core pharmaceutical business focuses its resources on the targeted areas of cardiovascular medicine, gastroenterology, obstetrics and gynecology, and psychiatry while also providing medicines for intractable diseases and generics including biosimilars, to meet medical needs. Mochida is working to provide value in terms of “support for the different stages of a woman’s life,” and aims to help realize a society in which women enjoy better health and can actively participate.

About Duchesnay

Duchesnay Inc. (https://duchesnay.com), member of Duchesnay Pharmaceutical Group (DPG), is a specialty pharmaceutical company with a long-standing commitment to women’s health. Until recently, the company focused on filling the void in terms of scientific research and education and on developing pharmacological solutions that are safe and effective for use during pregnancy and breastfeeding. Today, Duchesnay has broadened its portfolio of products to offer safe and effective therapeutic options that meet the health and quality of life needs of women and their family members at different stages of their lives. Believing that women around the world deserve to have access to specialized treatments for their conditions, Duchesnay now distributes its products internationally.

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