

Press Release

Ono Pharma Announces Results from Five Phase 2 Clinical Studies of ONO-1110, an Endocannabinoid Modulator

- Efficacy signals suggesting improvements in pain scores were observed in Phase 2 clinical studies in postherpetic neuralgia, fibromyalgia, and Hunner-type interstitial cystitis ; further clinical studies are being planned.
- No efficacy signals were observed in the studies in major depressive disorder or social anxiety disorder, and no further clinical studies are planned in these indications.
- ONO-1110 demonstrated a favorable safety profile across all five studies.

Osaka, Japan, October 29, 2026 -- Ono Pharmaceutical Co., Ltd. (Headquarters: Osaka, Japan; President and COO: Toichi Takino; "Ono") today announced that ONO-1110, an endocannabinoid modulator, demonstrated efficacy signals in Phase 2 clinical studies in postherpetic neuralgia (PHN), fibromyalgia (FM), and Hunner-type interstitial cystitis (HIC). Additional Phase 2 clinical studies of ONO-1110 were conducted in major depressive disorder (MDD) and social anxiety disorder (SAD).

Although the ONO-1110-04, ONO-1110-05, and ONO-1110-06 studies in PHN, FM, and HIC, respectively, did not meet their primary endpoints, efficacy signals suggesting improvement in pain scores assessed using the Numerical Rating Scale (NRS) were observed in prespecified subgroup analyses and exploratory post hoc analyses. ONO-1110 also demonstrated a favorable safety profile across all five studies.

Based on these results, Ono is planning further clinical studies of ONO-1110 in PHN, FM, and HIC. No efficacy signals were observed in MDD or SAD, and no further clinical studies are planned in these indications.

Detailed results from these studies will be presented at future conferences and through other appropriate channels.

About ONO-1110

ONO-1110 is an orally available endocannabinoid modulator created by Ono. Endocannabinoids are substances produced in the body and are known to play an important role in regulating various physiological functions of the central nervous system, including pain and emotion.

ONO-1110 is expected to regulate pain by modulating endocannabinoids produced in response to neuronal activity, including pain transmission¹⁻⁴. ONO-1110 has the potential to become a novel treatment for chronic pain that provides analgesic effects with a favorable tolerability profile by acting on an endogenous physiological mechanism.

About ONO-1110-04 Study

ONO-1110-04 study is a multicenter, randomized, placebo-controlled Phase 2 clinical study conducted in Japan in patients with PHN (target enrollment: 140 patients). The study was designed to evaluate the efficacy, safety, tolerability, and pharmacokinetics of ONO-1110 compared with

placebo. Patients received ONO-1110 or placebo orally once daily for eight weeks.

About ONO-1110-05 Study

ONO-1110-05 study is a multicenter, randomized, placebo-controlled Phase 2 clinical study conducted in Japan in patients with FM (target enrollment: 160 patients). The study was designed to evaluate the efficacy, safety, tolerability, and pharmacokinetics of ONO-1110 compared with placebo. Patients received ONO-1110 or placebo orally once daily for eight weeks.

About ONO-1110-06 Study

ONO-1110-06 study is a multicenter, randomized, placebo-controlled Phase 2 clinical study conducted in Japan in patients with HIC (target enrollment: 50 patients). The study was designed to evaluate the efficacy, safety, tolerability, and pharmacokinetics of ONO-1110 compared with placebo. Patients received ONO-1110 or placebo orally once daily for twelve weeks.

About Postherpetic Neuralgia (PHN)

PHN is a complication of herpes zoster and neuropathic pain caused by nerve damage associated with varicella-zoster virus infection. PHN is characterized by persistent pain and sudden, sharp, electric shock-like pain and is often accompanied by allodynia, in which normally non-painful stimuli cause pain⁵. These symptoms are known to cause considerable distress and impair patients' quality of life⁶. Current treatment primarily consists of pharmacotherapy aimed at relieving symptoms. However, adverse reactions may prevent patients from receiving adequate treatment, highlighting the need for new treatment options with both safety and efficacy⁷.

About Fibromyalgia (FM)

FM is a disorder primarily characterized by chronic, widespread pain of unknown cause and generalized stiffness, accompanied by a variety of physical, neurological, and psychiatric symptoms⁸. Chronic severe pain and fatigue are known to substantially disrupt sleep and activities of daily living and impair quality of life⁹. Currently available treatments may not provide adequate symptom relief and may be associated with central nervous system-related adverse effects, highlighting the need for therapies with novel mechanisms of action¹⁰.

About Hunner-Type Interstitial Cystitis (HIC)

Interstitial cystitis/bladder pain syndrome is defined as a condition characterized by chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder, accompanied by lower urinary tract symptoms such as urinary urgency and frequency, in the absence of other diseases that could be confused with the condition. Cases with Hunner lesions are classified as HIC¹¹. The cause is unknown, and distress associated with urinary frequency and bladder pain impairs quality of life. Given the lack of highly effective and well tolerated oral treatment options, new therapies are needed.

References:

1. Palazzo E, et al. Pharmaceuticals (Basel). 2010;3:2661-73.
2. Petrosino S, et al. Neuropharmacology. 2007;52:415-22.

3. Olango WM, et al. Br J Pharmacol. 2012;165:2549-60.
4. Hashimoto-dani Y, et al. J Neurosci. 2011;31:3104-9.
5. The Japan Society of Pain Clinicians, Pain Clinic Treatment Guideline, 2019.
6. Johnson RW, et al. N Engl J Med. 2014;371:1526-33.
7. Clarivate Plc: <https://clarivate.com/life-sciences-healthcare/report/algopn0002-2024-biopharma-postherpetic-neuralgia-treatment-algorithms-claims-data-analysis-us-2024/>
8. The Committee for Clinical Practice Guideline for the Management of Chronic Pain, Clinical Practice Guidelines for the Management of Chronic Pain, 2021.
9. Fibromyalgia Clinical Practice Guideline Development Group. Clinical Practice Guidelines for Fibromyalgia. Japan Medical Journal, 2017.
10. Clarivate Plc: <https://clarivate.com/life-sciences-healthcare/report/unnecg0027-2024-biopharma-fibromyalgia-unmet-need-unmet-need-fibromyalgia-us-eu/>
11. The Society of Interstitial Cystitis of Japan, Clinical Guideline for Interstitial Cystitis/Bladder Pain Syndrome, 2019.

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