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Otsuka Announces FDA Plans to Host an Advisory Committee Meeting to Discuss the sNDA for Brexpiprazole in Combination with Sertraline for the Treatment of Adults with Post-Traumatic Stress Disorder (PTSD)

January 9, 2025 – Princeton, N.J. and Tokyo, Japan – Otsuka America Pharmaceutical, Inc., (OAPI) and Otsuka Pharmaceutical, Co. Ltd. (Otsuka) announce that the U.S. Food and Drug Administration (FDA) plans to host a Psychopharmacologic Drugs Advisory Committee (PDAC) meeting to seek input on issues related to the Supplemental New Drug Application (sNDA) for brexpiprazole in combination with sertraline for the treatment of adults with post-traumatic stress disorder (PTSD).

The FDA's decision to host a PDAC meeting does not reflect a final decision on the approvability. A final date for the meeting has yet to be set by the FDA, but it is currently anticipated to occur during the first half of 2025.

This decision means that the Prescription Drug User Fee Act (PDUFA) target action date, originally planned for February 8, 2025, will be delayed.