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Otsuka and Lundbeck Receive Complete Response Letter from U.S. FDA for sNDA of REXULTI® (brexpiprazole) in Combination with Sertraline for the Treatment of Adults with Post-Traumatic Stress Disorder (PTSD)

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announce that Otsuka has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the supplemental New Drug Application (sNDA) for use of REXULTI® (brexpiprazole) in combination with sertraline for the treatment of adults with post-traumatic stress disorder (PTSD). The CRL states that the FDA has completed their review but cannot approve the application in the current form, further stating that the application does not provide substantial evidence of effectiveness to support the approval.