

Ono Pharma seeks Japanese approval for tirabrutinib

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ONO Submits an Application for Manufacturing and Marketing Approval in Japan for Tirabrutinib Hydrochloride (ONO-4059), a BTK Inhibitor, for the Treatment of Waldenstrom Macroglobulinemia and Lymphoplasmacytic Lymphoma



Japan based Ono Pharmaceutical Co., Ltd. has announced that ONO submitted an application of tirabrutinib hydrochloride (ONO-4059) ("Tirabrutinib"), a Bruton's tyrosine kinase ("BTK") inhibitor, for the manufacturing and marketing approval in Japan for the treatment in patients with Waldenstrom macroglobulinemia ("WM") and lymphoplasmacytic lymphoma ("LPL").

This application is based on the result from a multi-center, open-label, uncontrolled Phase II study (ONO-4059-05) evaluating Tirabrutinib in 27 patients with untreated recurrent or refractory WM and LPL. Tirabrutinib was designated as an orphan drug for the indication of WM and LPL by the Ministry of Health, Labour and Welfare (MHLW) in Japan on November 19, 2019.

WM and LPL are one of the malignant lymphomas and are classified as "indolent lymphoma" which means one with relatively slow progression. It is estimated that there are approximately 240 new cases^{2,3} with LPL per year in Japan. WM and LPL generally grow and spread slowly in the clinical course, with a median survival of more than 5 years, but these are intractable diseases that cannot be cured with existing therapies.

In Japan, standard treatment has not been established in patients with untreated recurrent or refractory WM and LPL, so a new treatment option is expected for these patient populations.

On August 28, 2019, ONO submitted an application of Tirabrutinib for the manufacturing and marketing approval in Japan for the treatment of recurrent or refractory primary central nervous system lymphoma (PCNSL).