Mundipharma EDO

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Mundipharma EDO GmbH: US FDA Grants Orphan Drug Designation for Tinostamustine in Very Rare Blood Cancer

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- T-cell prolymphocytic leukaemia is an extremely rare and aggressive T-cell leukaemia, with very limited effective treatment options1,2

- Tinostamustine is in very early phase clinical trials to investigate it as a potential future treatment option in this area of significant unmet patient need

Mundipharma EDO GmbH, and Imbrium Therapeutics L.P., an operating subsidiary of Purdue Pharma L.P., today announced that the US FDA has granted Orphan Drug Designation (ODD) to tinostamustine, an alkylating deacetylase inhibiting molecule for the treatment of T-cell prolymphocytic leukaemia (T-PLL).3

The FDA grants ODD status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US. T-PLL is an extremely rare and typically aggressive blood cancer. It is so rare that healthcare professionals may only see one case of T-PLL every five to 10 years.4 Due to its rarity, T-PLL can be misdiagnosed, resulting in poor patient outcomes.4 Patients have a median survival of around seven months to one year, and the disease is typically resistant to conventional chemotherapy.4,5

Dr Thomas Mehrling, CEO of Mundipharma EDO added: *"Currently there are no licensed treatment options for T-PLL, therefore, the development of new therapeutic approaches is essential for these patients. We are pleased that the FDA has granted tinostamustine orphan drug designation in this area. At Mundipharma EDO, our focus is to develop treatments for rare and difficult-to-treat cancers, such as T-PLL, and we are progressing the development of tinostamustine in early phase clinical trials, in conjunction with Imbrium Therapeutics."*

To find out more about tinostamustine and the Mundipharma EDO oncology clinical trials programme and view the full press release visit: www.edoncology.com

References:

1. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues (Revised 4th edition) IARC: Lyon 2017 (pg 272)
2. T-cell prolymphocytic leukemia (T-PLL) information page. Leukemia and Lymphoma Society. Available at: https://www.lls.org/leukemia/t-cell-prolymphocytic-leukemia-t-pll. Last accessed 26 March 2019.
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4. Dearden C. *Blood*. 2012; 120(3):538-55.
5. NIH NCI SEER Database. Available at: https://seer.cancer.gov/seertools/hemelymph/51f6cf58e3e27c3994bd53f3/. Last accessed 26 March 2019.

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