



General AML

FDA grants Fast Track Designation to CX-01 for the treatment of patients with newly diagnosed acute myeloid leukemia

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On 27th August 2018, the US Food and Drug Administration (FDA) granted Fast Track Designation to CX-01, a low anti-coagulant heparin, for the treatment of patients aged over 60 receiving induction therapy for newly diagnosed acute myeloid leukemia (AML).¹ In January 2018, CX-01 was granted Orphan Drug Designation by the FDA for the treatment of AML.

Therapy for AML is associated with pancytopenia and a high failure rate due to resistant leukemia stem cells that use CXCL12/CXCR4 axis to home to marrow niches. Additionally, Platelet Factor 4 (PF4) negatively regulates bone marrow recovery after chemotherapy. CX-01 binds and inhibits PF4, thus neutralizing its activity and may also disrupt the CXCL12/CXCR4 axis, therefore improving the efficacy of AML therapy.

Preliminary data from a phase IIa non-randomized trial have demonstrated that CX-01 in combination with induction chemotherapy is well-tolerated and may enhance count recovery and treatment efficacy in patients with newly diagnosed primary AML.² The drug manufacturers, Cantex Pharmaceuticals, noted that the Fast Track Designation granted by the FDA to CX-01 “represents recognition of CX-01’s potential to address a significant unmet need in the treatment of AML by enhancing the efficacy of front-line AML chemotherapy”.

At present, CX-01 is being explored in a phase II randomized study (NCT02873338) in combination with standard chemotherapy for patients with newly diagnosed AML. CX-01 is also being evaluated in a phase I study (NCT02995655) in combination with azacitidine for patients with relapsed or refractory AML.

References

1. PR Newswire: Cantex Pharmaceuticals, Inc. Receives FDA Fast Track Designation For CX-01 For The Treatment Of Patients Over Age 60 With Newly Diagnosed Acute Myeloid Leukemia (AML). 2018 Aug 27.
<https://www.prnewswire.com/news-releases/cantex-pharmaceuticals-inc-receives-fda-fast-track-designation-for-cx-01-for-the-treatment-of-patients-over-age-60-with-newly-diagnosed-acute-myeloid-leukemia-aml-300702508.html>
[Accessed 2018 Aug 28].
2. Kovacsovics T.J. *et al.* CX-01, a Low Anticoagulant Heparin, May Enhance Count Recovery and Treatment Efficacy in Acute Myeloid Leukemia. Blood. 2016; 128: 5220.

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