The FDA accepts New Drug Application for Vyxeos® for the treatment of AML and grants Priority Review status

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On 31st May 2017, the U.S. Food and Drug Administration (FDA) accepted the recently filed New Drug Application (NDA) for Vyxeos® (CPX351), a liposomal formulation of cytarabine plus daunorubicin co-encapsulated at a molar ratio of 5:1, for the treatment of patients with Acute Myeloid Leukemia (AML). In addition to the NDA acceptance, Vyxeos® was also granted priority review status by the FDA[1]

The NDA submission was based on clinical data from five studies including a pivotal phase III study (NCT01696084), which was presented at the American Society of Clinical Oncology meeting 2016 by Jeffrey E. Lancet from the Lee Moffitt Cancer Center & Research Institute, Florida, USA, and colleagues. The results of the phase III study showed that CPX-351 improved the survival of older patients with AML.[2]

CPX-351 is currently being explored in multiple studies in patients with newly diagnosed and relapsed/refractory AML.

References:

1. PRNewswire: Jazz Pharmaceuticals Announces FDA Acceptance of NDA for VYXEOS™ (CPX-351), an Investigational Treatment for Acute Myeloid Leukemia, with Priority Review Status. 2017 May 31. http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-announces-fda-acceptance-of-nda-for-vyxeos-cpx-351-an-investigational-treatment-for-acute-myeloid-leukemia-with-priority-review-status-300466520.html [Accessed 2017 Jun 1].

2. Lancet J.E. *et al*. Final results of a phase III randomized trial of CPX-351 versus 7+3 in older patients with newly diagnosed high risk (secondary) AML. Oral Abstract #7000. American Society of Clinical Oncology Meeting 2016.
