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FDA grants Annamycin Fast Track Designation for relapsed or refractory AML

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Annamycin, a next-generation liposome formulated anthracycline, was granted Fast Track Designation by the FDA on 18 April 2019. The drug will be used for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML).

According to the manufacturers, Moleculin Biotech, the drug has little to no cardiotoxicity, and avoids multidrug resistance. In patients where standard of care has failed, Annamycin has shown activity.

Efficacy of the drug has been tested in phase I and II trials, resulting in little to no reported cardiotoxicity, with the therapy even clearing patients' leukemic blasts to a level sufficient for bone marrow transplant.[1]

The drug has demonstrated clinical activity in a patient population for whom there is currently no effective therapy, and since it can avoid multi-drug resistance, it will not go on to limit the effectiveness of currently approved anthracyclines.

Two separate phase I/II trials are being conducted using patients with relapsed or refractory AML, in Poland (NCT03388749) and in the US (NCT03315039). Results of these trials could determine whether Annamycin receives accelerated approval, and assuming that similar results to previous trials are achieved, this would seem likely.

Reference

1. Wetzler, M. *et al*. Phase I/II trial of nanomolecular liposomal annamycin in adult patients with relapsed/refractory acute lymphoblastic leukemia. *Clin Lymphoma Myeloma Leuk*. 2013 Jun 10.13(4):430-434. DOI: 1016/j.clml.2013.03.015