FDA grants annamycin Investigational New Drug Application approval for treatment of R/R AML

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On 26th September 2017, the U.S. Food and Drug Administration (FDA) granted Investigational New Drug (IND) application approval for annamycin, an anthracycline antibiotic, for the treatment of patients with Relapsed or Refractory (R/R) Acute Myeloid Leukemia (AML).[1] This IND approval comes after the Orphan Drug Designation granted by the FDA and the recent IND application, which the AGP reported in March and August respectively.

Current anthracyclines such as doxorubicin used in standard chemotherapy for AML patients are associated with risk of cardiotoxicity as well as drug resistance.[2] Annamycin (liposomal annamycin) is a liposome-encapsulated form of the anthracycline doxorubicin, with antineoplastic activity. Annamycin evades cellular Multidrug-Resistance (MDR) mechanisms and eliminates cardiotoxicity.[3]

The IND approval granted by the FDA allows annamycin to be evaluated in R/R AML patients in clinical trials. Moleculin, the drug manufacturers noted that the trial aims to evaluate the potential of annamycin in becoming the "first 2nd line therapy suitable for the majority" of R/R AML patients.[1]

The FDA IND approval also allows the drug manufacturers to make a submission to the Polish authorities which is required for a planned phase I/II clinical trial with annamycin to be conducted in Poland.[1]

References:

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2. Jungsuwadee P. Doxorubicin-induced cardiomyopathy: an update beyondoxidative stress and myocardial cell death. Cardiovasc Regen Med. 2016; 3: e1127. DOI: 10.14800/crm.1127.

3. 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 Aug; 13(4): 430–434. DOI: 10.1016/j.clml.2013.03.015. Epub 2013 Jun 10.
