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The FDA to review annamycin Investigational New Drug application for R/R AML

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On 29th August 2017, an Investigation New Drug (IND) application was submitted to the U.S. Food and Drug Administration (FDA) for the study of for annamycin, an anthracycline antibiotic, in patients with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML).

Moleculin Biotech, a preclinical stage pharmaceutical company, are aiming to acquire approval of annamycin for R/R AML and, if the IND application is accepted and implemented (a decision is normally made within 30 days of submission), then the company will begin clinical trials in the last quarter of this year.

An IND application has been submitted previously by Moleculin Biotech for annamycin; however, the FDA requested some protocol revisions, as well as required some additional information and data related to Chemistry and Manufacturing Controls (CMC). This initial IND was withdrawn in order for Moleculin Biotech to gather and develop the required information and CMC data, which was submitted in the current IND application.

References

1. Markets Insider. Moleculin Announces Filing with FDA of IND for its Leukemia Drug Annamycin. 2017 Aug 29. http://markets.businessinsider.com/news/stocks/Moleculin-Announces-Filing-with-FDA-of-IND-for-its-Leukemia-Drug-Annamycin-1002291102. [Accessed 2017 Aug 30].