



General AML

## FDA approves the Investigational New Drug Application for PCM-075 for the treatment of AML

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On 27<sup>th</sup> July 2017, the U.S. Food and Drug Administration (FDA) accepted the Investigational New Drug (IND) application for PCM-075, a Polo-like Kinase 1 (PLK1) inhibitor, for the treatment of Relapsed or Refractory (R/R) patients with Acute Myeloid Leukemia (AML).<sup>1</sup>

In most normal tissues, PLK1 is expressed at very low levels, however it has been found to be overexpressed in multiple AML cell lines and also in leukemia blasts from AML patients. Overexpression of PLK1 in AML patients have been reported to be associated with poor prognosis in these group of patients.<sup>2</sup> PCM-075 selectively inhibits the PLK1 enzyme thereby inducing cell cycle arrest and apoptosis in cancer cells.<sup>3</sup>

The IND approval granted by the FDA allows PCM-075 to be evaluated in a phase Ib/II clinical trial which aims to evaluate the safety and efficacy of PCM-075 in combination with decitabine in patients with AML, who are in relapse or refractory.

### References

1. PR Newswire: Trovogene Announces FDA Approval of IND for Phase 1b/2 Trial of PCM-075 in Patients with Acute Myeloid Leukemia. 2017 Jul 27. <http://www.prnewswire.com/news-releases/trovogene-announces-fda-approval-of-ind-for-phase-1b2-trial-of-pcm-075-in-patients-with-acute-myeloid-leukemia-300495015.html> [Accessed 2017 Jul 28].
2. Brandwein J. M. Targeting polo-like kinase 1 in acute myeloid leukemia. Ther Adv Hematol. 2015 Apr; 6(2): 80–87. DOI: [10.1177/2040620715571077](https://doi.org/10.1177/2040620715571077).
3. NCI Drug Dictionary: Polo-like kinase 1 inhibitor NMS-1286937. <https://www.cancer.gov/publications/dictionaries/cancer-drug?cdrid=660210> [Accessed 2017 Jul 28].

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