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USFDA accepts BLA for moxetumomab pasudotox by AstraZeneca

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The FDA has granted the moxetumomab pasudotox BLA Priority Review status with a Prescription Drug User Fee Act date set for the third quarter of 2018



AstraZeneca and MedImmune, its global biologics research and development arm has announced that the US Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for moxetumomab pasudotox, an investigational anti-CD22 recombinant immunotoxin and a potential new medicine for the treatment of adult patients with hairy cell leukaemia (HCL) who have received at least two prior lines of therapy.

Moxetumomab pasudotox (formerly CAT-8015 or HA22) is an investigational anti-CD22 recombinant immunotoxin and a potential new medicine with the opportunity to be a first-in-class treatment in the US for patients with relapsed or refractory HCL who have received at least two prior lines of therapy.

The '1053' trial is a single-arm, multicentre Phase III clinical trial assessing the efficacy, safety, immunogenicity and pharmacokinetics of moxetumomab pasudotox monotherapy in patients with relapsed or refractory HCL who have received at least two prior therapies. The trial is being conducted in 80 patients across 34 sites in 14 countries.

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The Phase III ('1053') moxetumomab pasudotox clinical trial met its primary endpoint of durable complete response in adult patients with relapsed or refractory HCL, for which there is currently no established standard of care and few treatments available.

Priority Review is granted by the FDA to applications for medicines that, if approved, would offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions.