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GSK, Genmab leukemia drug gets FDA breakthrough status

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Singapore: The US Food and Drug Administration (FDA) has granted Genmab and GlaxoSmithKline (GSK) breakthrough therapy designation for Arzerra (ofatumumab) in combination with chlorambucil for the treatment of patients with chronic lymphocytic leukemia (CLL), who have not received prior treatment and are inappropriate for fludarabine-based therapy.

Ofatumumab is not approved or licensed anywhere in the world for use in this treatment setting. Breakthrough therapy designation is the newest of the FDA's programs aimed at accelerating the development and review times of drugs for serious or life-threatening conditions. CLL is the most common form of leukemia in adults and presently, there are no curative chemotherapy available for the disease.

The breakthrough therapy designation was based on the results from an international, multicenter, randomized phase III clinical trial in more than 400 patients with previously untreated CLL. Headline results from this trial were announced in May 2013 and the full study results have been submitted for presentation at the 2013 American Society of Hematology Annual Meeting in December.

"We are exceedingly proud to receive the Breakthrough Therapy designation, the second this year for GSK. This FDA program is intended to expedite not just the development but also the review of drugs for serious or life threatening conditions," said Dr Kathy Rouan, VP and head of biopharmaceutical development, GlaxoSmithKline. "We are actively working on our submission and look forward to the enhanced regulatory interaction allowed for breakthrough therapies."

"Both of Genmab's lead products, ofatumumab and daratumumab, have now been granted Breakthrough Therapy designations from the FDA. This designation for ofatumumab reflects Genmab's mission to create differentiated products aimed at improving the lives of patients suffering from debilitating diseases and for whom existing treatments are inadequate," said Dr Jan van de Winkel, CEO, Genmab.