

Roche study: Obinutuzumab better than Rituxan

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Singapore: Roche reported that an independent data monitoring committee has obtained positive results from the phase III CLL11 study. The committee determined that the study met its primary endpoint showing that Obinutuzumab (GA101) plus chlorambucil helped people live significantly longer without their disease worsening as compared to MabThera/Rituxan plus chlorambucil.

The CLL11 study is being conducted in cooperation with the German CLL Study Group (GCLLSG). These final data were reached well ahead of the target completion date in 2014 as a result of the magnitude of difference seen between the two study arms.

No new safety signals for GA101 or MabThera/Rituxan were identified in this analysis, and adverse events were similar to those observed in the first stage of the study which was previously reported earlier this year.

GA101 is the first type II anti-CD20 medicine that is glycoengineered, which means specific sugar molecules in GA101 were modified to change its interaction with the body's immune cells. This modification creates a unique antibody that is designed to act as an immunotherapy, engaging the patient's own immune system to help attack the cancerous cells; in addition, GA101 binds to CD20 with the aim of inducing direct cell death.

"The positive final results from the CLL11 study show the promise that GA101 could hold for people with CLL," said Hal Barron, M.D., Roche's Chief Medical Officer and Head, Global Product Development. "It is important to explore the potential of this medicine in other types of blood cancer, and our broad development program includes studies in aggressive and indolent lymphoma that compare GA101with MabThera/Rituxan."