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Genentech receives FDA approval for Gazyva

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The sBLA adds to the label data from Stage 2 of the CLL11 study showing significant improvements with Gazyva plus chlorambucil across multiple clinical endpoints when compared head-to-head with Rituxan (rituximab) plus chlorambucil.

The approval includes complete response (CR) and minimal residual disease (MRD) data from Stage 2 of the study.

Additionally, overall survival (OS) data was added from Stage 1 of the study comparing Gazyva plus chlorambucil to chlorambucil alone.

"Gazyva is the first and only medicine to significantly help people live without their disease worsening when combined with chlorambucil compared to Rituxan and chlorambucil in people with previously untreated chronic lymphocytic leukemia," said Dr Sandra Horning, chief medical officer and head of global product development. "These new data enhance our understanding of the disease and its treatment, and this approval affirms an important treatment option for people with this difficult-to-treat disease."