BioSpectrum the business of Bio & Health Sciences

Roche gets FDA approval for Venclexta plus Gazyva

16 May 2019 | News

Approval for expanded use of Venclexta offers more adults with chronic lymphocytic leukaemia a new treatment option

Roche announced that the US Food and Drug Administration (FDA) has approved Venclexta® (venetoclax) in combination with Gazyva®(obinutuzumab) for the treatment of people with previously untreated chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).

“Venclexta plus Gazyva is the only chemotherapy-free option of fixed duration that provides durable responses to help people live longer without progression of their disease, compared to a standard-of-care,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Today’s approval represents our long-standing commitment to helping people with blood cancers throughout the course of their disease, and we are excited to provide this new option for untreated chronic lymphocytic leukaemia.”

The approval is based on the results of the randomised phase III CLL14 study, which evaluated 12-month, fixed-duration treatment with Venclexta plus Gazyva compared to Gazyva plus chlorambucil. Results showed the combination of Venclexta plus Gazyva produced a durable and significant reduction in the risk of disease worsening or death.

The FDA rapidly reviewed and approved the supplemental New Drug Application (sNDA) under the FDA’s Real-Time Oncology Review (RTOR) and Assessment Aid pilot programmes. This is the second regimen of Roche medicines approved under the RTOR pilot programme, which is exploring a more efficient review process to ensure safe and effective treatments are available to patients as early as possible.

The sNDA was also granted Priority Review, a designation given to medicines that the FDA has determined to have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease. The FDA previously granted Breakthrough Therapy Designation for Venclexta in combination with Gazyva for the treatment of previously untreated CLL with co-existing medical conditions. Additional submissions of the CLL14 data to health authorities around the world are ongoing.

Venclexta is being developed by AbbVie and Roche. It is jointly commercialised by AbbVie and Genentech, a member of the Roche group, in the US and commercialised by AbbVie outside of the US.