Inotuzumab ozogamicin in acute lymphoblastic leukaemia

Adults with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL) achieve improved outcomes when treated with the antibody–drug conjugate inotuzumab ozogamicin (InO) compared with standard-of-care chemotherapy, according to final results of the INO-VATE trial.

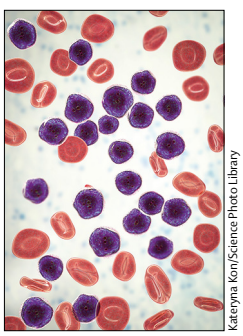
In the phase 3, randomised study, Hagop M Kantarjian (University of Texas MD Anderson Cancer Center, Houston, TX, USA) and colleagues enrolled adults diagnosed with relapsed or refractory B-cell precursor ALL. 326 patients were randomly assigned to receive either InO monotherapy (n=164) or standard of care (n=162), of whom 307 received at least one dose of study drug (164 in the InO group and 143 in the standard-of-care group). The primary endpoints were the proportion of patients achieving a complete remission or complete remission with incomplete haematological recovery and overall survival.

The final results, at a minimum of 2 years' follow-up for each patient, showed that the proportion of patients who achieved a complete remission or complete remission with incomplete haematological recovery was significantly higher with InO than with standard of care (121 [73·8%] of 164 patients *vs* 50 [30·9%] of 162; one-sided p<0·0001). Median overall survival was 7·7 months (95% CI 6·0–9·2) with InO and 6·2 months (4·7–8·3) with standard of care (hazard ratio [HR] 0·75 [97·5% CI 0·57–0·99]; one-sided p=0·0105). The treatment-related serious adverse event of veno-occlusive liver disease or sinusoidal obstruction syndrome occurred more frequently in the InO group (23 [14%] of 164 patients) than in the standard-of-care group (three [2·1%] of 143).

"Antibodies targeting CD22 (inotuzumab) and CD19 (blinatumomab; bispecific antibody construct targeting CD19) may revolutionise the treatment of ALL," commented Kantarjian. "However, the best treatment results are when using them in combination with chemotherapy, or in additional double-antibody cocktails in both salvage and frontline therapy in ALL."

"While it is notable that InO remains superior to standard-of-care chemotherapy for the treatment of relapsed ALL, this long-term follow-up study highlights the fact that, of 326 patients randomised, only 41 remained alive at the end of the 5-year study period," added Adele Fielding (University College Hospital, London, UK). "Receipt of bone marrow transplant was critical for long-term survival in both arms."

Elizabeth Gourd



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For the **study by Kantarjian and colleagues** see *Cancer* 2019; published March 28. DOI:10.1002/cncr.32116