

New Drug Approvals

Generic Name (Trade Name) Company

June 8, 2018

Venetoclax

Uses/Notes

[FDA granted regular approval](#) to venetoclax for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.

Approval was based on MURANO, a randomized (1:1), multicenter, open-label trial of venetoclax with rituximab (VEN+R) versus bendamustine with rituximab (B+R) in 389 patients with CLL who had received at least one prior line of therapy. Patients in the VEN+R arm completed a 5-week ramp-up venetoclax schedule and then received venetoclax 400 mg once daily for 24 months measured from the rituximab start date.

Rituximab was initiated after venetoclax ramp-up and given for six cycles (375 mg/m² intravenously on cycle 1, day 1 and 500 mg/m² intravenously on day 1 of cycles 2–6, with a 28-day cycle length). The comparator arm received six cycles of B+R (bendamustine 70 mg/m² on days 1 and 2 of each 28-day cycle and rituximab at the above described dose and schedule).

Efficacy was based on progression-free survival (PFS) as assessed by an independent review committee. After a median follow-up of 23 months, the median PFS was not reached in the VEN+R arm and was 18.1 months (95% CI 15.8–22.3) in the B+R arm (hazard ratio [HR] 0.19 [95% CI 0.13–0.28]; *P*

In patients treated with VEN+R, the most common adverse reactions (incidence ≥20%) were neutropenia, diarrhea, upper respiratory tract infection, fatigue, cough, and nausea. Grade 3 or 4 neutropenia developed in 64% of these patients, and grade 4 neutropenia developed in 31%.

Serious adverse reactions occurred in 46% of patients. Serious infections developed in 21% of patients, most commonly pneumonia (9%).

Due to rapid reduction in tumor volume, tumor lysis syndrome (TLS) is an important identified risk with venetoclax treatment. See the prescribing information for

(Venclexta—AbbVie, Genentech)

FDA approves new drug for CLL or SLL, with or without 17 p deletion, after one prior therapy

TLS risk stratification, prophylaxis, and monitoring.

All approved venetoclax regimens begin with a 5-week ramp-up. Full prescribing information is available at [Venclexta PI](#).

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<http://aphanet.org/new-drug-approvals/fda-approves-new-drug-ctl-or-sll-or-without-17-p-deletion-after-one-prior-therapy>

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