Lunsumio™ (mosunetuzumab-axgb) – New orphan drug approval

- On December 22, 2022, Genentech announced the FDA approval of Lunsumio (mosunetuzumab-axgb), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
    - This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s)
- FL is the most common slow-growing (indolent) form of non-Hodgkin's lymphoma, accounting for about one in five cases. The disease typically becomes harder to treat each time a patient relapses, and early progression can be associated with poor long-term prognosis.
    - In the U.S., approximately 13,000 new cases of FL will be diagnosed in 2022.
- Lunsumio is a first-in-class CD20xCD3 T-cell engaging bispecific antibody designed to target CD20 on the surface of B cells and CD3 on the surface of T cells. This dual targeting activates and redirects a patient's existing T cells to engage and eliminate target B cells by releasing cytotoxic proteins into the B cells.
- The efficacy of Lunsumio was established in an open-label, multicenter study of 90 patients with relapsed or refractory FL who had received at least two prior therapies. Lunsumio was administered for 8 cycles unless patients experienced progressive disease or unacceptable toxicity. Efficacy was established on the basis of objective response rate (ORR) and duration of response (DOR).
    - ORR was 80% (95% CI: 70, 88).
    - Median DOR was 22.8 months (95% CI: 10, not reached).
- Lunsumio carries a boxed warning for cytokine release syndrome (CRS).
- Warnings and precautions for Lunsumio include neurologic toxicity, infections, cytopenias, tumor flare, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Lunsumio use were CRS, fatigue, rash, pyrexia, and headache.
- The most common grade 3 to 4 laboratory abnormalities (≥ 10%) with Lunsumio use were decreased lymphocyte count, decreased phosphate, increased glucose, decreased neutrophil count, increased uric acid, decreased white blood cell count, decreased hemoglobin, and decreased platelets.
- The recommended dose of Lunsumio should be administered as an intravenous infusion for 8 cycles, unless patients experience unacceptable toxicity or disease progression. For patients who achieve a complete response, no further treatment beyond 8 cycles is required. For patients who achieve a partial response or have stable disease in response to treatment with Lunsumio after 8 cycles, an additional 9 cycles of treatment (17 cycles total) should be administered, unless a patient experiences unacceptable toxicity or disease progression. The recommended Lunsumio dose and schedule (21-day treatment cycles) is as follows:

Continued . . .

Day of treatment		Dose of Lunsumio	Rate of infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions from Cycle 1 were well-tolerated
Cycle 3+	Day 1	30 mg	

- Genentech plans to launch Lunsumio in the coming weeks. Lunsumio will be available as a preservative-free solution in single dose vials containing 1 mg/mL and 30 mg/mL.