

Sanofi Secures EU Approval for Subcutaneous Sarclisa in Multiple Myeloma

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The approval makes Sarclisa the first anticancer treatment in the EU to be administered through an on-body injector, giving patients with multiple myeloma a more flexible treatment option.



Sanofi has received European Commission approval for subcutaneous Sarclisa, or isatuximab, in combination with standard-of-care regimens for patients with multiple myeloma.

This is important because multiple myeloma often requires repeated and prolonged treatment visits. For patients and caregivers, this can create a long-term burden, especially when therapy has to be administered in hospital or outpatient settings over many cycles.

The new approval allows Sarclisa to be given subcutaneously through Enable Injections' CirCLIQ on-body injector, as well as through manual subcutaneous administration. It is the first anticancer treatment in the EU to be administered through an on-body injector and is approved across all existing EU indications for the intravenous formulation.

The approval was supported by the pivotal Phase 3 IRAKLIA study in relapsed or refractory multiple myeloma. The study showed non-inferiority of Sarclisa subcutaneous administration compared with intravenous Sarclisa, with an objective response rate of 71.1 percent for the on-body injector arm compared with 70.5 percent for the intravenous arm.

Patient experience data also supports the shift. In IRAKLIA, 70 percent of patients receiving Sarclisa through the on-body injector reported being satisfied or very satisfied with their injection, compared with 53.4 percent for intravenous treatment. In the Phase 2 IZALCO study, 74.5 percent of patients preferred the on-body injector over manual injection after experiencing both methods.

The commercial relevance goes beyond convenience. If treatment can be delivered more flexibly in outpatient or home settings where permitted, it may reduce clinic pressure and improve patient experience. However, adoption will still depend on local healthcare pathways, reimbursement, home administration rules and clinician confidence.

The approval reflects a wider shift in oncology towards treatment models that consider delivery burden, not just drug efficacy. For multiple myeloma care, subcutaneous and device-enabled administration could become increasingly important as patients live longer and remain on therapy for extended periods.