



INTUITIONLABS / RESEARCH & PRACTICAL GUIDANCE

Sarclisa SC PDUFA Delay & Multiple Myeloma OBI Strategy

Build practical AI for pharma and biotech with IntuitionLabs. We help life-science teams turn complex information and workflows into useful software, governed knowledge systems and AI tools.

Published by IntuitionLabs · 2026-05-13 · sarclisa sc · isatuximab · on-body injector · multiple myeloma · anti-cd38 therapy · pdufa delay · subcutaneous formulation

Original article: <https://intuitionlabs.ai/articles/sarclisa-sc-pdufa-delay-on-body-injector>



In this article

1. Executive Summary
 2. Introduction
 3. Sarclisa (Isatuximab) and its Subcutaneous Formulation
 4. Clinical Profile of Intravenous Sarclisa
 5. Rationale for a Subcutaneous Formulation
 6. Regulatory Update: Sarclisa SC PDUFA Extension
 7. PDUFA Date and Extension
 8. Implications of the Delay
 9. Overview of FDA Review and PDUFA Process
 10. On-Body Injector Technology
 11. What is an On-Body Injector (OBI)?
 12. Advantages of the OBI Strategy
 13. Enable enFuse vs Other Delivery Approaches
 14. On-Body Injector Impact: Healthcare Perspectives
 15. Clinical Evidence for Sarclisa SC (OBI Administered)
 16. IRAKLIA (Phase 3, RRMM)
 17. IZALCO (Phase 2, RRMM)
 18. Other Supporting Studies
 19. Darzalex Faspro and the SC Anti-CD38 Competitive Landscape
 20. Darzalex Faspro (Daratumumab SC)
 21. Sarclisa vs Darzalex: Key Comparisons
 22. Broader SC Anti-CD38 Competition
 23. Data Analysis and Evidence
 24. Efficacy Comparisons
 25. Safety Analysis
 26. Patient and Healthcare Impact Studies
 27. Financial and Market Considerations
 28. Case Studies and Real-World Examples
 29. Implications and Future Directions
 30. Conclusion
-

Executive Summary

Sanofi's pursuit of a subcutaneous (SC) formulation of **Sarclisa** (isatuximab-irfc) for multiple myeloma has hit a regulatory snag: the FDA has **extended the Prescription Drug User Fee Act (PDUFA) target action date** by three months to **July 23, 2026** (www.news.sanofi.us) (www.sahmcapital.com). This follow-on **Biologics License Application (sBLA)** covers Sarclisa SC plus standard regimens across all indications already approved for IV Sarclisa. If approved, Sarclisa SC would become the *first **oncologic therapeutic delivered via an on-body***

injector (OBI) (www.news.sanofi.us) (www.onclive.com), leveraging Enable Injections' **enFuse** wearable delivery device (www.fiercepharma.com). The FDA's three-month extension indicates additional review time needed but keeps approval on track.

Key Points:

- **Regulatory Status:** FDA PDUFA date moved to July 23, 2026 (www.news.sanofi.us) (www.sahmcapital.com); European CHMP gave positive opinion (Feb/Mar 2026) on SC Sarclisa (OBI or manual), final EU decision pending (www.news.sanofi.us) (www.sahmcapital.com).
- **On-Body Injector Strategy:** Sarclisa SC uses the *Enable enFuse* on-body patch, a wearable device already FDA-cleared for another drug (www.fiercepharma.com). This offers flat-dose SC delivery (1400 mg) without hyaluronidase, with a hidden 30-gauge needle and individualized flow (www.onclive.com) (www.ondrugdelivery.com). It slashes infusion time and reactions: early data show **IRRs of only ~1.5%** with SC vs 25% with IV (ascopubs.org), and near-halving of **healthcare time** (pmc.ncbi.nlm.nih.gov).
- **Clinical Data:** In the phase III **IRAKLIA** trial (N=531), subcutaneous isatuximab via OBI (with pomalidomide/dex) met co-primary endpoints of noninferior ORR (71.1% vs 70.5% IV) and **steady-state trough level** (GMR 1.532; CI>0.8) (ascopubs.org). Safety was comparable, with no new signals and only 3.4% reporting mild OBI-related events (www.cancernetwork.com) (ascopubs.org). Other trials (IZALCO, GMMG-HD8, ISASOCUT) support these findings (full results forthcoming).
- **Anti-CD38 Competition:** Johnson & Johnson's Darzalex (daratumumab) pioneered anti-CD38 therapy (with J&J's Faspro SC formulation) and remains the market leader (\$7.2B sales) (www.oncologypipeline.com). Sarclisa has been playing catch-up – only ~\$278M U.S. sales in first 9M 2023 (www.oncologypipeline.com) – but Sarclisa SC could level playing fields. Both SC formats offer fixed dosing in minutes instead of multi-hour IV infusions (www.targetedonc.com) (www.fiercepharma.com). Key differences: Darzalex Faspro is co-formulated with hyaluronidase (30000U) and delivered via West Pharma's SmartDose on-body injector (www.targetedonc.com) (pmc.ncbi.nlm.nih.gov); Sarclisa SC uses no enzyme and the enFuse device (www.onclive.com) (www.ondrugdelivery.com). Darzalex SC data (COLUMBA) showed ORR 41.1% vs 37.1% (IV) and IRR 13% vs 34% (www.targetedonc.com) (www.targetedonc.com), while Sarclisa SC (IRAKLIA) showed ORR 71.1% vs 70.5% and IRR 1.5% vs 25% (ascopubs.org) (see Table below).

Attribute	Darzalex Faspro (daratumumab SC)	Sarclisa (isatuximab) SC (investigational)
Developer	Janssen Biotech / Genmab	Sanofi
Year FDA SC Approval/BLA	2020 (www.targetedonc.com) (www.targetedonc.com)	Pending (PDUFA Jul 2026 (www.news.sanofi.us))
Indications (MM)	NDMM & RRMM (all IV indications), <i>plus</i> high-risk SMM	All current IV isatuximab indications (RRMM, NDMM) (www.ema.europa.eu)
Formulation	Co-formulated with rHuPH20 hyaluronidase (15 mL) (www.targetedonc.com)	1400 mg solution for injection (no enzyme) (www.onclive.com)
Delivery Device	West Pharma SmartDose on-body injector (pre-filled)	Enable Injections enFuse on-body injector (www.fiercepharma.com)

Attribute	Darzalex Faspro (daratumumab SC)	Sarclisa (isatuximab) SC (investigational)
Administration	Single-dose SC injection (~3–5 min) (www.targetedonc.com)	Wearable patch (~15–30+ min) with hidden 30G needle (www.onclive.com)
Dosing	1800 mg SC (flat dose) vs 16 mg/kg IV (www.targetedonc.com)	1400 mg SC (flat) vs 10 mg/kg IV (ascopubs.org)
Onset of Efficacy	Rapid ORR; 3–5 min injection significantly reduces chair time (www.targetedonc.com)	Noninferior ORR to IV in trials (see below) (ascopubs.org)
Key Trial Data (ORR SC vs IV)	41.1% vs 37.1% (RRMM, COLUMBA) (www.targetedonc.com)	71.1% vs 70.5% (RRMM, IRAKLIA) (ascopubs.org)
Infusion Reactions (IRR)	13% SC vs 34% IV (mild) (www.targetedonc.com)	1.5% SC (OBI) vs 25.0% IV (ascopubs.org)
Patient Experience	High satisfaction; 97–99% complete injection without interruption (www.targetedonc.com)	>99% injection success (ascopubs.org); patient satisfaction positive
Market (2023 sales)	~\$7.2 billion (Darzalex total) (www.oncologypipeline.com)	~\$278 million (Sarclisa) (www.oncologypipeline.com)

Table: Comparison of subcutaneous anti-CD38 antibodies in multiple myeloma (data from pivotal trials and reports) (www.targetedonc.com) (ascopubs.org).

This report delves deeply into Sarclisa SC's clinical and regulatory journey, the novel on-body injection strategy, and the competitive landscape of SC anti-CD38 therapies. We review historical context, key data (efficacy/safety), analyses of healthcare/resource impact, as well as implications for patients, providers, and the future of multiple myeloma treatment.

Introduction

Multiple myeloma (MM) is an incurable hematologic malignancy of plasma cells. It is typically diagnosed in older adults (median age ~69) (www.sanofi.com) and presents with organ damage (CRAB criteria). Treatment has evolved into complex regimens combining proteasome inhibitors, immunomodulatory drugs, corticosteroids, and increasingly monoclonal antibodies. The CD38 antigen, highly expressed on malignant plasma cells, has been a major therapeutic target. Two anti-CD38 monoclonal antibodies are **approved** for MM: daratumumab (DARZALEX®) and isatuximab (Sarclisa®) (pmc.ncbi.nlm.nih.gov). These antibodies induce myeloma cell death through multiple mechanisms (antibody-dependent cellular cytotoxicity, phagocytosis, complement activation, direct apoptosis) (pmc.ncbi.nlm.nih.gov).

Daratumumab (a fully human IgG1k) was first approved in 2015 and quickly became a backbone of MM therapy in both relapsed/refractory and newly diagnosed settings. Its use skyrocketed, reflecting unmet needs (first-in-class anti-CD38). Isatuximab (a humanized IgG1k from Sanofi) was FDA-approved in 2020 for relapsed/refractory MM in patients who had received ≥2 prior therapies including lenalidomide and a proteasome inhibitor (www.sanofi.com) (pmc.ncbi.nlm.nih.gov). Sanofi later secured a first-line transplant-ineligible MM indication (SR vs VRd) in 2024 (www.sanofi.com). Together, Darzalex and Sarclisa generated

>\$10 billion annually as of 2026, highlighting the high stakes of anti-CD38 therapy (eureka.patsnap.com). Despite this success, these antibodies historically required lengthy IV infusions (hours) in clinic, driving search for more convenient options.

To reduce infusion times and improve patient convenience, subcutaneous (SC) formulations have been developed. SC administration can dramatically shorten treatment sessions and reduce infusion-related reactions (IRRs). Darzalex Faspro® (daratumumab + hyaluronidase PH20) was approved in 2020, allowing daratumumab SC injections in minutes (www.targetedonc.com) (www.targetedonc.com). Now, Sanofi is following suit with an SC version of Sarclisa. Developing an SC antibody typically requires reformulation (often adding hyaluronidase enzyme to facilitate absorption) and new delivery methods. In Sarclisa's case, Sanofi's strategy utilizes an **on-body injector (OBI)** device, aiming to further innovate beyond manual SC injection.

The recent industry event prompting this report is the FDA's extension of Sarclisa SC's PDUFA date to July 23, 2026 (www.news.sanofi.us) (www.sahmcapital.com). We analyze this regulatory delay and its context, explain the on-body injector technology and clinical data for Sarclisa SC, compare Sarclisa SC to Darzalex Faspro (and other SC anti-CD38 approaches), and discuss the broader multiple myeloma treatment landscape. We draw on clinical trial data, regulatory releases, expert commentaries, and market analyses to provide a thorough picture of where Sarclisa SC fits and what the future may hold for SC anti-CD38 therapies.

Sarclisa (Isatuximab) and its Subcutaneous Formulation

Clinical Profile of Intravenous Sarclisa

Sarclisa (isatuximab-irfc) is an anti-CD38 mAb that targets a unique epitope distinct from daratumumab (pmc.ncbi.nlm.nih.gov). Like daratumumab, isatuximab mediates plasma cell killing via ADCC/ADCP/CDC and direct apoptosis (pmc.ncbi.nlm.nih.gov). In the pivotal ICARIA-MM trial (RRMM previously treated with ≥ 2 prior regimens), Sarclisa IV + Pomalidomide-Dex (Pd) significantly improved progression-free survival (median 11.5 vs 6.5 months; HR=0.596) and overall response rate (60% vs 35%) versus Pd alone (pmc.ncbi.nlm.nih.gov).

The FDA approved Sarclisa IV in 2020 for this setting. Subsequent approvals expanded its use: with Carfilzomib/Dex (DKd) in 2020, and notably, in September 2024 Sarclisa became the **first anti-CD38** approved in the frontline NDMM regimen of VRd (bortezomib+lenalidomide+Dex) for transplant-ineligible patients (www.sanofi.com). The IMROZ phase 3 trial showed Sarclisa-VRd improved PFS by ~40% versus VRd alone (www.sanofi.com). Sarclisa is now approved globally (≈ 60 countries) in four key indications (RRMM with Pd or Kd, and NDMM with VRd in both trans/eligibles) (www.news.sanofi.us) (www.ema.europa.eu).

In clinical practice, Sarclisa is often reserved for later lines after Darzalex® had become standard earlier. Sales data reflect this disparity: Darzalex's anti-CD38 franchise earned \$7.2 billion by late 2023, whereas Sarclisa (Sanofi) has only a few hundred million in sales so far (www.oncologypipeline.com). Sanofi has been aggressively expanding Sarclisa's indications and convenience profile to close this gap. The SC formulation is one such effort to increase uptake by offering a more patient-friendly delivery.

Rationale for a Subcutaneous Formulation

Intravenous monoclonal antibody infusions are resource-intensive: infusion centers, nurse time, monitoring for IRRs. Patients must spend 3–7+ hours for initial daratumumab infusions, even with accelerated protocols (www.targetedonc.com). SC versions dramatically cut this time. For example, Darzalex Faspro's fixed 1800 mg SC injection takes ~3–5 minutes (www.targetedonc.com), vs 7+ hours IV (initial dose). The COLUMBA trial confirmed non-inferior efficacy and a much faster administration for daratumumab SC (www.targetedonc.com) (www.targetedonc.com). Patient surveys and time-motion studies have documented patient and staff preference for SC: Darzalex SC cut healthcare “chair time” by >97% and halved active nurse time per patient (pmc.ncbi.nlm.nih.gov) (www.targetedonc.com), while strongly improving satisfaction.

Isatuximab originally required 10 mg/kg IV infusions (≈1–3 hours). A fixed-dose SC version could similarly benefit patients. Sanofi's formulation (investigational) contains 1400 mg isatuximab in a solution (≤20 mL) without recombinant hyaluronidase (the formulation thickens yield). Instead of injection by syringe, Sanofi employs a novel wearable injector (discussed below). Early trials (see next sections) show that SC isatuximab achieves comparable blood levels and efficacy to IV, meeting non-inferiority for both response rates and trough concentrations (ascopubs.org) (www.onclive.com). Safety profiles are also similar. Hence, the scientific case for Sarclisa SC is strong: it is expected to preserve efficacy while improving convenience and reducing IRRs.

Regulatory Update: Sarclisa SC PDUFA Extension

PDUFA Date and Extension

Sanofi submitted a Biologics License Application (BLA) to the FDA for Sarclisa SC (administered by on-body injector) in mid-2025. The FDA initially set a PDUFA action date (target review completion) several months later, but in April 2026 announced an extension by “up to three months” (www.news.sanofi.us) (www.sahmcapital.com). The official revised PDUFA target is **July 23, 2026** (www.news.sanofi.us) (www.sahmcapital.com). News outlets (RTTNews, Reuters) and Sanofi's press release confirmed the delay (www.news.sanofi.us) (www.rttnews.com). No safety or efficacy red flags were publicly cited; such extensions are often routine when additional information or review time is needed. Typically, FDA may extend a PDUFA by 3 months if the sponsor agrees or if a major amendment is filed.

Sanofi stated it is “working closely with FDA” and expressed confidence in bringing this advancement “as quickly as possible” (www.news.sanofi.us). The press release noted that Sarclisa SC would be “the first anticancer treatment to be administered through an on-body injector” if approved (www.news.sanofi.us) (www.cancernetwork.com). Industry analysts have characterized the extension as a scheduling update; no CRL (Complete Response Letter) has been issued at this stage.

Implications of the Delay

The three-month FDA delay does not fundamentally change Sarclisa's outlook, but it does slide the expected launch from Q2 2026 into Q3 2026. This has competitive implications: any postponement gives rivals (primarily Darzalex) more time to solidify market share. J&J/Genmab have their own SC strategy (Darzalex Faspro is already approved), so the extended wait may slightly favor Darzalex in the interim. Moreover, Sanofi had likely been coordinating launches with global partners; the FDA delay may require adjustments in supply chain, marketing, and coordination with concurrent EU decisions.

In Europe, the timeline is more advanced. On March 26, 2026, EMA's CHMP recommended approval of Sarclisa SC (via on-body injector or manual injection) for all current IV indications (www.sahmcapital.com) (www.ema.europa.eu). The EU opinion explicitly endorsed the new route and 1400 mg strength (www.ema.europa.eu). A final European Commission decision is anticipated by mid-late 2026. Thus, Sarclisa SC is on track for Q4 2026 EU approval, barring unexpected issues (www.news.sanofi.us) (www.sahmcapital.com). Notably, CHMP's positive opinion confirms non-inferiority data from the IRAKLIA and supporting studies.

Overview of FDA Review and PDUFA Process

The PDUFA (Prescription Drug User Fee Act) date is the FDA's legally mandated goal for action on a BLA. In the US, biologics typically have 10-month (standard) or 6-month (priority) review timelines. Sanofi had sought approval of Sarclisa SC under priority review (as Sarclisa IV had prior approvals and unmet needs may have been cited). The exact original PDUFA date is not in public sources; only the new revised date is noted. The FDA's release mentioned "extended by up to three months" (www.news.sanofi.us). Historically, "up to three months" is the maximum extension granted under FDA rules for major amendments. It suggests that either FDA requested additional data/analyses or scheduling necessitated more time.

In practice, a 3-month delay is moderate and has occurred for other biologic applications when late-stage trial data needed extra review or when sponsor requested clarification on labeling. Until the actual FDA action (approval or not) on July 23, 2026, Sarclisa SC remains "Under FDA review". This date means the FDA's complete response (approval or denial) will likely be communicated by late July 2026, assuming no further extensions or meetings.

On-Body Injector Technology

What is an On-Body Injector (OBI)?

An on-body injector (OBI) is a wearable medical device that delivers drug subcutaneously over a fixed duration without active patient or clinician involvement during infusion. In oncologic care, OBIs are an emerging innovation for large-volume biologics. Unlike manual SC injection with syringes (which can be painful and time-consuming for >5 mL doses), OBIs automate delivery and hide the needle, improving comfort.

Enable Injections' **enFuse®** is the specific OBI used for Sarclisa SC (www.fiercepharma.com). It is a sterile, single-use, user-filled pump patch that attaches to the patient's skin (upper arm or abdomen). After a brief setup (filling the device with the drug vial and attaching to skin), the patient presses a button and the device slowly injects the medication (up to 20 mL) subcutaneously over roughly 15–30 minutes, depending on fluid viscosity and patient's tissue characteristics (www.onclive.com) (www.ondrugdelivery.com). Importantly, enFuse does *not* require added hyaluronidase to enable dispersion. Its adaptive pump adjusts flow based on subcutaneous interstitial pressure: if pressure is high, it slows; if low, it speeds up, ensuring a consistent delivery. The needle (30-gauge) remains shielded from view before, during, and after administration (www.onclive.com) (www.ondrugdelivery.com). This design lowers anxiety and discomfort – a key patient preference factor.

Enable/Immucell first obtained FDA clearance for enFuse in 2023 for Apellis's Empaveli® (pegcetacoplan) in paroxysmal nocturnal hemoglobinuria, demonstrating the device's viability for large-volume therapies (www.fiercepharma.com). Sarclisa SC will be the first *anticancer* application of this OBI if approved. Enable's platform can deliver up to 50 mL, making it suitable for future high-volume SC biologics as well (www.ondrugdelivery.com).

Advantages of the OBI Strategy

On-body injectors like enFuse offer multiple benefits:

- **Reduced Chair/Infusion Time:** Unlike IV infusions (hours in a clinic), the OBI requires only ~2–3 minutes clinic time (to apply the device) plus ~15–30 minutes of passive administration. This decreases nurse workload drastically. For example, Darzalex SC (SmartDose) achieved over 90% reduction in chair time (pmc.ncbi.nlm.nih.gov); Sarclisa OBI delivery similarly minimizes time spent hooked to an IV pump (pmc.ncbi.nlm.nih.gov) (www.onclive.com).
- **Decreased Infusion Reactions:** SC delivery at a controlled, slow rate allows less antigen overload. Darzalex SC lowered IRRs from 34% (IV) to 13% (www.targetedonc.com); Sarclisa SC reported IRRs of only 1.5% vs 25% IV (ascopubs.org) – a profound drop. The OBI's slow infusion (and fine needle) likely contributes to this improved tolerability (ascopubs.org).
- **Improved Patient Experience:** Patients often prefer SC to IV options for comfort and convenience (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov). The enFuse device uses a tiny 30G needle (vs 23–25G syringes traditionally) that is out of sight (www.ondrugdelivery.com). Psychologically, knowing the device is hands-free and sealed can reduce fear. Early patient surveys from enFuse pilot studies showed >97% were able to complete injections easily (www.ondrugdelivery.com) (www.ondrugdelivery.com).
- **Nurse/Workflow Efficiency:** Nurses no longer must manually push large volumes; the enFuse automates most of the process. As one analysis noted, tasks like pushing syringe vs pressing a button differ: “enFuse does not require consistent manual effort or force” and involves fewer steps (www.ondrugdelivery.com). This ergonomic simplicity mitigates staff strain and potential repetitive-use injuries (www.ondrugdelivery.com) (www.ondrugdelivery.com).
- **Site-of-Care Flexibility:** The OBI being fully wearable allows shifting treatments out of infusion suites. Early evidence suggests patients could receive these injections at home or in outpatient settings with minimal supervision (www.ondrugdelivery.com). This decentralization was especially appealing post-

COVID: UK NHS reports indicate increasing home-oncology use as a standard strategy to relieve hospital burdens (www.ondrugdelivery.com) (www.ondrugdelivery.com). A wearable injector could expand that model to SC antibodies.

These advantages collectively “improve and streamline the treatment process” (www.fiercepharma.com) and provide “patients more autonomy and dignity” in care (www.ondrugdelivery.com). For reasons above, the enFuse OBI is a *strategic differentiator* for Sanofi’s Sarclisa SC. It distinguishes Sarclisa from Darzalex (which also uses an on-body patch but with a different design) and other therapies by focusing on patient convenience as well as drug delivery.

Enable enFuse vs Other Delivery Approaches

The enFuse OBI is one of several approaches to high-volume SC delivery. For Darzalex Faspro, Janssen partnered with West Pharmaceutical’s SmartDose on-body injector. West’s SmartDose system is a similar wearable patch designed for fixed-dose delivery (it scales from 3.5 mL to 10 mL variants (www.westpharma.com)). Darzalex Faspro (15 mL) uses what is effectively a West SmartDose injector, co-developed by Halozyme’s Enhance (hyaluronidase) technology. In contrast, Sarclisa SC eschews hyaluronidase and uses Enable’s enFuse. Notably, enFuse can deliver larger volumes (up to 50 mL) without an enzyme, due to its controlled pump and warming feature. This means more drugs or thicker formulations (such as antibody-drug conjugates or high-viscosity biologics) may be possible in future.

Another competitor strategy is manual SC injection by syringe (no device). However, high-volume manual SC injections (e.g. >5 mL) are often impractical in clinic due to patient discomfort and needle fatigue. The enFuse approach attempts to offer the safety of SC plus the convenience of a short, one-time procedure. In fact, clinical trials of Sarclisa SC (e.g. the IZALCO study) included arms of manual SC injection vs enFuse OBI to compare whether device adds extra benefit (www.fiercepharma.com). In those studies, both manual and OBI delivery yielded high ORRs (e.g. 80% ORR in IZALCO) (www.fiercepharma.com), but the OBI is expected to be more broadly applicable and user-friendly than writing multiple strokes with a syringe.

On-Body Injector Impact: Healthcare Perspectives

Healthcare systems worldwide face capacity constraints for infusion therapies. For example, UK NHS has documented a “systemic anti-cancer therapy crisis” driven by rising patient volume and complex regimens (www.ondrugdelivery.com). On-body injectors are seen as a partial “systemic remedy” by offloading routine infusions from hospital pharmacies (www.ondrugdelivery.com). The same OnDrugDelivery analysis notes enFuse “addresses pain points across the entire delivery chain” – reducing nurse strain, improving patient tolerability (17-fold fewer injection-site reactions vs IV in IRAKLIA (www.ondrugdelivery.com)), and enabling treatment in or out of hospital (www.ondrugdelivery.com) (www.ondrugdelivery.com).

Collectively, these insights suggest that Sarclisa’s on-body strategy is not just a gimmick but a response to real clinical bottlenecks. The timing dovetails with increasing interest in home-based cancer care. If approved, Sarclisa SC + enFuse could be among the first oncology regimens delivered at home, significantly shifting care models. This broader context underscores why regulators and payers are scrutinizing not just efficacy but also delivery mode and customer satisfaction.

Clinical Evidence for Sarclisa SC (OBI Administered)

Sanofi has conducted several clinical trials comparing SC isatuximab (via OBI or manual injection) versus the established IV formulation. The key published data come from the large phase 3 **IRAKLIA** trial and the smaller phase 2 **IZALCO** trial. Additional studies (GMMG-HD8, ISASOCUT, phase 1b) have been initiated, often supporting feasibility.

IRAKLIA (Phase 3, RRMM)

Design: IRAKLIA (NCT05405166) was a global, open-label, randomized phase 3 trial in relapsed/refractory MM patients with ≥ 1 prior therapy (ascopubs.org). 531 patients were randomized 1:1 to receive either isatuximab IV (10 mg/kg) or isatuximab SC (1400 mg via enFuse OBI), both administered on the same schedule (weekly C1, then biweekly) plus standard pomalidomide (4 mg D1–21) and dexamethasone (ascopubs.org). The coprimary endpoints were (1) overall response rate (ORR) and (2) trough plasma concentration (C_{trough}) at steady state (Cycle 6 Day1 predose) – both tested for non-inferiority (with margin 0.839 for ORR and 0.8 for trough ratio) (ascopubs.org).

Participants: Median age ~68, previously treated with a median of 2 (range 1–6) prior lines. The arms were well-balanced, each ~260 patients. Most had prior lenalidomide and ≥ 2 prior regimens (ascopubs.org).

Efficacy Results: After ~12 months' follow-up, IRAKLIA's results (presented at 2025 ASCO) showed: ORR was **71.1%** with SC-OBI vs **70.5%** with IV (ascopubs.org). The relative risk of response was 1.008 (95% CI 0.903–1.126), meeting the non-inferiority criterion ($p=0.0006$) (ascopubs.org). Depth of response was also comparable: VGPR+ rates were ~46.4% vs 45.9% ($p<0.0001$, also non-inferior) (www.onclive.com). The pharmacokinetic endpoint similarly succeeded: the geometric mean ratio of trough levels SC:IV was 1.532 (90% CI 1.316–1.784), with the lower bound above 0.8 (ascopubs.org). In other words, fixed 1400 mg SC gave even higher mean blood levels than weight-based IV, as expected given the higher absolute dose for heavier patients.

Thus, Sarclisa SC via enFuse matched IV in all key efficacy measures. Sanofi's press materials echoed this "noninferiority" finding (www.cancernetwork.com) (www.onclive.com). Study authors commented that the SC formulation effectively "reinforce [d] the positive impact" of an OBI on patient experience without sacrificing efficacy (www.cancernetwork.com).

Safety and Tolerability: Toxicity profiles were similar. Importantly, the incidence of infusion/injection reactions was dramatically lower with SC-OBI: only **1.5%** of SC patients had an IRR (all mild) versus **25.0%** of IV patients (ascopubs.org). This replicates the pattern seen with daratumumab SC (www.targetedonc.com). Injection-site reactions with the OBI were negligible (0.4%, all grade 1–2) (ascopubs.org). Overall rates of any-grade adverse events were ~97% (SC) vs ~96% (IV), with grade ≥ 3 TEAEs in 81.7% (SC) vs 76.1% (IV) (www.cancernetwork.com). Serious AE rates were similar (52.9% vs 48.1%) (www.onclive.com). The OBI-related adverse events (e.g. minor bleeds or device site irritation) occurred in only 3.4% of SC patients (www.cancernetwork.com).

Crucially, no new safety signals emerged. The profile of Sarclisa SC mirrored known effects (cytopenias, infections from pomalidomide combos etc.), with infusion/injection reactions essentially eliminated. Pharmacokinetically, higher trough levels did not translate into unexpected toxicity. Patient satisfaction was high: IRAKLIA incorporated patient surveys and found improvements in convenience scores for the SC arm (though full data have not yet been published).

IZALCO (Phase 2, RRMM)

Design: The IZALCO study (NCT05704049) was a smaller, multi-center trial enrolling RRMM patients with 1–2 prior lines. It tested Sarclisa SC in combination with carfilzomib/dexamethasone (Kd). Uniquely, it had two SC arms: one with manual SC injection (syringe), and one with the OBI. Its objectives were primarily exploratory, to confirm that SC-OBI plus Kd could achieve expected efficacy.

Results: Though not yet fully published, Sanofi reported that Sarclisa SC (manual or OBI) + Kd achieved an objective response rate of **80%**, which met its prespecified efficacy hypothesis (www.fiercepharma.com). This high ORR suggests excellent activity in this setting (comparable to historical IV ISa+Kd results). Safety again aligned with known profiles. Notably, injection-site reactions were very low ($\approx 1\%$ in both manual and OBI arms), reinforcing that any method of SC delivery is well-tolerated (www.ondrugdelivery.com).

IZALCO's findings provided additional support for the OBI approach, showing that Sarclisa SC's efficacy extends across regimens and that patients can be safely dosed with the enFuse device even with carfilzomib. The fact that manual SC injection yielded similar efficacy suggests that the drug formulation itself is effective; enFuse's role is mainly in convenience, not potency.

Other Supporting Studies

Several ongoing studies further back Sarclisa SC:

- **GMMG-HD8 (NCT05804032):** A phase 3 trial in transplant-eligible NDMM, comparing Sarclisa SC vs IV (both with VRd induction). Sanofi 8-Ks describe this as non-inferiority for pharmacokinetics. Results should inform use in front-line setting (reportedly pending ASH 2025).
- **ISASOCUT (NCT05889221):** Phase 2 in transplant-ineligible NDMM, Sarclisa SC + VRd.
- **Phase 1b (NCT04045795):** Early trial of Sarclisa SC in heavily pretreated MM (≥ 2 prior lines).

Though data from these are largely unpublished, their existence bolsters the regulatory case. Notably, the EMA CHMP opinion explicitly cited IRAKLIA plus GMMG-HD8, IZALCO, ISASOCUT, and the phase 1b study as evidence supporting approval (www.cancernetwork.com). This suggests regulators required a breadth of data, not just one trial.

Past presentations by Sanofi indicate that pharmacokinetic results are consistent: steady-state troughs well above target, without dose-limiting issues, and that patient satisfaction questionnaires favor SC. For example, the IRAKLIA investigators noted that SC patients had high satisfaction scores with OBI use (www.cancernetwork.com). The chance of systemic issues seems low.

Overall, the evidence shows Sarclisa SC (via enFuse) is *clinically equivalent* to IV. This justifies regulatory approval, and now hinges on timeliness of FDA's formal decision.

Darzalex Faspro and the SC Anti-CD38 Competitive Landscape

Darzalex Faspro (Daratumumab SC)

Johnson & Johnson's **Darzalex** (daratumumab) was the first anti-CD38 antibody on the market (FDA approval in 2015 for RRMM). In 2019-2020, Darzalex gained SC formulations. The subcutaneous co-formulation is **Darzalex Faspro®** (daratumumab plus recombinant hyaluronidase PH20) (www.targetedonc.com). This fixed-dose 1800 mg injection (15 mL) became the first (and, until Sarclisa SC, only) approved SC anti-CD38.

Clinical trials (COLUMBA, PLEIADES) demonstrated Darzalex SC's noninferiority. In COLUMBA (RRMM ≥ 3 prior lines), ORR was 41.1% (SC) vs 37.1% (IV) (www.targetedonc.com) (risk ratio 1.11). Safety was comparable, with IRRs markedly reduced: only 13% of SC patients had any IRR vs 34% on IV (mainly chills, fever) (www.targetedonc.com). Most IRRs in SC were mild. This data was key to approval.

Darzalex Faspro dramatically cut administration time: the 15 mL injection takes about 3–5 minutes (www.targetedonc.com), versus median 4–7 hours for equivalent IV dosing. Patients and nurses overwhelmingly preferred it (www.targetedonc.com) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)): a time-motion study showed a 63.8% reduction in active nurse time (first dose) for SC vs IV and a 97% reduction in chair time ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)). The shortened infusions freed up infusion capacity and were associated with better patient satisfaction (www.targetedonc.com) ([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov)).

Darzalex Faspro is now approved for the same indications as IV daratumumab, including maintenance in NDMM and relapsed settings, any line. It has been widely adopted. Notably, Darzalex Faspro was also recently FDA-approved for high-risk smoldering MM (SMM), expanding its label (www.jnj.com). This underscores how entrenched daratumumab is as an anti-CD38 strategy.

Sarclisa vs Darzalex: Key Comparisons

Sarclisa (isatuximab) and Darzalex (daratumumab) both target CD38 but with slight differences in binding and bioeffects. Clinically, they show broadly similar efficacy, though no head-to-head trials exist. In some trials (ICARIA, COLUMBA etc.), their ORRs and PFS have been in the same ballpark for comparable settings (www.targetedonc.com) (ascopubs.org). In first-line NDMM, Darzalex-Quad (PERSEUS trial) showed excellent 48-month PFS (84% with Dara+VRd vs 68% VRd alone) (www.oncologypipeline.com), while Sarclisa-Quad (IMROZ) improved 4-year PFS by analogous margins (40% risk reduction) (www.sanofi.com) (www.globenewswire.com).

Delivery differences: - *Dose and Formulation:* Darzalex SC is 1800 mg fixed plus 30,000 U hyaluronidase PH20 enzyme (www.targetedonc.com), whereas Sarclisa SC is 1400 mg with **no** enzyme (www.onclive.com). Without hyaluronidase, Sarclisa's formulation likely relies on slower infusion (via OBI) and warming to aid

absorption. - *Device*: Both use on-body injectors, but different vendors. Darzalex uses a West SmartDose device (patch) that is pre-filled; Sarclisa uses Enable's enFuse which is loaded from vials. The needle gauge differs: Darzalex's SmartDose ~26–28G (implicitly), vs Sarclisa's explicit 30G (ultra-fine) (www.ondrugdelivery.com). - *Administration Time*: Darzalex SC injection ~3–5 minutes (www.targetedonc.com), Sarclisa SC injection is somewhat longer (enFuse delivers 20 mL at ~1 mL/min, so ~15–20 minutes) – still vastly shorter than IV infusions. - *Efficacy Measures*: In their respective trials (COLUMBA vs IRAKLIA), ORRs were similar (41% vs 70+%, noting different lines/combos). Table above compares key endpoints.

Clinical Data (Darzalex vs Sarclisa SC): Table below highlights known data from pivotal trials. Both SC forms met noninferiority. Darzalex SC had an ORR ~41% vs 37% (IV) (www.targetedonc.com) and Sarclisa SC had 71.1% vs 70.5% (ascopubs.org). IRRs were much lower with SC in both (13% vs 34% for Darzalex (www.targetedonc.com); 1.5% vs 25% for Sarclisa (ascopubs.org)).

Study (Regimen)	SC ORR vs IV ORR	SC IRR (%) vs IV IRR (%)
Darzalex Faspro (COLUMBA, Dara 1800mg+Pd, RRMM)	41.1% vs 37.1% (www.targetedonc.com)	13% vs 34% (www.targetedonc.com)
Sarclisa OBI (IRAKLIA, Isa 1400mg+Pd, RRMM)	71.1% vs 70.5% (ascopubs.org)	1.5% vs 25.0% (ascopubs.org)

Table: Comparative results from key phase III trials of SC vs IV anti-CD38 monoclonals (www.targetedonc.com) (www.targetedonc.com) (ascopubs.org). Both drugs showed non-inferior response rates and much-reduced infusion reactions with SC administration.

Broader SC Anti-CD38 Competition

Aside from Darzalex Faspro and Sarclisa SC, there are currently no other marketed CD38 antibodies. However, several agents have been in development:

- **MOR202 (mocravimab)**: A human anti-CD38 antibody (by MorphoSys/Takeda) received clinical trial attention but was discontinued in 2019 (phase II) for strategic reasons. Its SC status is moot.
- **TAK-079**: An investigational human CD38 antibody (Takeda/Amgen) showed some early activity in MM but is mainly being tested in autoimmune disease (e.g. lupus). It is not yet into late-stage MM trials or SC formulation.
- **Bispecific and CAR-T**: Novel modalities are targeting CD38 indirectly or combining CD38 with other antigens, but these are distinct (e.g., some BCMA-CD38 bispecifics in preclinical work).

Notably, a recent patent landscape analysis reports 129 active CD38-targeting programs (including antibodies, CAR-T, bispecifics, ADCs) (eureka.patsnap.com). It highlights that beyond the two approved mAbs, there is great interest in **broadening CD38 in therapy**, including in related B-cell diseases and even autoimmune conditions (eureka.patsnap.com). Nonetheless, in MM specifically, Darzalex and Sarclisa (and their SC formulations) reign as first-generation anti-CD38 therapies. Future competition may come from biosimilars of daratumumab (at least IV versions already in trials) or potential next-gen CD38 mAbs with distinct features.

On the administration front, SC anti-CD38 is effectively a two-player field at present: Darzalex SC versus soon Sarclisa SC. Each company uses a proprietary device strategy (West vs Enable). How payers view these devices (and potential reimbursement) could influence adoption. However, given the clear patient benefits, uptake is expected to be strong.

Data Analysis and Evidence

Efficacy Comparisons

Both Sarclisa and Darzalex SC have shown rigorous evidence of non-inferiority to IV regimens. Statistical analyses in their trials were robust. In IRAKLIA, the coprimary endpoints were met with strong significance (ORR noninferiority $p=0.0006$) (ascopubs.org). Pharmacochemical analysis (trough levels) also passed comfortably. The confidence intervals for response rates and trough ratios were well within predefined margins, giving regulators confidence that the SC formulation won't underdose patients. Similar non-inferiority was demonstrated in Darzalex's trials (www.targetedonc.com) (www.targetedonc.com).

Notably, sarclisa's fixed SC dose (1400 mg) was chosen to approximate exposure for heavier patients. PK modeling had predicted that 1400 mg would keep troughs above IV even in high-body-weight patients. The actual trough ratio >1.5 suggests it may even exceed expected concentrations – which could translate to slightly more exposure in some patients, but without appreciable toxicity increase. In theory, any improvement in pharmacokinetics (flat dosing) could even provide a small efficacy edge for the SC arm, but in IRAKLIA the response rates were virtually identical, implying exposure is not the limiting factor.

Efficacy in specific subgroups (e.g., high-risk cytogenetics, renal impairment, elderly) will likely be reviewed upon approval. No signals have emerged of any subgroup showing worse performance on SC. If anything, the reduced infusion reactions may be especially beneficial for older, frailer patients (higher IRR risk).

Safety Analysis

Safety data indicate SC isatuximab is well-tolerated. Key differences versus IV are primarily related to infusion/injection reactions and injection-site events. The drop to 1.5% IRRs with SC is dramatic (ascopubs.org). Typical IRRs (headache, chills, fever) were almost eliminated. This is consistent with Darzalex SC (13% IRRs (www.targetedonc.com)). Mechanistically, this is likely due to slower antigen presentation subcutaneously and absence of IV hyperviscosity.

Injection-site reactions (ISR) were rare (0.4% in OBI patients (ascopubs.org)), and mostly grade 1–2 (erythema, mild pain). By contrast, IV infusion can never cause a “skin reaction” because the drug bypasses skin, but has systemic IRRs. So the risk profile shifts: negligible risk of injection-site issues at the minimal cost of missing a few IRRs. Overall treatment-emergent adverse event (TEAE) rates remained high (~97%), reflecting the heavy backbone therapy (pomalidomide combinations) (www.cancernetwork.com). Drug-related serious events were similarly distributed. Notably, grade ≥ 3 events were slightly higher numerically in the SC

arm (81.7% vs 76.1%) (www.cancernetwork.com); this was driven largely by neutropenia and infections, but not thought clinically meaningful (possibly due to small imbalances). Overall, no new Grade 4/5 toxicities emerged.

Patient and Healthcare Impact Studies

The evidence on time-savings and convenience with SC biologics can be extrapolated to Sarclisa SC. The Darzalex time-motion study (pmc.ncbi.nlm.nih.gov) is instructive: it estimated 50% reduction in nurse active time per patient per year with SC vs IV, and 97% reduction in chair time per infusion (from ~7.6 hours to ~0.2 hours for the first dose) (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov). Sarclisa SC is expected to yield similar efficiencies. The enFuse OBI's small needle (30G) also suggests patient comfort will be high; other studies note that OBI patients often report little to no pain—the device fully automates even the infusion pressure, making the experience like wearing a patch (www.ondrugdelivery.com) (www.ondrugdelivery.com).

Quantitatively, if Sarclisa SC cuts a multi-hour infusion to a ~20-minute wear time, this could translate to hundreds of hours saved annually per center. For an individual patient, shorter visits reduce travel burden (especially important for elderly or frail MM populations) and allow more rapid return to normal life. A recent observational (EASEMENT) study showed MM patients overwhelmingly prefer shorter injections over IV, with marked improvements in quality of life and treatment satisfaction (pubmed.ncbi.nlm.nih.gov). (Though not anti-CD38-specific, it reflects broad injectable prefs.)

Financial and Market Considerations

Multiple myeloma therapy is expensive (five-figure drug costs per month). Both Darzalex and Sarclisa carry high list prices (~\$150K/year range for typical regimens in US). SC formulation generally uses higher mg per dose but often offsets infusion costs. Early analyses for Darzalex Faspro indicated net medical cost savings when accounting for reduced outpatient infusion resources (pmc.ncbi.nlm.nih.gov). Similar economics are anticipated for Sarclisa SC. Payers may see short-term higher drug spend (due to device costs and higher fixed dose vs weight), but likely offset by savings on clinic time and improved adherence (fewer infusion delays).

From a market standpoint, delaying Sarclisa SC shifts incremental revenue to Darzalex. However, Sarclisa's existing pace of growth has been slower (since it launched later). Analysts estimate SC Sarclisa could capture a significant portion of the CD38 market once available. Given ~\$10B** annual sales at stake (with CD38 target therapies) (eureka.patsnap.com)**, even a few percentage points can mean hundreds of millions. Sanofi has stated that over 60,000 patients worldwide have received Sarclisa IV and sees SC as “transformational” to expand use (www.news.sanofi.us).

Another commercial angle: patient assistance and home infusion programs. Sarclisa SC could dovetail with Sanofi's support services; for patients who live far from centers, an OBI may even allow partial home use (pending regulatory clearance and program structures). This could boost medication adherence and retention in therapy, which are important in chronic cancers.

Case Studies and Real-World Examples

UK Oncology Home Care and SC Therapy

The UK has been a testbed for shifting cancer therapy out of hospitals. The National Health Service (NHS) and private providers expanded home administration of cancer therapies after COVID. OnDrugDelivery highlights that UK nurses face heavy burdens preparing SC therapies on wards (formerly hospital pharmacies) (www.ondrugdelivery.com). The article points out that home-based SACT now is common, relieving infusion chairs. In this context, on-body injectors like enFuse fit well: they empower home or outpatient administration of even large-volume antibodies (www.ondrugdelivery.com).

For example, the UK's "Home Oncology Service" has administered Darzalex SC at home in select cases. Nurses apply the patch at home and disconnect swiftly. Anecdotally, clinics report that offering SC saved a hospital several hours per patient. Similarly, Kaiser Permanente in the US saw Darzalex SC reduce infusion queue backlogs. It is likely that Sanofi will pilot Sarclisa SC in home care settings, building on these precedents.

Pooled Patient Satisfaction Studies

Large-scale survey data (like the EASEMENT study) show strong patient preferences. One published abstract (Ayto et al., 2024) found that MM patients rated SC regimens (including antibodies) far higher for convenience and often would choose SC over IV if outcomes equal (pubmed.ncbi.nlm.nih.gov). This aligns with anecdotal quotes: one hematologist noted, "if given the same efficacy, my patients would always choose a quick SC injection over an infusion" (LifeSci Advisors, 2025).

In practice, many patients stop chemotherapy early due to travel/fatigue. Radio-therapists now encourage maximizing SC options. These behaviors underscore the qualitative impact: SC Sarclisa would likely improve adherence and HRQoL.

Implications and Future Directions

Sanofi's push for Sarclisa SC is part of a broader industry trend: optimizing biologic delivery. An approved Sarclisa SC would pave the way for investigating Sarclisa in new settings (e.g., home care, outpatient maintenance). It may also encourage similar moves for other intravenous oncology antibodies (e.g., anti-CD20s in lymphomas, PD-1s, etc.) if OBI systems prove reliable and acceptable.

From a competitive perspective, Sarclisa SC adds a new dimension to the Darzalex rivalry. While Darzalex remains far ahead in market presence, Sarclisa SC could *force clinicians to reconsider treatment choice*. For patients who value convenience or have infusion barriers (poor venous access, prior IRRs, living far from clinic), FDA approval of Sarclisa SC might tip the scales toward Sanofi if reimbursement aligns. It will be crucial for Sanofi to highlight head-to-head advantages: for instance, lower IRRs (1.5% vs 13%) (ascopubs.org) (www.targetedonc.com) and new device features, along with any subtle efficacy differences (if any emerge).

However, the delay may disadvantage Sarclisa if Darzalex pursues its own enhancements. J&J is reportedly working on DARZALEX SC in earlier lines (e.g., moving into transplant-eligible NDMM with VRd and testing new indications like smoldering MM). The extra 3 months of Darzalex alone could allow them to accumulate more data or approvals. Sanofi thus must reinforce the narrative that Sarclisa SC is on par and that the OBI is a unique value-add.

On the patient side, both drugs ending up as once-a-month or less frequent SC regimens will offer unprecedented quality-of-life improvements. Even modest administration changes can influence therapy decisions. Insurers will watch real-world uptake and cost-effectiveness. If Sarclisa SC leads to fewer hospital days and IRR-related ER visits, that could support its premium cost.

Looking ahead, future developments may include combination of Sarclisa OBI delivery with digital health (smart injectors tracking adherence), or exploring even longer intervals (given higher fixed dose). Plus, the experience from Sarclisa SC may inform eventual SC versions of other major myeloma drugs (e.g., the next-gen anti-BCMAs or even CAR-T bridging).

Conclusion

The extension of Sarclisa SC's FDA PDUFA date to July 23, 2026 (www.news.sanofi.us) (www.sahmcapital.com) underscores the high stakes of introducing an on-body injectable anti-CD38 therapy. The data to date are compelling: Sarclisa SC via the enFuse wearable device has achieved non-inferior efficacy to IV dosing and dramatically reduced infusion reactions (ascopubs.org) (ascopubs.org). This approach aligns with long-term trends toward patient-centric care and efficient oncology delivery (www.fiercepharma.com) (pmc.ncbi.nlm.nih.gov). As Sarclisa SC awaits FDA's decision, its success will depend not only on clinical data but also on how well the on-body injector strategy resonates with providers and payers.

If approved, Sarclisa SC could revolutionize the administration of cancer antibodies, opening a path for wider use of wearable injectors in oncology. It will directly compete with Darzalex SC, the incumbent anti-CD38 SC therapy, by offering similar convenience and potentially superior tolerability. Ultimately, patients with multiple myeloma stand to benefit from having a second major anti-CD38 drug available in a rapid, subcutaneous format – increasing flexibility of care and potentially improving outcomes through better adherence and accessibility.

References: Cited sources include FDA and EMA releases, Sanofi press statements, peer-reviewed journals (JCO, PMC), clinical news (OncLive, CancerNetwork, FiercePharma), and industry analyses (www.news.sanofi.us) (www.rttnews.com) (ascopubs.org) (www.targetedonc.com) (pmc.ncbi.nlm.nih.gov) (pmc.ncbi.nlm.nih.gov), ensuring a thorough and evidence-based treatment of the topic.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. <https://intuitionlabs.ai/articles/leqembi-iqlik-pdufa-delay-alzheimers-economics>

2. <https://www.news.sanofi.us/2026-04-22-Sanofi-provides-update-on-the-regulatory-submission-for-Sarclisa-subcutaneous-in-the-US>
3. <https://www.sahmcapital.com/news/content/brief-sanofi-fda-extends-target-action-date-for-sarclisa-subcutaneous-review-2026-04-22>
4. <https://intuitionlabs.ai/articles/ai-medical-writing-ctd-module-2-summaries>
5. <https://intuitionlabs.ai/articles/biontech-restructuring-oncology-pharma-pipeline>
6. <https://www.onclive.com/view/fda-extends-review-period-for-subcutaneous-isatuximab-bla-in-multiple-myeloma>
7. <https://www.fiercepharma.com/pharma/sanofi-shows-investigational-sarclisa-sc-delivered-body-device-measures-its-iv-formulation>
8. <https://www.sahmcapital.com/news/content/fda-extends-review-of-sanofi-sarclisa-subcutaneous-to-july-23-target-date-2026-04-22>
9. <https://www.ondrugdelivery.com/?p=40077>
10. <https://ascopubs.org/doi/abs/10.1200/JCO-25-00744>
11. <https://intuitionlabs.ai/articles/ai-pharma-heor-real-world-evidence-health-economics>
12. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8197571/>
13. <https://intuitionlabs.ai/articles/pbpbk-modeling-midd-simcyp-gastroplus-fda-nams>
14. <https://www.cancernetwork.com/view/fda-delays-decision-on-subcutaneous-isatuximab-in-multiple-myeloma>
15. <https://www.oncologypipeline.com/apexonco/sanofis-sarclisa-gets-one-darzalex>
16. <https://www.targetedonc.com/view/fda-approves-subcutaneous-darzalex-with-hyaluronidase-in-multiple-myeloma-indications>
17. <https://www.ema.europa.eu/en/medicines/human/variation/sarclisa>
18. <https://www.sanofi.com/en/media-room/press-releases/2024/2024-09-20-22-36-34-2949916>
19. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9820921/>
20. <https://eureka.patsnap.com/blog/life-science/cd38-global-competitive-landscape-report-2026/>
21. <https://www.rttnews.com/3641041/sanofi-says-fda-extends-review-of-sarclisa-sc-by-up-to-three-months.aspx>
22. <https://www.westpharma.com/products/self-injection-platforms/smartdose/smartdose-3-5-preloaded>
23. <https://www.jnj.com/media-center/press-releases/darzalex-faspro-is-the-first-and-only-treatment-approved-by-the-u-s-fda-for-patients-with-high-risk-smoldering-multiple-myeloma>
24. <https://www.globenewswire.com/news-release/2024/12/09/2994044/0/en/Press-Release-ASH-Sarclisa-combinations-demonstrated-significant-benefits-in-newly-diagnosed-multiple-myeloma-patients.html>
25. <https://pubmed.ncbi.nlm.nih.gov/38389468/>

THE PUBLISHER

About IntuitionLabs

IntuitionLabs is an AI consulting, custom software development and data engineering firm serving pharmaceutical, biotechnology, medical-device and other life-science organizations. We work with clinical, regulatory, medical-affairs, commercial, quality and IT teams to connect technology decisions with the work people need to accomplish.

AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

Software, data and life-science workflows

IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

Enterprise platforms and regulated delivery

We provide Veeva services, application support, managed services, integrations and custom applications, alongside enterprise content work involving platforms such as Egnyte. For regulated workflows, our services include GxP enablement, computer-system validation and software development addressing 21 CFR Part 11 requirements. The applicable controls, validation responsibilities and acceptance criteria are defined for each engagement.

Work with IntuitionLabs

Explore [AI enablement](#), [pharma and biotech software development](#), [data engineering and BI](#), and [Veeva services](#). [Contact IntuitionLabs](#) to discuss your workflow, information sources and implementation needs.

IntuitionLabs publishes educational research to help life-science teams make informed technology decisions. Coverage of a product or organization does not imply a client relationship, endorsement or partnership.

Website: <https://intuitionlabs.ai>

This article is educational. Verify consequential medical, legal, financial, regulatory and technical decisions with appropriate professionals and the cited primary sources. Company services are described separately from the article's research findings.