# Mendus

## Positive CML safety readout supports strategy

Clinical update

Healthcare

11 September 2026

**Mendus has reported a positive first-stage readout from its Phase Ib VITAL-CML trial, following review by the data safety monitoring board (DSMB). The DSMB concluded that vididencel in combination with ongoing tyrosine kinase inhibitor (TKI) treatment raised no safety or tolerability concerns in the first eight patients, all of whom completed four vididencel doses. This result supports continued enrolment in VITAL-CML, which has now recruited 12 out of a planned 24 participants, and keeps the programme on track for additional readouts in Q426 and initial top-line data from all 24 patients in mid-2027. Importantly, the positive safety assessment also enables Mendus to initiate the distinct Phase IIa VITAL-TFR2 study, planned for Q426, in patients who previously failed a treatment-free remission (TFR) attempt. We view the outcome as encouraging for the pace of Mendus's expanded chronic myeloid leukaemia (CML) strategy, with the next key steps being further VITAL-CML data and launch of VITAL-TFR2 in Q426.**

| Year end | Revenue (SEKm) | PBT (SEKm) | EPS (SEK) | DPS (SEK) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/24 | 5.0 | (128.4) | (2.64) | 0.00 | N/A | N/A |
| 12/25 | 7.9 | (113.3) | (2.17) | 0.00 | N/A | N/A |
| 12/26e | 15.0 | (89.9) | (1.44) | 0.00 | N/A | N/A |
| 12/27e | 94.8 | (16.1) | (0.26) | 0.00 | N/A | N/A |

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS is adjusted 20:1 for share consolidation (June 2024).

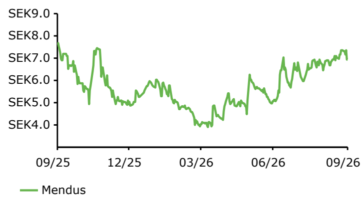
The latest readout represents a key safety milestone, rather than an efficacy result, for vididencel in this new patient population. VITAL-CML is designed first to establish safety and tolerability in chronic phase CML patients with suboptimal responses to TKIs, before assessing whether vididencel can deepen molecular remissions through immune-mediated disease control. The initial eight-patient cohort has therefore met its immediate objective, with no safety or tolerability concerns identified by the DSMB after four doses. In our view, this removes an important execution hurdle and supports continued development in this setting.

The clinical rationale remains centred on TFR. TKIs have transformed CML outcomes, with survival now similar to the general population, but many patients remain dependent on long-term treatment. Mendus estimates that fewer than 25% achieve durable TFR because of relapse after treatment discontinuation. VITAL-CML targets patients who are currently ineligible for TFR because molecular responses remain suboptimal despite ongoing TKI therapy. The aim is to strengthen immune control of residual disease and potentially deepen responses enough for treatment discontinuation. The trial has recruited 12 of 24 planned patients, with additional readouts expected in Q426 and initial top-line data from the full cohort in mid-2027.

The positive safety assessment also enables the second CML development path. VITAL-TFR2 is scheduled to start in Q426 and will assess whether vididencel can improve durable TFR in patients who previously relapsed after stopping TKIs. We see progression of both studies as encouraging for Mendus's expanded clinical strategy. In AML, the same principle of immune control over residual disease underpins the CADENCE and DIVA trials, which remain central to broadening vididencel's value proposition across myeloid malignancies. For a more detailed discussion, we direct readers to our prior update note.

| Price | SEK6.95 |
|---|---|
| Market cap | SEK450m |
| | SEK9.68/US$ |
| Net cash at 30 June 2026 | SEK29.0m |
| Shares in issue | 64.8m |
| Free float | 25.0% |
| Code | IMMU |
| Primary exchange | OMX |
| Secondary exchange | N/A |

### Share price performance




### Business description

Mendus is an immuno-oncology company focused on immunotherapies for myeloid blood cancers. Its lead clinical candidate is vididencel, an off-the-shelf cellular immunotherapy that has demonstrated durable clinical remissions in acute myeloid leukaemia (AML). Mendus is developing vididencel as a broadly applicable post-remission treatment in AML and has expanded indications to include chronic myeloid leukaemia. Earlier-stage programmes are focusing on ovarian cancer and other solid tumours.

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