Mendus has entered into a collaboration with the Australasian Leukaemia & Lymphoma Group (ALLG) to initiate the ALLG AMLM22 CADENCE trial for its lead asset, vididencel, in combination with Onureg (oral azacitidine) as a maintenance treatment in acute myeloid leukaemia (AML). This progression is encouraging for Mendus’s lead programme as there are very few maintenance treatment options currently available, and we expect the collaboration to support the programme’s development. The adaptive, randomised, multi-centre Phase II CADENCE trial will be based in Australia and employ regional test sites leveraging ALLG’s local expertise. The trial is anticipated to commence enrolment from early-2024. As a reminder, we expect that management’s 11 December presentation (at the American Society of Hematology (ASH) 2023 meeting) of updated survival data from the ongoing ADVANCE II trial (assessing vididencel as a monotherapy for AML relapse) will be the next near-term catalyst for Mendus.

Management has shared details of the ALLG AMLM22 CADENCE trial, which we view as positive for the progression of its lead asset, vididencel. The adaptive, randomised, multi-centre Phase II trial (expected n=140) will consist of two stages. The first stage will assess safety in 40 patients randomised to receive either vididencel in combination with Onureg, or Onureg alone. The second stage will assess the efficacy of the combination in an additional 100 patients. Participants in the experimental arm will receive four biweekly intradermal injections of vididencel, followed by three booster injections up to six months post initiation of treatment. All patients will be monitored across 18–24 months, and we understand that there is a possibility of expanding the study into a pivotal trial lasting 24–36 months further, provided the interim data are supportive. Mendus and ALLG intend to commence enrolment once approval is received from the central ethical committee of participating hospitals, most likely in early-2024.

As a reminder, vididencel is Mendus’s lead cell-based, off-the-shelf, non-patient-specific cancer vaccine. It has thus far been investigated in AML maintenance as a monotherapy in the ongoing Phase II ADVANCE II trial (n=20), currently in the long-term follow-up stage. Interim data reported in Q422 showed a safe, and potentially competitive profile over Onureg, which is the current standard of care. We anticipate that updated survival data (expected 11 December 2023) could corroborate the durable efficacy of vididencel. Mendus recently published additional Phase I data, supporting the combination of vididencel with Onureg. With this collective information, we believe the CADENCE combination trial could help maximise the opportunity for vididencel, which has the potential to offer a novel and effective maintenance treatment option to prolong relapse-free survival for AML patients in clinical remission.

<table>
<thead>
<tr>
<th>Year end</th>
<th>Revenue (SEKm)</th>
<th>PBT* (SEKm)</th>
<th>EPS* (SEK)</th>
<th>DPS (SEK)</th>
<th>P/E</th>
<th>Yield (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/21</td>
<td>0.0</td>
<td>(133.4)</td>
<td>(0.73)</td>
<td>0.0</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>12/22</td>
<td>3.4</td>
<td>(136.8)</td>
<td>(0.70)</td>
<td>0.0</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>12/23e</td>
<td>0.3</td>
<td>(97.2)</td>
<td>(0.18)</td>
<td>0.0</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>12/24e</td>
<td>0.0</td>
<td>(124.5)</td>
<td>(0.14)</td>
<td>0.0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

**Business description**

Mendus is a clinical-stage immuno-oncology company based in Sweden and the Netherlands. The company specialises in allogeneic dendritic cell biology and currently has two lead cell-based, off-the-shelf therapies under development for haematological and solid tumours.

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Edison profile page

*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

**Clinical update**

8 December 2023

**Price**

SEK0.69

**Market cap**

SEK596m

Net cash (SEKm) at 30 September 2023: 142.5

Shares in issue: 863.1m

Free float: 37%

Code: IMMU

Primary exchange: Nasdaq Stockholm

Secondary exchange: N/A
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