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Immix Biopharma

Clinical trial update

Marching towards US clinical trials for NXC-201

Pharma and biotech

Immix Biopharma is closer to dosing its first US patient for lead CAR-T asset NXC-201, with the appointment of the Memorial Sloan Kettering Cancer Center as the main clinical site for the company's US multi-site NEXICART-2 trial assessing NXC-201 in relapsed/refractory (r/r) amyloid light chain amyloidosis (ALA). NXC-201 targets B-cell maturation antigen (BCMA) and is differentiated by its low neurotoxicity and short cytokine release syndrome (CRS) duration to date, supporting Immix's long-term aspiration to launch the first outpatient CAR-T therapy. The NEXICART-2 study will aim to reproduce the initial results from the Phase Ib/IIa NEXICART-1 study, which reported an overall response rate (ORR) of 100% for the first 10 patients treated. Top-line data from the first 40 patients in the NEXICART-2 trial are expected in 2025, which, if positive, will likely be followed by a biologic license application, a significant milestone for the Immix. The pipeline remains engaged, with IMX-110 in Phase Ib/IIa studies for solid tumors and NXC-201 also targeting multiple myeloma (MM) and, potentially, other autoimmune indications (starting H124).

Year end	Revenue (US$m)	PBT* (US$m)	EPS* (US$)	DPS (US$)	P/E (x)	Yield (%)
12/21	0.0	(1.31)	(0.36)	0.0	N/A	N/A
12/22	0.0	(7.70)	(0.55)	0.0	N/A	N/A
12/23e	0.0	(11.96)	(0.70)	0.0	N/A	N/A
12/24e	0.0	(17.38)	(0.88)**	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments. **FY24e EPS has not been adjusted for increased share count following February 2024 equity raise.

The US trial (NEXICART-2) will be a Phase Ib open-label, single-arm, multi-site dose expansion trial, aiming to recruit c 40 patients (starting H124) with r/r ALA. The study will evaluate both the safety and efficacy of the treatment. Following the selection of the Memorial Sloan Kettering Cancer Center as the first trial site, we expect patient enrollment to commence imminently. Management anticipates that the trial will be fully enrolled within 18 months, which may lead to a possible data readout as early as late 2025. Immix received investigational new drug approval from the FDA in November 2023 and NXC-201 holds the orphan drug designation for ALA in both the US and Europe. Given the drug's favorable safety profile to date and short duration of CRS (one day vs four-to-seven days for currently approved CAR-Ts, based on available Phase I data), management asserts that the drug holds the potential to become the first outpatient CAR-T. This also builds the case for the drug to be explored in other autoimmune conditions, which Immix plans to pursue beginning in H124.

In addition to ALA (currently the primary focus for Immix), NXC-201 is also being evaluated in patients with MM (NEXICART-1). The most recently reported study data delivers an ORR of 90% for the 50 patients treated at the recommended Phase II dose of 800m cells (total study size: 100). The company's second asset, IMX-110, utilizes Immix's tissue-specific therapeutics (TSTx) and is involved in two Phase Ib/IIa clinical programs, one for the treatment of soft tissue sarcomas (STS) and the other for solid tumors. The Phase I monotherapy arm in STS is expected to conclude in 2024, with readouts expected through the year. Following the recent $15m equity raise, we estimate the company to be funded through FY25, past key data readouts for NXC-201 in ALA and potentially MM.

26 March 2024

Price	**US$3.19**
Market cap	**US$81m**
Net cash (US$m) at 30 September 2023 (including c $15m raised from the February 2024 equity issue)	34.6
Shares in issue (following February 2024 equity raise)	25.5m
Free float	52%
Code	IMMX
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance

Business description

Immix Biopharma is developing a new class of tissue-specific therapeutics targeting oncology and immune-dysregulated disease. IMX-110 is being investigated in a Phase Ib/IIa study for the treatment of soft tissue sarcoma and a Phase Ib/IIa trial in solid tumors in combination with tislelizumab. Immix's subsidiary Nexcella (94% owned) is also developing a CAR-T therapy, NXC-201, which is in the NEXICART-1 study for the treatment of AL amyloidosis and multiple myeloma.

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