EDISON

Transgene

Clinical trial data

TG4001 first efficacy data presented at ESMO

Pharma & biotech

At the 2019 European Society for Medical Oncology (ESMO) conference, Transgene presented the first efficacy data for TG4001 in combination with avelumab (Bavencio) in patients with human papillomavirus (HPV) positive cancers. In the Phase I trial, three out of nine patients treated demonstrated a durable partial response, and no dose-limiting toxicities were observed among the nine patients. All patients had metastatic disease and had previously undergone multiple lines of therapy. The tumour types selected have historically demonstrated low response rates to immune checkpoint inhibitors and we view this early data as positive for TG4001. We retain our valuation of Transgene at €287m (€3.45/share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (€)	Yield (%)
12/17	8.1	(35.0)	(0.53)	0.0	N/A	N/A
12/18	42.9	(36.8)	(0.45)	0.0	N/A	N/A
12/19e	16.9	(15.9)	(0.21)	0.0	N/A	N/A
12/20e	4.9	(27.6)	(0.33)	0.0	N/A	N/A

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

ESMO data hints at potential of ICI combinations

TG4001 is a therapeutic vaccine based on an MVA vector engineered to express HPV 16 antigens E6 and E7, in addition to IL2. It is currently being tested in a Phase II portion of a Phase Ib/II trial in patients with HPV positive cancers. The Phase Ib data was presented at ESMO and highlighted the treatment of nine patients across two dose cohorts with oropharyngeal (five), anal (two), cervical (one) or vaginal (one) cancer. Patients had refractory or metastatic cancers and had received at least two prior treatment regimens. No dose-limiting toxicities or serious adverse events (AEs) were observed. Three out of the nine patients had a partial response (PR). Phenotypic and gene findings supported the idea of a shift in tumours from a 'cold' state to an immunologically 'hot' state in some patients.

Efficacy readout of TG4010 ICI combo in Q419

Efficacy data from the Phase II TG4010 (+nivolumab +chemotherapy) trial in first-line NSCLC is due in December and will be central to determining Transgene's long-term immune oncology (IO) strategy. Transgene continues to progress its technology; notably, in H119 it announced a partnership with AZN to develop five novel armed oncolytic viruses ($10m upfront, potential future milestones and royalties). Additional early-stage development continues with the advancement of the first product candidate (TG4050) from the company's myvac platform into the clinic (initiating clinical trials in Q419).

Valuation: €287m (€3.45/share)

We retain our valuation of Transgene at €287m (€3.45/share) based on a risk-adjusted NPV model of TG4010, TG4001, TG1050 and TG6002, in addition to assumed net cash of €55.5m (boosted by the recent €48.7m capital raise and the $10m AZN upfront). For a full overview of our valuation, please see our recently published outlook note PHOCUS turns to earlier-stage assets.

4 October 2019

Price	**€1.85**
Market cap	**€154m**

Gross cash and short-term investments (€m) at 30 June 2019 (excluding gross €48.7m raise and $10m AZN upfront)	12.8
Shares in issue	83.3m
Free float	40%
Code	TNG
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	7.3	(23.1)	(37.1)
Rel (local)	8.0	(20.6)	(35.6)
52-week high/low		€3.18	€1.65

Business description

Transgene is a French drug discovery and development company focused on the treatment of cancer and infectious diseases with immunotherapies. Its products are TG4010, TG4001, TG1050, TG6002 and TG4050.

Next events

TG4010 + nivolumab + chemo efficacy data in first-line NSCLC	December 2019
Start of clinical trials with TG4050 in ovarian cancer and HPV-negative head and neck cancer	Q419
TG6002 Phase I safety data	Q419

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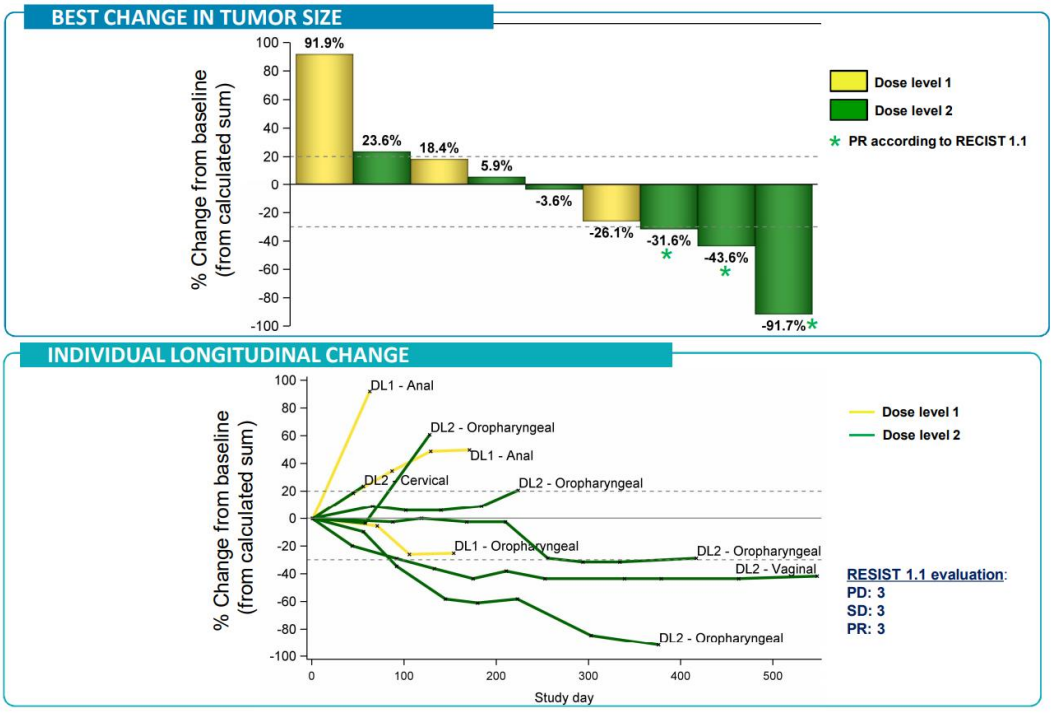
Edison profile page

TG4001 high dose demonstrates promising efficacy

In the Phase Ib trial, TG4001 was administered subcutaneously (SC) weekly for six weeks, every two weeks up to month six, and every 12 weeks thereafter. Additionally, all patients one week after the first TG4001 dose received avelumab at 10mg/kg and continued to receive it subsequently every two weeks. Three patients received a low dose (5×10^6 plaque forming units (pfu)) of TG4001 and the other six a high dose (5×10^7 pfu). Across cohorts, patients' mean age was 57.8 (range: 39–78) and they had undergone a median of two rounds of chemo (range 1–3). All patients had distant metastases. No treatment-related serious adverse events were observed, with the majority of reported AEs mild to moderate in nature (grade 1–2). Only two grade 3 AEs were observed in the study, and they both occurred in the same patient in the lower dose group.

In total across both dose cohorts, three patients had a PR, three had stable disease and three had progressive disease. As observed in Exhibit 1, the largest changes in tumour size came at the highest dose of TG4001 of 5×10^7 pfu.

Exhibit 1: Tumour responses to TG4001 and avelumab



Source: Transgene ESMO TG4001 presentation

In addition to efficacy and safety, immunological data was recorded. Of note four out of five evaluable patients had a significant increase in PD-L1 expression, while T-cell ratios shifted towards a positive immune environment (increase in CD3 and CD8 cells).

In the expansion cohort (Phase II), 40 patients with HPV-positive head and neck squamous cell carcinoma (HNSCC) are being enrolled into a single-arm cohort. Patients are receiving the highest dose tested in the Phase Ib component of the trial. The primary outcome of the Phase II part will be efficacy as measured by objective response rate (ORR). Interim results are expected in H120. We note, the trial is funded by Transgene, while Pfizer and Merck will provide avelumab. Pfizer and Merck do not have exclusive rights to the data or TG4001, both of which remain Transgene's.

Exhibit 2: Financial summary

€000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	8,144	42,919	16,887	4,936
Cost of Sales	0	0	0	0
Gross Profit	8,144	42,919	16,887	4,936
R&D expenses	(30,359)	(27,349)	(23,247)	(23,479)
G&A expenses	(5,674)	(6,991)	(7,061)	(7,132)
EBITDA	(26,352)	9,101	(12,045)	(24,291)
Operating Profit (before amort. and except).	(28,043)	7,368	(13,367)	(25,623)
Intangible Amortisation	0	0	(54)	(52)
Exceptionals (restructuring costs/discontinued operations)	0	0	0	0
Operating Profit	(28,043)	7,368	(13,421)	(25,675)
Other	0	0	0	0
Net Interest	(2,287)	(2,017)	(2,573)	(1,961)
Profit Before Tax (norm)	(35,048)	(36,786)	(15,940)	(27,584)
Profit Before Tax (IFRS)	(30,330)	5,351	(15,994)	(27,636)
Tax	0	0	0	0
Minority interest	(1,944)	2,675	0	0
Profit After Tax (norm)	(32,961)	(27,809)	(17,440)	(27,584)
Profit After Tax (IFRS)	(32,274)	8,026	(15,994)	(27,636)
Number of Shares Outstanding (m)	62.1	62.3	83.3	83.3
EPS - normalised (c)	(53.1)	(44.7)	(20.9)	(33.1)
EPS - IFRS (€)	(0.52)	0.13	(0.19)	(0.33)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	42,137	78,789	78,887	79,049
Intangible Assets	250	180	172	168
Tangible Assets	13,604	13,217	13,322	13,488
Other	28,283	65,392	65,392	65,392
Current Assets	58,736	29,754	51,915	26,605
Stocks	270	443	443	443
Debtors	2,564	784	6,477	1,893
Cash	41,405	16,900	33,368	12,642
Other	14,497	11,627	11,627	11,627
Current Liabilities	(16,866)	(19,537)	(14,688)	(12,358)
Creditors	(2,868)	(4,791)	(2,325)	(2,348)
Short term borrowings	0	0	0	0
Short term leases	(10,283)	(11,207)	(8,824)	(6,471)
Other	(3,715)	(3,539)	(3,539)	(3,539)
Long Term Liabilities	(55,918)	(52,305)	(42,177)	(41,612)
Long term borrowings	0	(10,000)	0	0
Long term leases	(51,717)	(38,369)	(38,241)	(37,676)
Other long term liabilities	(4,201)	(3,936)	(3,936)	(3,936)
Net Assets	28,089	36,701	73,937	51,684
CASH FLOW				
Operating Cash Flow	(37,657)	(30,398)	(22,296)	(21,149)
Net Interest	2,287	2,017	(2,383)	(2,353)
Tax	0	0	0	0
Capex	(462)	(1,404)	(1,473)	(1,546)
Acquisitions/disposals	0	0	0	0
Financing	13,272	0	47,000	0
Dividends	0	0	0	0
Other	8,935	5,702	5,749	4,887
Net Cash Flow	(13,625)	(24,083)	26,596	(20,162)
Opening net debt/(cash)	6,794	20,595	42,676	13,697
HP finance leases initiated	(120)	2,033	2,383	2,353
Other	(56)	(31)	0	0
Closing net debt/(cash)	20,595	42,676	13,697	31,505

Source: Transgene accounts, Edison Investment Research

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