EDISON

Genkyotex

Clinical update

GKT831 clinical development on track

Pharma & biotech

As expected, Genkyotex has initiated enrolment in the Phase II trial of GKT831 in patients with primary biliary cholangitis (PBC) in the first clinical trial site in the US. The trial plans to test GKT831 in 102 patients over 24 weeks. Interim data are expected in H118 and full data in H218. Moreover, the company has announced a Phase II investigator-sponsored trial in patients with Type 1 diabetes (T1D) and kidney disease. The trial will start in Australia in H217 and will be entirely funded and run by public bodies. These new trials demonstrate that Genkyotex is executing on its clinical development plan. Our valuation is €268m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16e	1.3	(21.7)	(27.8)	N/A	N/A	N/A
12/17e	0.0	(12.0)	(15.4)	N/A	N/A	N/A
12/18e	0.0	(13.0)	(16.7)	N/A	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments. 2016e is our pro forma estimate, based on available data.

Phase II PBC trial starts patient enrolment

Shortly after announcing that the FDA had accepted the Investigational New Drug Application, the company commenced enrolment in the US in the Phase II trial of GKT831 in PBC. The first patient will be dosed soon. The study will enrol 102 patients with PBC in over 50 centres in the US, Canada and Europe. Interim top-line data are expected in H118 and full results in H218. PBC is a rare autoimmune disease that causes liver fibrosis, cirrhosis and, eventually, liver failure. We estimate there are c 46,000 diagnosed patients in the US and EU and forecast peak sales for GKT831 of c $1.1bn. A successful clinical outcome would support development in larger liver fibrosis indications such as non-alcoholic steatohepatitis (NASH). Prevalence data suggest c 60m patients could be affected in the EU and US, and there are no approved products for NASH.

Phase II study in diabetic kidney disease planned

Furthermore, Genkyotex announced that an investigator-sponsored trial of GKT831 in T1D patients with diabetic kidney disease (DKD) will start enrolling patients in H217. The trial will be conducted at up to 15 centres in Australia led by two world renowned experts in the field, Prof Mark Cooper and Prof Jonathan Shaw. Moreover, it will be funded by the Juvenile Diabetes Research Foundation Australia and the Baker Institute; therefore, it will not represent a financial burden for Genkyotex, which will provide GKT831 under Good Manufacturing Practices (GMP). DKD is the most common cause of end-stage renal disease; it is estimated that in 2015 there were 20.2m cases of DKD in the US, Japan and EU-5.

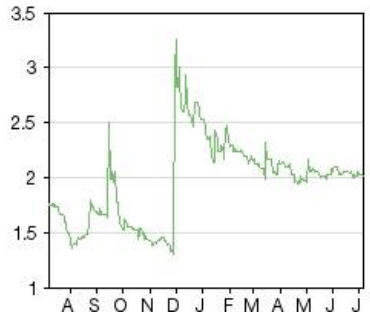
Valuation: maintain risk-adjusted NPV of €268m

Our valuation of Genkyotex is €268m based on an rNPV and includes the PBC indication, the deal with the Serum Institute of India (SIIL) and net cash of €20.8m at 31 March 2017. As described in our initiation report, should the company pursue NASH, we estimate this could add €30m to €90m. We look to add the DKD indication to our valuation once the clinical trial has commenced.

6 July 2017

Price	**€2.01**
Market cap	**€157m**
Net cash (€m) at 31 March 2017	20.8
Shares in issue	77.9m
Free float	50.6%
Code	GKTX
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(3.8)	(2.4)	16.2
Rel (local)	(1.3)	(4.5)	(7.4)
52-week high/low		€3.2	€1.3

Business description

Genkyotex is a biopharma company focused on NOX science in fibrosis and other indications. It has two main products: GKT831, in Phase II for PBC and GKT771, in preclinical stage. Additionally Genkyotex has a partnership with the Serum Institute of India.

Next events

GKT831 Phase II DKD	H217
GKT771 Phase I ready	End 2017
GKT831 Phase II interim data	H118
GKT831 Phase II full data	H218

Analysts

Juan Pedro Serrate +44 (0)20 3681 2534

Jonas Peciulis +44 (0)20 3077 5728

healthcare@edisongroup.com

Edison profile page

Focus on GKT831 clinical development

Phase II in PBC starts enrolment

Genkyotex has initiated patient enrolment in the US in the Phase II trial of GKT831 in PBC. The study will enrol 102 patients with PBC in over 50 investigational centres in the US, Canada and Europe. The first patient will be dosed soon. Patients will be administered placebo or two doses of GKT831, 400mg once a day or 400mg twice daily, during 24 weeks. The primary end point will be the change in serum gamma-glutamyl transferase (GGT), a marker of liver injury. Secondary end points will explore other markers of cholestasis and liver injury, inflammation and liver fibrosis. The company anticipates interim data in H118 and full data in H218.

We estimate the number of PBC patients that could be eligible for treatment with GKT831 at c 46,000 and project peak sales of $1.1bn in this indication, with launch in 2023. We believe that the PBC trial, if successful, could also support development of GKT831 in the larger liver fibrosis opportunity, in particular NASH, which could target c 60 million people in the EU and US. Patent protection for GKT831 in the US, Europe and Japan extends until 2029.

Phase II in diabetic nephropathy: higher dose for longer time

The company has announced an investigator-sponsored Phase II study in patients with T1D and DKD (also known as diabetic nephropathy). The study is planned to start in H217 and will be conducted at up to 15 centres in Australia led by Prof Mark Cooper, head of the department of diabetes at Monash University and Prof Jonathan Shaw, deputy director at the Baker Heart and Diabetes Institute in Melbourne. Importantly, the study will be entirely funded by the Juvenile Diabetes Research Foundation and the Baker Institute. Genkyotex will provide GMP-produced GKT831. The primary end point of the study will be the change from baseline in urine albumin-to-creatinine ratio (UACR) after 48 weeks. A key secondary end point of the study will be changes in estimated glomerular filtration rate, which measure the effect of GKT831 on renal function. Patients will receive 200mg of oral GKT831 or placebo twice a day for 48 weeks.

A previous Phase II study run by Genkyotex of GKT831 in diabetic nephropathy did not meet the primary efficacy end point of reduction of proteinuria at 12 weeks, but results were statistically significant ($p<0.05$) in the pre-defined secondary end points of changes in liver enzymes such as GGT and markers of inflammation. We note that the new trial is testing a higher dose (200mg twice/day vs the previous 100mg/day for six weeks followed by 200mg/day for six weeks) during a longer duration of treatment (48 weeks vs 12 weeks previously). This provides rationale for an improved effect in the new trial.

DKD is one of the long-term complications of diabetes that leads to damage of the kidneys' filtering system. It is characterised by persistent albuminuria, progressive decline in the glomerular filtration rate and elevated arterial blood pressure. It is the most common cause of end-stage renal disease. According to Datamonitor Healthcare in 2015, there were 20.2m prevalent cases of DKD in the adult diabetic population in the US, EU-5, and Japan.

GKT831 has proven safe in four Phase I studies in a total of 117 healthy subjects in a single ascending dose, in multiple ascending doses as well as the food effect and drug interaction. In these studies, GKT831 showed no safety issues and there were no dose-limiting toxicities. Moreover, adverse events in the previous DKD Phase II trial were significantly lower in the GKT831 arm vs placebo.

Financials and valuation

We estimate Genkyotex had c €20.8m net cash at 31 March 2017, which should be sufficient to fund clinical development of GKT831 and GKT771 over the next two years, according to our forecasts. The company expects to receive an additional €3m in tax credits. Currently, our forecasts remain unchanged. On 27 July 2017, the company will provide a business and cash update for Q217. H117 financial results will be released on 21 September.

Taking conservative market share and pricing assumptions and using our standard 12.5% discount rate produces a risk-adjusted NPV of €268m or €3.5 per share, based on 77.85m shares. Our valuation of Genkyotex is based on GKT831 in the PBC indication and the SIIL deal, leaving all other product development opportunities and additional indications as upside. We do not typically include any contribution for indications until clinical development commences; therefore, our GKT831 estimates do not include any potential in DKD or NASH. However, a sensitivity analysis suggests NASH could add between c €30m and €90m, excluding milestones or upfront payments, depending on the commercial strategy.

Exhibit 1: Financial summary

€ 000	2016e	2017e	2018e
Year End December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	1,304	0	0
Cost of Sales	0	0	0
Gross Profit	1,304	0	0
R&D expenses	(12,687)	(7,000)	(10,000)
G&A expenses	(14,324)	(5,500)	(5,000)
EBITDA	(21,698)	(12,000)	(13,000)
Operating Profit (before amort. and except.)	(21,698)	(12,000)	(13,000)
Intangible Amortisation	0	0	0
Exceptionals	0	0	0
Other	0	0	0
Operating Profit	(21,698)	(12,000)	(13,000)
Net Interest	23	13	2
Profit Before Tax (norm)	(21,675)	(11,987)	(12,998)
Profit Before Tax (FRS 3)	(21,675)	(11,987)	(12,998)
Tax	0	0	0
Profit After Tax (norm)	(21,675)	(11,987)	(12,996)
Profit After Tax (FRS 3)	(21,675)	(11,987)	(12,997)
Average Number of Shares Outstanding (m)	77.9	77.9	77.9
EPS - normalised (c)	(27.8)	(15.4)	(16.7)
EPS - (IFRS) (c)	(27.8)	(15.4)	(16.7)
Dividend per share (p)	0.0	0.0	0.0
Gross Margin (%)	NA	NA	NA
EBITDA Margin (%)	NA	NA	NA
Operating Margin (before GW and except.) (%)	NA	NA	NA
BALANCE SHEET			
Fixed Assets	11,995	11,995	11,995
Intangible Assets	11,829	11,829	11,829
Tangible Assets	167	167	167
Fixed term investments	155	155	155
Other	0	0	0
Current Assets	30,383	18,397	5,398
Stocks	0	0	0
Debtors	3,512	3,512	3,512
Cash	26,871	14,884	1,886
Other	0	0	0
Current Liabilities	(4,901)	(4,901)	(4,901)
Creditors	(4,303)	(4,303)	(4,303)
Short term borrowings	(598)	(598)	(598)
Long Term Liabilities	(1,384)	(1,384)	(1,384)
Long term borrowings	(336)	(336)	(336)
Other long term liabilities	(1,049)	(1,049)	(1,049)
Net Assets	36,093	24,106	11,108
CASH FLOW			
Operating Cash Flow	(22,693)	(12,000)	(13,001)
Net Interest	23	13	2
Tax	0	0	0
Capex	(13)	0	0
Acquisitions/disposals	0	0	0
Equity Financing	13,776	0	0
Other items	(345)	(600)	(601)
Net Cash Flow	(9,252)	(12,587)	(13,600)
Opening net debt/(cash)	N/A	(25,938)	(13,951)
HP finance leases initiated	0	0	0
Other	0	600	600
Closing net debt/(cash)	(25,938)	(13,951)	(950)

Source: Edison Investment Research, Genticel and Genkyotex accounts. Note: 2016e relates to our pro forma estimates for the combined entity as described above.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia