EDISON

Sunesis Pharmaceuticals

Clinical update

400mg data similar to previous cohort

Pharma & biotech

On 18 March, Sunesis released the first assessments of the 400mg cohort in its ongoing dosing study of vecabrutinib for B-cell malignancies. Two (of three) patients in this cohort showed stable disease (SD), with one showing a 48% response. These results are largely similar to those seen with the 300mg cohort (one near-responder SD, two stabilized SD, and one progressor). We would like to have seen more definitive activity in this cohort, but there is still the possibility that Sunesis will cross the line of generating partial responses (PRs) in the upcoming 500mg cohort.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/18	0.2	(26.6)	(0.75)	0.0	N/A	N/A
12/19	2.1	(23.3)	(0.27)	0.0	N/A	N/A
12/20e	0.0	(28.5)	(0.24)	0.0	N/A	N/A
12/21e	0.0	(35.7)	(0.29)	0.0	N/A	N/A

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

No responders yet

The results from the 400mg cohort were disappointing, in our view, because they do not appear to signal any improvement over the 300mg cohort. We were encouraged by the 300mg data because one patient was very close to achieving a PR, so it appeared that the dose was on the cusp of activity. The 400mg dose did not improve on this profile, and moreover, that near-responder from the 300mg cohort remains on drug and has not yet quite reached PR status.

Is poor PK the explanation?

The company also presented pharmacokinetic (PK) data on the 400mg cohort, which may provide insight as to why it is not well differentiated from the 300mg dose. Serum levels of the drug were not well differentiated from 300mg and were in fact trending lower than 300mg at six hours post administration. Moreover, steady-state concentration of the drug at day 8 were lower for the 400mg cohort (vs 300mg), but this was not the case for the 500mg cohort, which is encouraging as it suggests that the drug has not reached saturating concentrations at these doses.

More cohorts might be needed

The last cohort in the study protocol is the 500mg cohort. The cohort is currently over-enrolling, and Sunesis has stated that it intends to release the initial response data (similar to those presented here) for the cohort in Q220. We believe the company would face no hurdles in adding additional higher dosing cohorts, which it may consider as we have still not seen definitive responses.

Valuation: Lowered to $188.7m or $1.56/diluted share

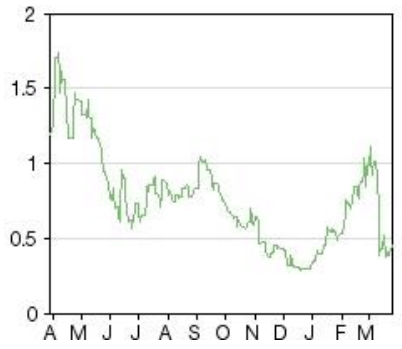
We have lowered our valuation to $188.7m or $1.56 per diluted share from $238.7m or $1.94 per diluted share, as we have reduced the probability of success for vecabrutinib to 15% from 20%. We expect to further update our assumptions with the release of data from the 500mg cohort.

26 March 2020

Price	**US$0.45**
Market cap	**US$50m**

Net cash ($m) at 31 December 2019	29.1
Shares in issue	111.4m
Free float	60%
Code	SNSS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(56.3)	42.1	(64.8)
Rel (local)	(44.8)	85.0	(60.3)

52-week high/low	US$1.74	US$0.28

Business description

Sunesis Pharmaceuticals is a pharmaceutical company focused on oncology. Its lead asset is vecabrutinib, a Bruton's tyrosine kinase inhibitor for chronic lymphocytic leukemia for Imbruvica-refractory patients. The program is in a dose-escalation Phase Ib/II. It has also developed pan-Raf inhibitor TAK-580, and the preclinical PDK1 inhibitor SNS-510.

Next events

500mg cohort readout	Q220

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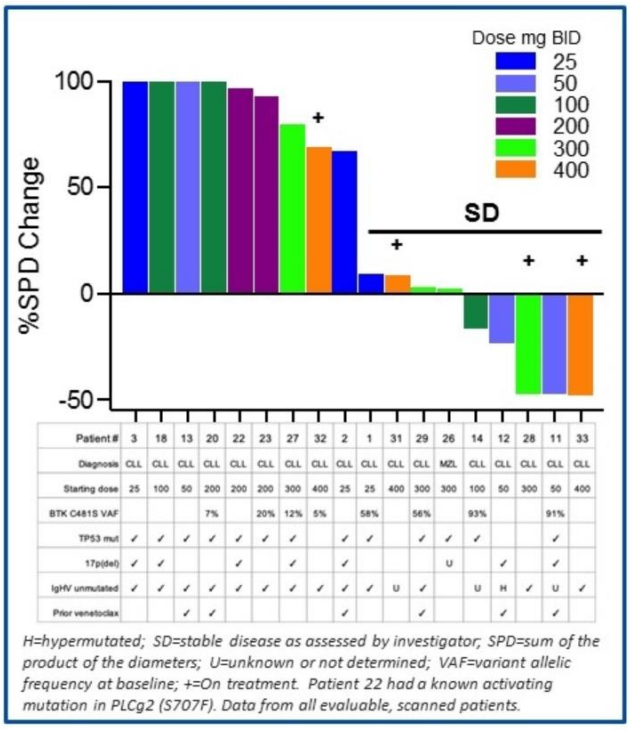
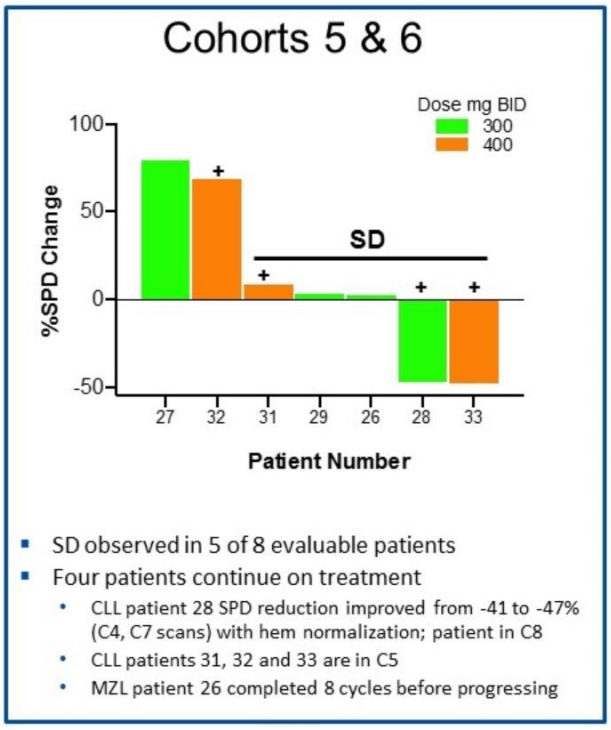
Edison profile page

400mg data similar to previous data

The data presented by Sunesis on the 400mg (n=3 patients) cohort fell short of providing definitive evidence of activity. This is discouraging, in our view, because the data on the 300mg (also n=3 patients) cohort showed one patient very close to a PR. This 300mg cohort patient had a response of 41% at the first report (ASH in December 2019) improving to a 47% response, which is what we would have hoped to see with an active drug. However, we would also like to have seen an increase in response rates for the higher 400mg dose. There was one near-responder (48%) in this cohort as well, which makes the data look roughly similar to 300mg. The drug could still potentially be on the cusp of clinical activity, but the question then becomes how high a dose will be needed. Neither one of these near-responders from either cohort was a C481S mutant, so as yet we cannot make any claims regarding the activity of this drug in this resistant population.

Exhibit 1: Vecabrutinib response data

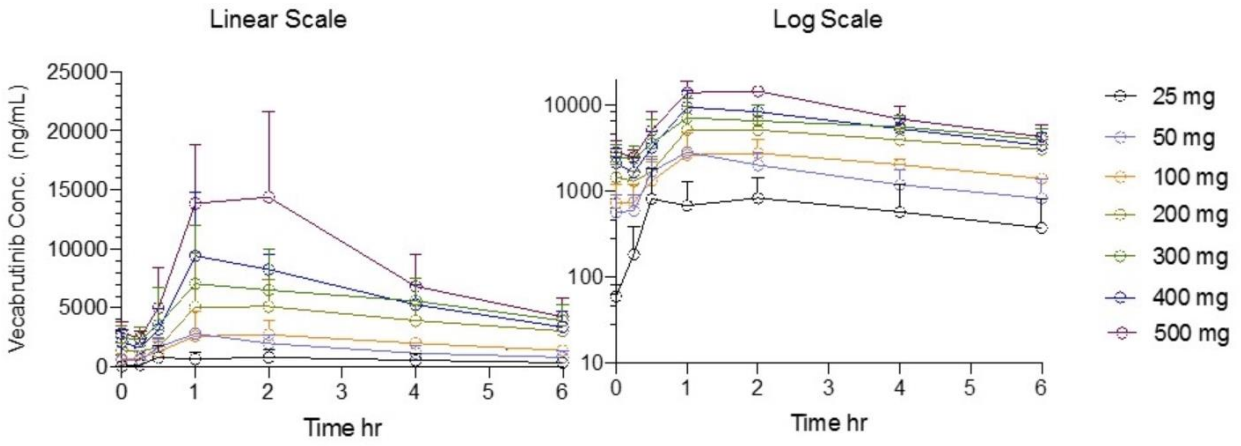




Source: Sunesis Pharmaceuticals

One explanation for why this cohort was poorly differentiated is available in the pharmacokinetic data presented by the company. At longer time points, the 400mg dose showed similar or lower serum concentrations than 300mg. 400mg showed on average similar serum concentrations after several hours, and the steady-state concentration after eight days of dosing BID (C1D8 C_{min}) was lower for the 400mg cohort compared to 300mg: 1,530ng/mL vs 1,950ng/mL, respectively. The reasons behind this are purely speculative, but it could have been caused by a single patient who, for whatever reason, eliminated the drug faster than expected, and this could have an exaggerated effect on the overall concentration data given that there were only three patients in each of these cohorts. It is worth noting that C_{max} and the area under the curve (AUC) were higher for the 400mg data, which suggests normal absorption. It is also important to note that this trend was not continued with the 500mg cohort, which was also presented (C1D8 C_{min} 2,555ng/mL, or higher than all lower dosed cohorts). This is important because it suggests that the 400mg dose was not saturating.

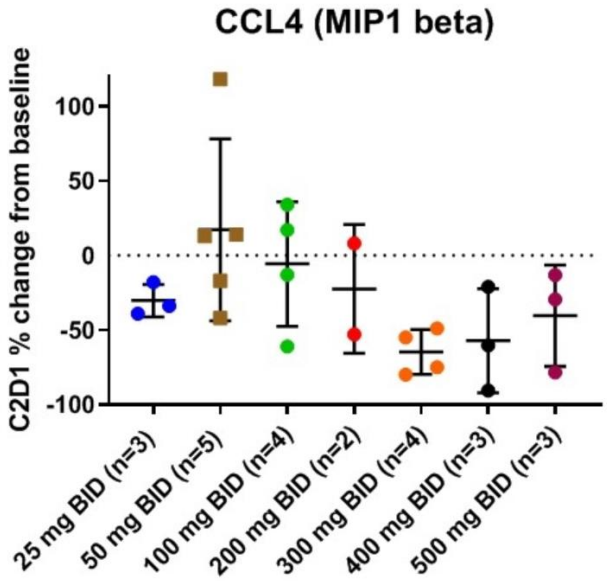
Exhibit 2: Pharmacokinetics of vecabrutinib by dose



Source: Sunesis Pharmaceuticals

The company also presented cytokine data as a biomarker for activity, which shows a trend in the direction of increasing activity with dose, but the trend does not appear to be statistically significant.

Exhibit 3: Cytokine CCL4 expression



Source: Sunesis Pharmaceuticals

Finally, a small hidden positive in the data presented by the company is that among the treatment-emergent adverse events (TEAEs) presented in the safety profile, Sunesis reported lymphocytosis for the first time in two patients. Lymphocytosis is seen in most chronic lymphocytic leukemia (CLL) responders to BTK inhibitors, and although considered an adverse event, is often indicative of activity in these patients. It is too early to make much of this result, but we should be looking for this value to increase with higher doses. It is also worth noting that lymphocytosis is not always present in responders (although it is seen in most ibrutinib CLL responders), and that it can appear as part of the normal progression of the disease in the absence of treatment, so it is not a perfect indicator.

Valuation

We have lowered our valuation to $188.7m or $1.56 per diluted share from $238.7m or $1.94 per diluted share. We have lowered the probability of success for vecabrutinib to 15% from 20% on account of the most recent data. Otherwise, our assumptions remain unchanged. We expect to update our models with the release of data from the 500mg cohort in Q220.

Exhibit 4: Valuation of Sunesis

Development program	Clinical stage	Expected commercialization	Probability of success	Launch year	Launch pricing ($)	Peak sales ($m)	Patent/ exclusivity protection	Royalty/ margin	rNPV ($m)
TAK-580	Phase I/II	Licensed to Takeda	5%	2025	500,000	600	2032	10%	$6
Vecabrutinib	Phase Ib/II	Proprietary	15%	2024	152,000	666	2034	55%	$149
SNS-510	IND ready	Proprietary	10%	2025	130,000	344	2031	51%	$26
Unallocated costs (discovery programs, administrative costs, etc)									($22)
Total									$160
Net cash and equivalents (YE19) ($m)									$29.1
Total firm value ($m)									$188.7
Total basic shares (m)									111.4
Value per basic share ($)									$1.69
Convertible pref stock (m)									19.7
Total diluted shares									131.1
Value per diluted share									$1.56

Source: Sunesis reports, Edison Investment Research

Financials

Our forecasts remain unchanged at this time. Please refer to our update report published on 12 March 2020 for further details.

Exhibit 5: Financial summary

$'000s	2018	2019	2020e	2021e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	237	2,073	0	0
Cost of Sales	0	0	0	0
Gross Profit	237	2,073	0	0
Research and development	(14,615)	(15,412)	(17,480)	(20,878)
Selling, general & administrative	(11,332)	(9,949)	(10,505)	(11,820)
EBITDA	(25,719)	(23,288)	(27,985)	(32,697)
Operating Profit (before GW and except.)	(25,710)	(23,288)	(27,985)	(32,697)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(25,710)	(23,288)	(27,985)	(32,697)
Net Interest	(905)	(42)	(467)	(3,029)
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(26,615)	(23,330)	(28,452)	(35,726)
Profit Before Tax (IFRS)	(26,615)	(23,330)	(28,452)	(35,726)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(26,615)	(23,330)	(28,452)	(35,726)
Profit After Tax (IFRS)	(26,615)	(23,330)	(28,452)	(35,726)
Average Number of Shares Outstanding (m)	35.6	87.1	117.0	122.2
EPS - normalised ($)	(0.75)	(0.27)	(0.24)	(0.29)
EPS - IFRS ($)	(0.75)	(0.27)	(0.24)	(0.29)
Dividend per share ($)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	124	918	10	19
Intangible Assets	0	0	0	0
Tangible Assets	11	3	10	19
Other	113	915	0	0
Current Assets	15,200	36,322	12,914	10,894
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	13,696	34,625	11,217	9,197
Other	1,504	1,697	1,697	1,697
Current Liabilities	(11,323)	(9,416)	(5,549)	(6,409)
Creditors	(3,927)	(3,951)	(5,549)	(6,409)
Short term borrowings	(7,396)	(5,465)	0	0
Long Term Liabilities	(8)	(281)	(5,746)	(35,746)
Long term borrowings	0	0	(5,465)	(35,465)
Other long term liabilities	(8)	(281)	(281)	(281)
Net Assets	3,993	27,543	1,629	(31,242)
CASH FLOW				
Operating Cash Flow	(24,404)	(22,185)	(23,401)	(32,011)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	0	0	(7)	(9)
Acquisitions/disposals	0	0	0	0
Financing	6,343	45,082	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(18,061)	22,897	(23,408)	(32,020)
Opening net debt/(cash)	(24,546)	(6,300)	(29,160)	(5,752)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	(185)	(37)	0	0
Closing net debt/(cash)	(6,300)	(29,160)	(5,752)	26,268

Source: Sunesis Pharmaceuticals reports, Edison Investment Research

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