EDISON

SUDA Pharmaceuticals

Development update

A potentially transformational acquisition

Pharma & biotech

SUDA recently announced that it will be licensing an invariant natural killer T (iNKT) cell therapy platform from Imperial College London that can be used in conjunction with chimeric antigen receptors (CARs) to target blood cancers. Specific financial terms are undisclosed but include an upfront fee, annual maintenance fees, milestones and a single-digit royalty. There are a number of potential benefits of CAR-iNKT, including the prospect of being an allogeneic 'off-the-shelf' therapy, significantly simplifying the manufacture of the therapy and its delivery to patients. The therapy is expected to enter the clinic in 12–24 months.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/19	1.2	(2.4)	(0.02)	0.0	N/A	N/A
06/20	0.5	(4.7)	(0.03)	0.0	N/A	N/A
06/21e	0.5	(4.3)	(0.01)	0.0	N/A	N/A
06/22e	1.0	(6.6)	(0.01)	0.0	N/A	N/A

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

Potential benefits of CAR-iNKT

SUDA's iNKT programme may have benefits over traditional CAR-T therapies, such as Yescarta, based on in vitro and in vivo testing. First, it can be allogeneic as acute graft versus host disease (GVHD) appears unlikely. CD19 targeting CAR-iNKT cells also appear effective against lymphoma in the brain, unlike CD19-targeting CAR-T. Finally, the dual targeting of CD1d and CD19 has been shown to improve the anti-tumour effect compared to CD19-targeting CAR-T alone.

NHL to be the initial indication

SUDA expects the first Phase I trial to be for the treatment of non-Hodgkin lymphoma (NHL). This is the indication for which Gilead's CD19 targeting CAR-T, Yescarta (axicabtagene ciloleucel), is approved (Yescarta is approved for large B-cell lymphoma, which is a type of NHL). Yescarta reported US$563m in sales in 2020 for this indication (expectations are for over US$1bn in 2026).

The NHL market is large, with room for a new entrant

According to Evaluate Pharma, sales for NHL treatments totalled US$11.8bn in sales in 2020. While the CAR-T Yescarta has promising data with a 51% complete remission rate, the median duration of response is 9.2 months for all patients and 2.1 months if only a partial response is observed. Any improvement in the duration of response would be expected to help patients survive longer.

Valuation: A$26m or A$0.05 per basic share

We now value SUDA at A$26m or A$0.05 per basic share (A$0.05 per diluted share), from A$23m or A$0.06 per basic share (A$0.05 per diluted share). We are not yet including the CAR-iNKT programme in our valuation but intend to do so when it enters the clinic. Given the sales of similar products as well as recent acquisition activity in this space, the resulting change to our valuation could be meaningful. Our total valuation increase at this time is due to higher net cash following the A$3.7m June offering, while the value per share declined due to more shares outstanding.

23 June 2021

Price	**A$0.05**
Market cap	**A$25m**
	A$1.30/US$
Net cash (A$m) at 31 March 2021 + offering	7.9
Shares in issue (post offering)	480.8m
Free float	83.8%
Code	SUD
Primary exchange	ASX
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	48.6	18.2	46.1
Rel (local)	42.2	8.9	16.6
52-week high/low	A$0.06		A$0.03

Business description

SUDA Pharmaceuticals has historically been a drug delivery company focusing on developing oro-mucosal spray versions of established medicines. It has the rights to ZolpiMist, the spray version of Ambien for insomnia, outside of North America. SUDA is also working on formulating an oro-mucosal version of anagrelide for the treatment of solid tumours, sumatriptan for migraine, cannabinoids for various conditions, as well as other projects. SUDA recently acquired a CAR-iNKT programme for haematological malignancies.

Next events

Progress on iNKT development	2021/22

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Edison profile page

Using iNKT cell therapy to treat blood cancers

SUDA recently announced it will be licensing an iNKT cell therapy platform from Imperial College London. Specific financial terms are undisclosed but include an upfront fee, annual maintenance fees, milestones and a single-digit royalty. The company has stated there should be no immediate material impact from signing the agreement.

Preclinical studies have shown that by introducing a CAR that targets CD19 into the iNKT cells, the iNKT cells can target both CD19 and CD1d. In vitro and in vivo testing has shown targeting CD19 and CD1d is more effective against tumours compared to targeting CD19 alone (as Gilead's Yescarta does) in CD1d-expressing lymphomas. Animal testing also suggests a much greater ability to target lymphomas that have crossed into the brain. In all but one animal receiving a CD19-targeting CAR-T and all untreated animals, brain lymphoma was above the level of detection. However, brain lymphoma was eliminated in 13 out of 18 CAR-iNKT-treated animals. Additionally, a second remission of relapsing disease was seen in mice that initially went into remission then subsequently relapsed, indicating the therapy may have a prolonged effect. Due to these benefits, 90% of the animals treated with CAR-iNKT survived compared to 60% of those treated with CAR-T. Importantly, no acute GVHD was seen in any of the mice tested and weight increased across all groups (>10% weight loss is a sign of acute GVHD).[1] Although much of the preclinical testing is complete, according to the company, perfecting the manufacturing process likely means human clinical testing will only start in 12–24 months. We will have a better idea of the clinical path for the programme when it gets closer to the clinic.

A further advantage to the CAR-iNKT cells is that the competitive landscape is much smaller than for traditional CAR-T, which has hundreds of active programmes. There are only two competitors in the clinic; one is a company, the other a Chinese academic trial. The company is Kuur Therapeutics, which has three CAR-iNKT programmes either in or close to the clinic. Kuur's most advanced programme is an autologous CAR-iNKT targeting GD2 in neuroblastoma in Phase I (it is completing the fourth dose level, 11 patients dosed so far). The fact that it is autologous (thus having a different manufacturing and convenience profile) and going after a solid tumour (rather than haematological cancers) suggests it is not a direct competitor with the SUDA programme. Kuur also has an allogeneic CD19 targeting CAR-iNKT, dubbed KUR-502, in a Phase I trial in haematological malignancies. Dose level 1 is expected to complete shortly. Kuur also has a GPC3 targeting CAR-iNKT dubbed KUR-503 in preclinical testing for hepatocellular carcinoma (liver cancer) with IND submission expected in H122. Importantly, Kuur is being acquired by Athenex for US$70m upfront and an additional US$115m in milestones. We believe this could be indicative of where SUDA's programme may be valued once it is in the clinic.

Another company developing CAR-iNKT cells is AgenTus, a subsidiary of Agenus Therapeutics. Its lead programme, Agent-797, is in Phase I for haematological malignancies and COVID-19-related pneumonia. However, it is not a CAR construct but rather the allogeneic iNKT cells themselves. The company's CAR-iNKT programme is preclinical with precise indications and targeting undisclosed.

SUDA's initial focus will be on CD19-expressing cancers, specifically NHL, which has an incidence of 81,560 patients per year according to the National Cancer Institute. Approximately 30% of NHL tumours express CD1d,[2] while the vast majority B cell malignancies express CD19 (80% of acute

1 Rotolo et al., Enhanced Anti-lymphoma Activity of CAR19-iNKT Cells Underpinned by Dual CD19 and CD1d Targeting. *Cancer Cell* (2018) 34, 596–610

2 Xu et al., Expression of CD1d and presence of invariant NKT cells in classical Hodgkin lymphoma. *American Journal of Hematology.* July 2010 85(7):539-41

lymphoblastic leukaemias, 88% of B cell lymphomas and 100% of B cell leukaemias).[3] Even if only 30% of the market can be addressed, it still leaves a rather large opportunity. According to Evaluate Pharma, sales for NHL treatments totalled US$11.8bn in 2020 (see Exhibit 1 for the top 10 selling drugs for NHL) and is expected to grow to US$25.0bn in 2026.

Exhibit 1: Top 10 drugs to treat NHL by sales in the indication in 2020

Product	Company	Generic name	Mechanism of action	First launch (WW)	2020 sales (US$m)
Rituxan	Roche	Rituximab	B-lymphocyte antigen CD20 antibody	1997	3,549
Revlimid	Bristol-Myers Squibb	Lenalidomide	Interleukin-6 antagonist; Natural killer cell stimulant; Natural killer T-cell stimulant; Tumour necrosis factor alpha inhibitor; Vascular endothelial growth factor inhibitor	2006	3,235
Imbruvica	AbbVie	Ibrutinib	Bruton's tyrosine kinase inhibitor	2013	956
Yescarta	Gilead Sciences	Axicabtagene ciloleucel	B-lymphocyte antigen CD19 CAR-T cell therapy	2017	563
Imbruvica	Johnson & Johnson	Ibrutinib	Bruton's tyrosine kinase inhibitor	2013	515
Gazyva	Roche	Obinutuzumab	B-lymphocyte antigen CD20 antibody	2013	499
Calquence	AstraZeneca	Acalabrutinib	Bruton's tyrosine kinase inhibitor	2017	331
Bendeka	Teva Pharmaceutical Industries	Bendamustine hydrochloride	DNA alkylation; Guanine alkylation; Guanine at N7 and adenine at N3 alkylation; Guanine at N7 and O6 alkylation; Guanine at N7 and O6 methylation	2016	270
Adcetris	Takeda	Brentuximab vedotin	Tubulin polymerisation inhibitor; Tumour necrosis factor receptor superfamily member 8 antibody	2011	225
Polivy	Roche	Polatuzumab vedotin	B-cell antigen receptor complex-associated protein beta chain antibody; Tubulin polymerisation inhibitor	2019	180
Adcetris	Seagen	Brentuximab vedotin	Tubulin polymerisation inhibitor; Tumour necrosis factor receptor superfamily member 8 antibody	2011	172

Source: Evaluate Pharma. Note: WW = worldwide.

Although the CAR-T Yescarta had promising data with a 51% complete remission rate, the median duration of response is 9.2 months for all patients and 2.1 months if only a partial response is observed. Any improvement in the duration of response would be expected to help patients survive longer and prove to be a competitive advantage for a new entrant like SUDA. Additionally, as the process for the preparation of a Yescarta dose can take two to three weeks, time is lost waiting for the treatment to be ready. Hence the 'off-the-shelf' nature of the autologous CAR-iNKT programme would have a significant time/convenience advantage.

Importantly, pricing for Yescarta is US$373,000 per treatment and it achieved US$563m in sales in 2020, with expectations of exceeding US$1bn in sales by 2026, according to EvaluatePharma. Also, Yescarta was approved on the basis of a single-arm, open-label trial in 101 patients, which could indicate the size of the trial that SUDA would need to run to gain approval for the CAR-iNKT programme. Note that Gilead had acquired Yescarta through its purchase of Kite Pharmaceuticals for US$11.9bn in 2017.

Valuation

We have slightly adjusted our valuation for SUDA to A$26m or A$0.05 per basic share (A$0.05 per diluted share) from A$23m or A$0.06 per basic share (A$0.05 per diluted share). The increase in the total value is due to higher net cash following the offering in June. The value per share has declined due to more shares outstanding. We are not yet including the iNKT cell therapy platform in our valuation given its preclinical stage (standard Edison methodology), but intend to do so when it

3 Poe et al., A c-Myc and Surface CD19 Signaling Amplification Loop Promotes B Cell Lymphoma Development and Progression in Mice. *Journal of Immunology* 2012 September 1; 189(5): 2318–2325

enters the clinic. Given the sales of Yescarta and the acquisition price for Kuur Therapeutics, the change in our valuation for SUDA could be quite meaningful.

Exhibit 2: SUDA valuation

Product	Main indication	Status	Probability of successful commercialisation	Approval year	Peak sales (A$m)	Economics	rNPV (A$m)
ZolpiMist	Insomnia	Registered (Australia) , pre-registration (other regions)	70%	2020	17.3	Double-digit royalties	17.9
Total							17.9
Net cash (as of 31 March 2021 + offering)							7.9
Total firm value (A$m)							25.8
Total basic shares – post offering (m)							480.8
Value per basic share (A$)							0.05
Options (m)							68.1
Total number of shares (m)							548.9
Diluted value per share (A$)							0.05

Source: Edison Investment Research

Financials

The company reported A$4.3m in cash at 31 March 2021 with operating cash burn of A$0.9m during the latest quarter (A$2.7m through the first nine months of the fiscal year). As mentioned, SUDA is raising an additional A$3.7m (before costs) through the issuance of 96.2m shares at A$0.038 per share to help fund development of the iNKT cell therapy platform. The raise announced on 22 June was heavily oversubscribed and is being carried out at a slight premium to the previous trading day's (17 June) closing price of A$0.036 per share. The new shares will be issued on 29 June 2021. Due to the acquisition of the CAR-iNKT programme, we have increased our expected R&D spending for FY22 by approximately A$2m. We forecast an additional A$12.5m in financing through FY23.

Exhibit 3: Financial summary

A$'000s	2019	2020	2021e	2022e
Year end 30 June	AIFRS	AIFRS	AIFRS	AIFRS
PROFIT & LOSS				
Revenue	1,219	533	485	1,041
Cost of Sales	0	0	0	0
Gross Profit	1,219	533	485	1,041
Sales, General and Administrative Expenses	(3,129)	(4,788)	(3,825)	(3,978)
Research and Development Expense	0	0	(500)	(3,000)
EBITDA	(1,878)	(4,112)	(3,618)	(5,937)
Operating Profit (before amort. and except.)	(2,349)	(4,684)	(4,248)	(6,568)
Intangible Amortisation	0	0	0	0
Other	32	143	222	0
Exceptionals	(6,277)	(5,938)	0	0
Operating Profit	(8,626)	(10,622)	(4,248)	(6,568)
Net Interest	(94)	22	(43)	(45)
Other	0	0	0	0
Profit Before Tax (norm)	(2,443)	(4,662)	(4,291)	(6,612)
Profit Before Tax (FRS 3)	(8,720)	(10,600)	(4,291)	(6,612)
Tax	925	656	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(1,518)	(4,006)	(4,291)	(6,612)
Profit After Tax (FRS 3)	(7,795)	(9,944)	(4,291)	(6,612)
Average Number of Shares Outstanding (m)	98.6	142.3	331.2	481.0
EPS - normalised (c)	(1.54)	(2.81)	(1.29)	(1.37)
EPS - Reported ($)	(0.08)	(0.07)	(0.01)	(0.01)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	10,658	4,673	4,893	5,243
Intangible Assets	10,291	4,251	4,385	4,613
Tangible Assets	367	365	421	543
Other	0	57	87	87
Current Assets	5,595	2,035	7,017	8,051
Stocks	45	22	22	22
Debtors	1,121	869	62	104
Cash	4,314	977	6,727	7,719
Other	115	166	206	206
Current Liabilities	(1,349)	(2,022)	(1,513)	(1,513)
Creditors	(1,312)	(2,010)	(1,513)	(1,513)
Short term borrowings	(36)	(12)	0	0
Long Term Liabilities	(927)	(550)	(46)	(7,550)
Long term borrowings	(17)	(4)	(4)	(7,504)
Other long term liabilities	(910)	(545)	(42)	(47)
Net Assets	13,978	4,135	10,351	4,231
CASH FLOW				
Operating Cash Flow	(2,495)	(2,884)	(3,819)	(6,019)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(1,384)	(388)	(484)	(489)
Acquisitions/disposals	0	0	0	0
Financing	8,095	0	10,071	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	4,215	(3,272)	5,768	(6,508)
Opening net debt/(cash)	1,951	(4,260)	(961)	(6,723)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	19	0
Other	1996	-27	-26	0
Closing net debt/(cash)	(4,260)	(961)	(6,723)	(215)

Source: Company reports, Edison Investment Research

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