EDISON

SymBio Pharmaceuticals

Business update

Treakisym has positive DLBCL results

Pharma & biotech

On 5 November 2019, SymBio announced it obtained positive results in its pivotal Phase III clinical trial of Treakisym (bendamustine) in patients with relapsed and refractory diffuse large B-cell lymphoma (DLBCL). The study met its primary endpoint of improvement in response rates, although the company did not give detailed data in its announcement. SymBio guided toward submission of the data to the PMDA in H120 and we expect initial sales in 2021, driving sustained profitability.

Year end	Revenue (¥m)	PBT* (¥m)	EPS* (¥)	DPS (¥)	P/E (x)	Yield (%)
12/17	3,444	(3,977)	(319)	0.0	N/A	N/A
12/18	3,836	(2,749)	(166)	0.0	N/A	N/A
12/19e	3,009	(4,182)	(186)	0.0	N/A	N/A
12/20e	4,043	(5,154)	(212)	0.0	N/A	N/A

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

Brincidofovir: Transformational licensing agreement

SymBio has entered into a global licensing agreement for brincidofovir from Chimerix for $5m upfront, $180m in milestones and double-digit royalties. The drug is an antiviral for DNA viruses that has been investigated to treat opportunistic infections. The company intends to pursue the drug for viral hemorrhagic cystitis (vHC) and HHV-6 encephalitis, starting in Japan then in the rest of the world, potentially transforming SymBio into a multinational specialty pharma company.

RTD formulation extends the product lifecycle

SymBio also announced that it has submitted an NDA for the approval of the RTD formulation of Treakisym, which is a difficult molecule to dissolve in water, necessitating extended prep times. The development of the RTD formulation is meant to enhance the convenience of the product for practitioners. The goal with the new formulations is to convert doctors over to the more convenient forms before the entry of generic bendamustine into the market in 2022. The company is targeting a launch of the RTD formulation in Q121.

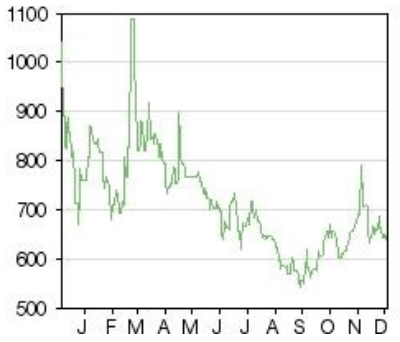
Valuation: Increased to ¥32.7bn ($300m)

We have increased our valuation to ¥32.7bn ($300m) or ¥1,342 ($12.31) per share from ¥28.9bn ($255m) or ¥1,185 ($10.49) per share. This is driven primarily by an increase in the probability of success for Treakisym in DLBCL to 90% from 60%. Additionally, the valuation is increased by the inclusion of brincidofovir in our model and offset by the upfront payment to Chimerix. At this time, we only include revenues for vHC in Japan, but we expect to update this in the future if the program progresses into other indications and geographies.

5 December 2019

Price	**¥640**
Market cap	**¥15,616m**
	¥109/US$
Net cash (¥m) at 30 September 2019	4,625
Shares in issue	24.4m
Free float	91.3%
Code	4582
Primary exchange	TYO
Secondary exchange	OTC US

Share price performance



%	1m	3m	12m
Abs	(7.4)	12.7	(35.7)
Rel (local)	(9.4)	(0.3)	(37.8)
52-week high/low	¥1088		¥542

Business description

SymBio Pharmaceuticals is a Japanese specialty pharma company with a focus on oncology and hematology. The Treakisym powder formulation was in-licensed from Astellas in 2005; liquid Treakisym was in-licensed from Eagle Pharmaceuticals in 2017. Rigosertib was in-licensed from Onconova. And brincidofovir was licensed from Chimerix in 2019.

Next events

DLBCL NDA filing	H120

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Treakisym meets primary endpoint in DLBCL

SymBio announced it had met is primary endpoint in its Phase III study of Treakisym (bendamustine) in relapsed and refractory DLBCL when combined with Rituxan (rituximab). The primary endpoint was overall response rate, with progression free survival and overall survival as secondary endpoints. The study was designed to enroll approximately 60 patients, although the planned enrolment was revised down to 40 patients. The study was open label and single arm, but this may be able to support a label expansion for the drug to this indication considering the well-demonstrated activity in other studies. Although bendamustine is not approved explicitly for DLBCL in the US (although it is approved for indolent NHL), it has been demonstrated to have activity when combined with Rituxan,[1] similar to the current study.

We estimate a target market of 11,200 second-line DLBCL patients, which would approximately double the current addressable market. SymBio did not release detailed data in the announcement of positive results, although we expect them to be presented shortly and we do not expect any surprises based on the historical data in this indication. It intends to have an NDA submission ready in H120. The DLBCL program is central to the company's stated objective of becoming profitable in 2021 and to date, everything appears to be going to plan.

SymBio licenses brincidofovir in transformational deal

The company announced at the end of September 2019 that it has licensed worldwide rights to the antiviral brincidofovir from Chimerix Pharmaceuticals. The deal includes a $5m upfront payment, double-digit royalties and $180m in downstream milestones payable to Chimerix. Chimerix will retain the rights to develop the drug for smallpox, but SymBio will be able to develop the drug worldwide for all other indications. The company has stated that it intends to develop the drug for viral hemorrhagic cystitis (vHC) and HHV-6 encephalitis (HHV-6), two viral diseases that typically only cause symptoms in immunocompromised individuals after hematopoietic stem cell transplant (HSCT) or kidney transplant.

Background and clinical history of brincidofovir

Brincidofovir is a derivative of the antiviral cidofovir, formed by conjugating a lipid tail to the drug. This improves the drug's properties by increasing cell permeability, and importantly, it reduces the dose-limiting renal toxicity that is characteristic of cidofovir. Both molecules are broad-spectrum inhibitors of DNA viruses that work by inhibiting DNA synthesis. The lipid tail also improves oral bioavailability and the oral formulation of the drug was the major development focus for Chimerix. However, the oral form of the drug has been implicated in some of the severe GI side effects that have been reported in clinical studies. The IV formulation has been explored and Chimerix previously published data from a Phase I study showing improved tolerability of this form of the drug. Some GI toxicity was seen with 20mg given once a week, but 10mg twice a week only had one patient with nausea (out of nine). Exposure at this dose was similar to the 100mg twice a week oral dosing used in the Phase III clinical study (more details below), which had 61% diarrhea, 34% abdominal plain, 31% nausea and 24% vomiting. Future studies will focus on the IV formulation.

Although there is little doubt that brincidofovir is an active molecule, its clinical development history has been complex. The lead indication of the drug for a long time under Chimerix was for the

[1] Arcari A. et al. (2014) Safety and Efficacy of Rituximab Plus Bendamustine in Relapsed or Refractory Diffuse Large B-Cell Lymphoma Patients. *Blood* 124, 3074.

treatment of cytomegalovirus (CMV) following stem cell transplant, which it investigated in a Phase III study that reported in 2015.[2] The study failed to reach its primary endpoint: no improvement in clinically significant CMV infection rates was seen at 24 weeks (51.2% for brincidofovir vs 52.3% for placebo), although the reasons behind this appear to be complex. The drug showed antiviral activity during the 14 weeks that patients were on the drug, but this benefit deteriorated during the follow-up period. Moreover, patients on the drug arm had higher reported rates of graft-vs-host disease (GVHD) and other infections following the treatment period. There was a numerically higher rate of all-cause mortality on the brincidofovir arm (HR=1.6), although it failed to reach statistical significance (p=0.11). When investigating the cause of these surprising results, the study coordinators found that patients on the drug arm had over eight times the level of exposure to corticosteroids than the placebo arm. Moreover, the excess diagnoses of GVHD were attributable to acute GI GVHD. The rate of GI toxicity was very high in the drug arm (60.7% vs 36.2% for placebo), and one plausible explanation advanced by the study authors is that this toxicity was misdiagnosed as GVHD, leading to higher rates of steroid use in the drug arm and subsequently higher rates of infection. However, the authors mention that they were unable to differentiate GI GVHD from toxicity via histopathology.

The company subsequently investigated the drug for a range of viral infections and announced positive results in Phase II for the treatment of adenovirus in pediatric stem cell transplant patients.[3] However the negative outcome for the CMV study appears to have had a lasting impact on the ability of the company to enroll patients in these new studies and in May 2019, it announced that it would be discontinuing all of its clinical programs for the drug due to enrolment difficulties across all of its trials. Chimerix continues to develop the drug for smallpox under the animal rule. The company also transitioned to a new management team during this period, signaling a major shift in its strategy going forward.

The future under SymBio

We view SymBio's decision to license brincidofovir as highly strategic. The limitations of the drug that have overshadowed its development appear to be largely related to the GI toxicity related with the oral formulation. The hope is that the IV formulation can substantially reduce these risks, which appears to be the case with the 10mg dose (although some toxicity was seen at higher doses). This leaves the company with the worldwide rights to a molecule with well understood antiviral activity across a range of indications. Moreover, the original drug cidofovir has never been approved in Japan, so brincidofovir approval could be the first of its kind in that country. We expect SymBio to initially seek approval in Japan and then expand to the US and other markets, potentially transforming itself into a multinational pharmaceutical company.

Similar to the previous development programs for the drug, the company will initially be developing it for two indications, vHC and HHV-6, which are complications of allogeneic HSCT. Both are caused by viruses that infect a wide swath of healthy individuals without any symptoms, but can cause major complications in immunocompromised patients. vHC is typically caused by a virus called BK virus, and is characterized by irritation in the bladder and blood in the urine. One study found that 16.6% of HSCT patients developed hemorrhagic cystitis, of which 90% could be linked to this virus.[4] HHV-6 more commonly causes symptoms in cord blood recipients (10% incidence) compared to HSCT (1%) for poorly understood reasons, and is characterized by cognitive

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2 Marty FM, et al. (2019) A Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial of Oral Brincidofovir for Cytomegalovirus Prophylaxis in Allogeneic Hematopoietic Cell Transplantation. *Biol Blood Marrow Transpl* 25, 369-381.

3 Hiwarkar P, et al. (2017) Brincidofovir is highly efficacious in controlling adenoviremia in pediatric recipients of hematopoietic cell transplant. *Blood* 129, 2033-2037.

4 Lunde LE, et al. (2015) Hemorrhagic Cystitis After Allogeneic Hematopoietic Cell Transplantation: Risk Factors, Graft Source, and Survival. *Bone Marrow Transpl* 50, 1432-1437.

disfunction and encephalitis.[5] HHV-6 is also associated with solid organ transplantation and is estimated to cause clinical disease in approximately 1% of patients. The disease manifestation in solid organ transplant patients is different and is characterized by fever, liver dysfunction, colitis and graft dysfunction. Chimerix previously performed a post hoc analysis of its CMV trial, investigating whether it could identify activity against HHV-6 in this population and found that the drug reduced the incidence and severity of the infection.

The clinical development plan for brincidofovir has not been finalized yet. We understand that the previous Phase I IV brincidofovir study included Japanese patients and could potentially be used for the same purpose in Japan. Based on company guidance, the finalized development should be announced by January. If the PMDA approves the use of the existing Phase I study data, the company has guided us towards initiation of a Phase II study in vHC starting in Q320.

RTD Treakisym up for approval now

One hurdle to the company's future operational plans is that Treakisym is slated to have generic competition in Japan starting in 2022. SymBio has therefore endeavored to protect its market share with the introduction of new formulations of the product, which provide a benefit to physicians using the product. As part of this the company in-licensed rights to patent-protected liquid formulations of Treakisym from Eagle in September 2017: the RTD (ready-to-dilute) formulation and the rapid infusion (RI) formulation. These formulations are protected by patents that extend to 2031. Both of these formulations improve the convenience factor for physicians by making the product easier to dilute and easier to infuse, respectively, and the company believes these factors can convert and retain physicians. The company reported in September 2019 that it has submitted the NDA for approval of the RTD formulation, which it expects to commercialize in Q121. The RI formulation is currently being investigated in a Phase III pivotal study that was initiated in April 2019. This product is expected to launch in 2022.

The RTD product is approved in the US under the name Bendeka and is marketed by Teva. Eagle reported revenue from the product of $25m in 2018, which based on the reported royalty rate of 25% suggests sales of approximately $100m during that period.

Valuation

We have increased our valuation to ¥32.7bn ($300m) or ¥1,342 ($12.31) per share from ¥28.9bn ($255m) or ¥1,185 ($10.49) per share. This is driven by an increase in the probability of success for Treakisym in DLBCL to 90% from 60%, which increased its valuation to ¥9.2bn from ¥5.3bn.

Additionally, our valuation is lifted by the inclusion of brincidofovir in our model (¥838m). We only include the initial indication of vHC in our model and only in Japan at this time, but we may revise at a later date as the company progresses its clinical development plans. At this time we also conservatively assume for the purposes of this model that the company will be required to perform a Phase I study by the PMDA. If the agency does not require this study, this would increase our valuation by approximately ¥250m. Regardless of the PMDA decision, we assign a 30% probability of success, which is average for drugs entering Phase II, because we find the Phase I IV study sufficient. We assume that the drug will be able to command both a high price (¥10m at launch) because it will be the only available medication to treat this rare disorder. Additionally, because the targeted patient audience is already under close medical supervision and the drug will be administered in conjunction with an ongoing medical procedure (allogeneic HSCT), we estimate

[5] HHV-6 foundation

very high penetration, up to 75% at peak. We assume a 15% royalty to Chimerix. We include $10m in clinical and regulatory milestones, but do not include commercial milestones given our low revenue expectations for this indication (¥4,200m at peak). Based on current rates of allogeneic HSCT in Japan (approximately 3,700 per year),[6] we estimate an addressable market of only 630 individuals per year in the country. We believe that the majority of the value of this asset will be in downstream label expansions and entrance into new geographies, but we want to see traction with the initial clinical program before including these in our estimates.

Exhibit 1: Valuation of SymBio

Valuation by NPV sum-of-the-parts Product	Indication	Launch	Peak sales (JPYm)	NPV (JPYm)	Probability	rNPV (JPYm)	rNPV/share (JPY/share)
Treakisym	Low grade NHL/MCL (r/r and 1st line); CLL	2010	8,600	17,559	100–95%	16,814	690.2
Treakisym (DLCBL)	r/r DLBCL	2021	9,600	10,373	90%	9,150	375.6
Rigosertib (IV)	r/r HR-MDS	2023	3,800	2,422	50%	978	40.1
Rigosertib (oral)	LR-MDS (mono) or First-line HR-MDS (combo)	2025	7,500	3,943	15%	277	11.4
Brincidofovir	vHC	2025	4,200	3,212	30%	838	34.4
Net cash (September 2019)				4,625	100%	4,625	189.8
Valuation				42,133		32,682	1,341.5

Source: SymBio Reports, Edison Investment Research

Financials

We have adjusted our expected financing requirement to ¥1.7bn from ¥1.8bn (included as illustrative debt in 2020) before profitability in 2021. This is driven by slightly lower than expected operational spending for Q319 (¥1.6bn), which includes the $5m upfront payment for brincidofovir.

[6] The Japanese Data Center for Hematopoietic Cell Transplantation

Exhibit 2: Financial summary

Accounts: JPN GAAP, Yr end: 31 December; ¥m	2016	2017	2018	2019e	2020e	2021e	2022e	2023e	2024e	2025e
Total revenues	2,368	3,444	3,836	3,009	4,043	9,159	11,418	12,705	13,988	15,336
Cost of sales	(1,464)	(2,413)	(2,663)	(2,106)	(2,830)	(2,052)	(2,254)	(1,897)	(2,090)	(2,292)
Gross profit	904	1,031	1,173	903	1,213	7,107	9,164	10,808	11,898	13,044
SG&A (expenses)	(1,364)	(1,961)	(1,996)	(2,556)	(3,806)	(5,406)	(6,226)	(7,252)	(7,707)	(8,318)
R&D costs	(1,667)	(3,018)	(1,833)	(2,453)	(2,603)	(765)	(1,585)	(1,597)	(1,765)	(866)
Other income/(expense) included in adjusted	0	0	0	0	0	0	0	0	0	0
Other income/(expense) excluded from adjusted	0	0	0	0	0	0	0	0	0	0
Reported EBIT	(2,127)	(3,947)	(2,656)	(4,106)	(5,196)	936	1,354	1,960	2,426	3,860
Finance income/ (expense)	5	3	1	(76)	41	12	26	65	137	217
Other income/(expense) included in adjusted	7	3	(0)	0	0	0	0	0	0	0
Other income/(expense) excluded from adjusted	(195)	(33)	(93)	0	0	0	0	0	0	0
Reported PBT	(2,309)	(3,974)	(2,749)	(4,182)	(5,154)	948	1,380	2,024	2,563	4,077
Income tax expense	(4)	(4)	(4)	(4)	(4)	(80)	(114)	(166)	(978)	(1,553)
Reported net income	(2,313)	(3,978)	(2,753)	(4,186)	(5,158)	868	1,266	1,858	1,585	2,524
Average number of shares - basic (m)	9.8	12.5	16.6	22.5	24.3	24.3	24.3	24.3	24.3	24.3
Basic EPS	(235.27)	(319.14)	(165.54)	(186.25)	(211.84)	35.66	51.98	76.32	65.11	103.66
Adjusted EBITDA	(2,101)	(3,917)	(2,621)	(4,068)	(5,117)	1,010	1,432	2,047	2,526	3,976
Adjusted EBIT	(2,127)	(3,947)	(2,656)	(4,106)	(5,196)	936	1,354	1,960	2,426	3,860
Adjusted PBT	(2,317)	(3,977)	(2,749)	(4,182)	(5,154)	948	1,380	2,024	2,563	4,077
Adjusted EPS	(236.02)	(319.35)	(165.54)	(186.25)	(211.84)	35.66	51.98	76.32	65.11	103.66
Adjusted diluted EPS	(236.02)	(319.35)	(165.54)	(186.25)	(211.84)	29.90	43.58	64.00	54.60	86.93
Balance sheet										
Property, plant and equipment	75	47	57	54	65	110	160	205	242	271
Goodwill	0	0	0	0	0	0	0	0	0	0
Intangible assets	42	69	71	201	153	118	93	74	61	52
Other non-current assets	77	100	73	73	73	73	73	73	73	73
Total non-current assets	193	216	201	328	290	301	326	352	376	396
Cash and equivalents	5,719	2,947	4,821	4,087	800	1,290	2,548	4,501	6,103	8,566
Inventories	273	363	534	173	233	169	185	156	172	188
Trade and other receivables	487	490	412	346	443	1,004	1,251	1,392	1,533	1,681
Other current assets	205	237	272	272	272	272	272	272	272	272
Total current assets	6,685	4,037	6,038	4,878	1,747	2,734	4,257	6,321	8,079	10,707
Non-current loans and borrowings	450	0	0	0	1,731	1,731	1,731	1,731	1,731	1,731
Trade and other payables	0	0	0	0	0	0	0	0	0	0
Other non-current liabilities	1	1	1	2	2	2	2	2	2	2
Total non-current liabilities	451	1	1	2	1,733	1,733	1,733	1,733	1,733	1,733
Trade and other payables	322	604	726	409	520	501	636	720	770	745
Current loans and borrowings	0	0	0	0	0	0	0	0	0	0
Other current liabilities	620	407	610	1,410	1,410	1,410	1,410	1,410	1,410	1,410
Total current liabilities	942	1,011	1,336	1,819	1,931	1,911	2,046	2,130	2,181	2,156
Equity attributable to company	5,485	3,239	4,902	3,386	(1,625)	(609)	804	2,810	4,543	7,214
Non-controlling interest	0	0	0	0	0	0	0	0	0	0
Cashflow statement										
Profit before tax	(2,309)	(3,974)	(2,749)	(4,182)	(5,154)	948	1,380	2,024	2,563	4,077
Depreciation and Amortisation	26	30	35	38	79	74	78	87	100	116
Share based payments	137	121	148	148	148	148	148	148	148	148
Other adjustments	197	42	61	76	(41)	(12)	(26)	(65)	(137)	(217)
Movements in working capital	(13)	(35)	184	909	(45)	(516)	(130)	(27)	(106)	(189)
Interest paid / received	6	3	1	(76)	41	12	26	65	137	217
Income taxes paid	(4)	(4)	(4)	(4)	(4)	(80)	(114)	(166)	(978)	(1,553)
Cash from operations (CFO)	(1,960)	(3,817)	(2,325)	(3,091)	(4,977)	574	1,361	2,066	1,727	2,598
Capex	(28)	(57)	(40)	(165)	(41)	(84)	(103)	(114)	(124)	(136)
Acquisitions & disposals net	0	0	0							
Other investing activities	(16)	(20)	14	0	0	0	0	0	0	0
Cash used in investing activities (CFIA)	(44)	(78)	(26)	(165)	(41)	(84)	(103)	(114)	(124)	(136)
Net proceeds from issue of shares	3,226	1,164	4,272	2,522	0	0	0	0	0	0
Movements in debt	450	0	0	0	1,731	0	0	0	0	0
Other financing activities	(18)	0	0	0	0	0	0	0	0	0
Cash from financing activities (CFF)	3,658	1,164	4,272	2,522	1,731	0	0	0	0	0
Currency translation differences and other	(196)	(42)	(47)	0	0	0	0	0	0	0
Increase/(decrease) in cash and equivalents	1,458	(2,772)	1,874	(734)	(3,287)	490	1,259	1,952	1,602	2,463
Opening Net (debt) cash	4,261	5,719	2,947	4,821	4,087	(931)	(441)	817	2,769	4,372
Cash and equivalents at end of period	5,719	2,947	4,821	4,087	800	1,290	2,548	4,501	6,103	8,566
Net (debt) cash	5,269	2,947	4,821	4,087	(931)	(441)	817	2,769	4,372	6,835
Movement in net (debt) cash over period	1,008	(2,322)	1,874	(734)	(5,018)	490	1,259	1,952	1,602	2,463

Source: SymBio reports, Edison Investment Research

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