Senhwa Bioscience (6492 TT); not rated	
Market cap	NT$4,766 mn
6M avg. daily turnover	NT$2 mn
Share price (date)	NT$64.0
FINI ownership	24.3%
Net debt/equity	(101.0%)

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Pharmaceutical Industry

Senhwa Bioscience (6492 TT; NR) – Analyst meeting takeaways

Company profile: Founded in 2012, Senhwa Bioscience focuses on development of first-in-class targeted therapies for cancer treatment, riding the trend of precision medicine for cancer treatment. Its cooperating partner, CCTG, presented phase I clinical data for Pidnarulex (CX-5461) at the spotlight presentation of San Antonio Breast Cancer Symposium (SABCS) on Dec 12, with the drug exhibiting a good safety profile and positive preliminary clinical efficacy. Looking forward, proven safety data for two of Senhwa's drug candidates supports clinical tests for different indications. Moreover, the company will leverage regulatory shortcuts to accelerate its new drugs' time to market.

Positive phase I clinical data to support strategy of pushing drug candidates on an accelerated approval pathway: Pidnarulex is a novel first-in-class G-quadruplex stabilizer targeting DNA damage repair (DDR). Based on phase I clinical data, Pidnarulex treatment has shown a good safety profile, with a side effect of reversible photosensitivity, and positive preliminary clinical efficacy. Four patients reached partial response (PR) and another four reaching stable disease (SD) for more than six months based on 32 assessable patients. In particular, the four patients reaching PR had homologous recombination defects (HRD), suggesting patients with HRD are sensitive to Pidnarulex treatment, which increases its chances to develop through tissue agnostic trials, accelerating its launch. Senhwa is discussing with US FDA for the approval of the expansion cohort studies. If it gets proof-of-concept in the expansion cohort studies, mgmt will initiate a tissue agnostic basket trial as the registration trial for NDA of Pidnarulex. Positive phase I data may support Pidnarulex's entry to an accelerated approval pathway.

Tissue agnostic therapies a trend for oncology drug development: There are three oncology new drugs approved by the US FDA through tissue agnostic trials, namely Keytruda®, Larotrectinib, and Entrectinib. Tissue agnostic therapies approval is based on a common biomarker across different kinds of tumors rather than the location in the body where tumors originated. The key to enter the tissue agnostic approval pathway is to have a predictable biomarker that can be measured and can predict the prognosis of the treatment. According to the recent approval timeline for tissue agnostic therapies, if Senhwa starts tissue agnostic trials of Pidnarulex, mgmt expects it will take only 3-4 years for approval of Pidnarulex for the treatment of patients with HRD in various cancers.

Potential target for M&A in targeted therapy: Senhwa's market cap of US$160 mn makes its cheap vs the average M&A deal size for a buyout of a biotech company that has completed a phase I clinical trial for a targeted therapy of US$518 mn.

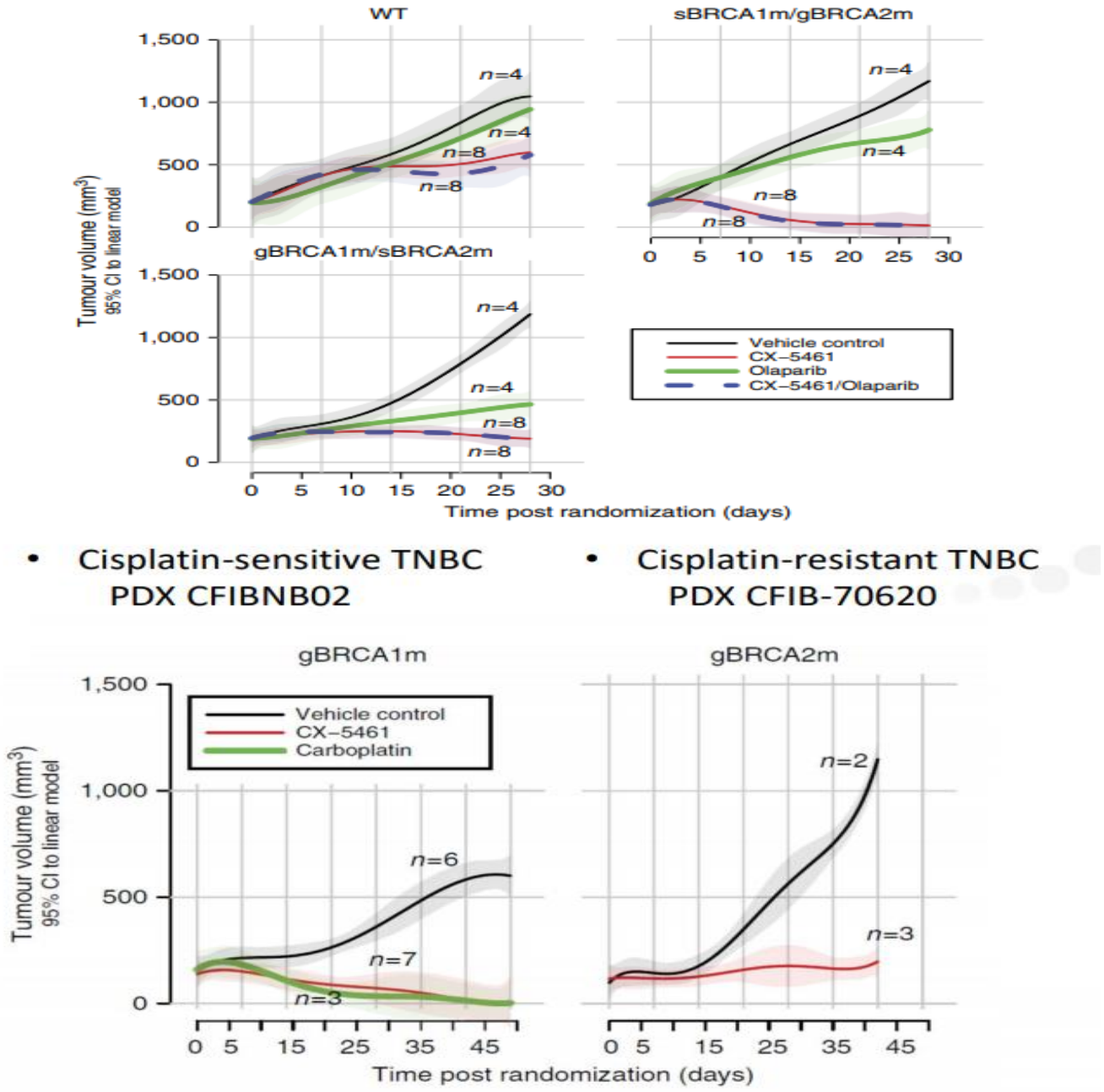
Two candidates with proof-of-concept in preclinical studies, & positive prelim clinical data

Pidnarulex (CX-5461)

Pidnarulex (CX-5461) is a novel first-in-class G-quadruplex stabilizer targeting DNA damage repair (DDR).

- **CX-5461 has previously shown efficacy in platinum-resistant, PARPi-resistant BRCA1/2 deficient PDX model:** The company evaluated CX-5461 in a taxane-pretreated TNBC PDX, and CX-5461 selectively reduced the tumor growth rate of BRCA1/2 deficient PDX tumors vs BRCA WT PDX tumor (Figure1, upper). Moreover, it found that CX-5461 could reduce tumor growth of a BRCA1/2 deficient PDX tumor that exhibited a weak response to Olaparib, suggesting that CX-5461 activity spectrum may in some cases transcend that of Olaparib. The combination effect of CX-5461 and Olaparib is similar to CX-5461 alone in the tested PDX models (Figure1, upper). On the other hand, CX-5461 significantly reduced tumor growth of a BRCA2 deficient PDX tumor that had minimal response to cisplatin (Figure1, lower). In summary, while CX-5461 activity partially overlaps PARP inhibitors and platinum salts in HR deficient tumors, CX-5461 exhibits additional activity in some tumors resistant to these agents.

Figure 1: CX-5461 selectively suppresses growth of BRCA deficient tumors in murine xenografts and chemo-resistant PDX models



Source: Nature Comm. 2017 8:14432, Yuanta Investment Consulting

- According to phase I clinical data, Pidnarulex treatment has a good safety profile, with side effects of reversible photosensitivity, and a positive preliminary clinical efficacy, with four patients reaching partial response (PR) and another four patients reaching stable disease (SD) for more than six months based on 32 assessable patients.
- Particularly, the mentioned four patients reaching PR had homologous recombination defects (HRD), suggesting patients with HRD are sensitive to Pidnarulex treatment, which increases chances of development of Pidnarulex through the tissue agnostic approval pathway. The company is discussing with the US FDA on approval of an expansion cohort study, which will include 5 examining cohorts, with 10-15 patients recruited for each cohort, to examine the clinical efficacy of Pidnarulex based on the treatment of patients with HRD in various cancers.

- Mgmt expects to spend only 3-4 years on the launch of Pidnarulex for the treatment of patients with HRD in various cancers if it develops Pidnarulex through the tissue agnostic approval pathway. The key to entering the tissue agnostic approval pathway is to have a predictable biomarker that can be measured and can predict the prognosis of the treatment. Positive preliminary phase I data may support the drug candidate's entry into tissue agnostic approval pathway.
- The only approved targeted therapies for BRCA mutation patients are PARP inhibitors. The global PARP inhibitor market was valued at US$887.7 mn in 2018, and is projected to reach US$8.8 bn by 2027, a CAGR of 32.4% from 2019 to 2027, according to Coherent Market Insights. Once approved, Pidnarulex has potential to gain market share, acting as a first-line treatment to compete with PARP inhibitors or as a second-line treatment for PARPi-resistant patients.

Figure 2: DDR drug deal case

DDR drug - License deal

Product	Licensor	Licensee	Deal	Date
Olaparib (Lynparza®)	AstraZeneca	Merck	• Global co-develop/market rights • Deal Size US$8.5 bn • Upfront US$1.6 bn • License options US$750 mn • Milestone US$6.15 bn • Gross profit shared equally	2017/7/26
Niraparib (Zejula®)	Tesaro	Takeda	• Regional Licensing including Japan, South Korea, Taiwan, Russian and Australia. • Deal Size US$241 mn • Upfront US$1 mn • Millstone US$240 mn • Royalties 15%-30%	2017/7/27

DDR drug - M&A deal

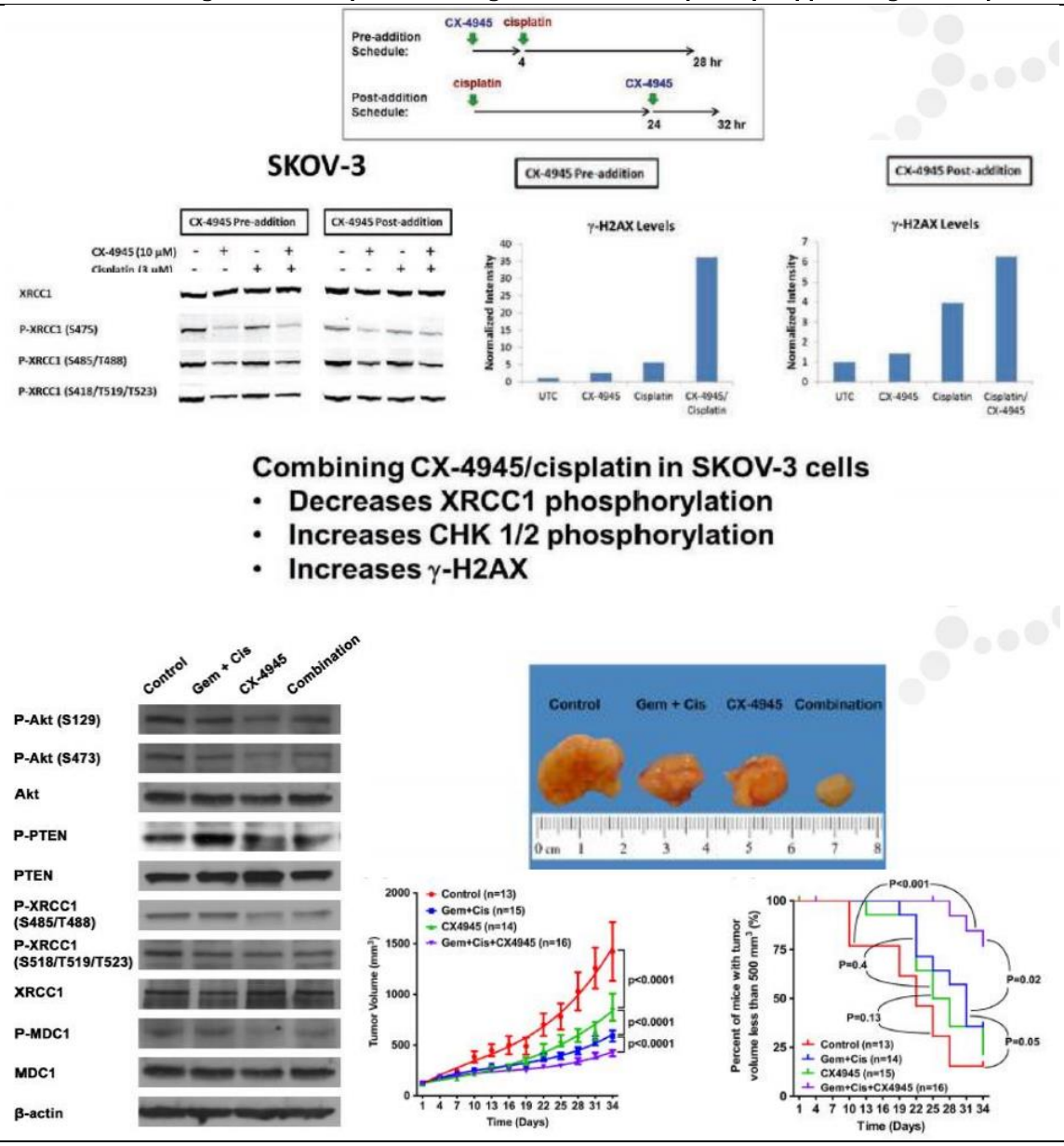
Product	Target	Acquirer	Deal	Date
Niraparib (Zejula®)	Tesaro	GSK	Deal Size US$5.1 bn (Cash)	2018/12/3

Source: Company data, Yuanta Investment Consulting

Silmitasertib (CX-4945)

- Silmitasertib (CX-4945) is a CK2 inhibitor, but does not have a specific target for various cancers, as it has multiple functions. For CCA, Silmitasertib has shown safety and preliminary clinical efficacy in phase I clinical trials.
- According to preclinical data, CX-4945 can augment efficacy of DNA-targeted chemotherapies by suppressing the DNA repair response. Previously, the company found that CX-4945 could reduce activation of the DNA repair mediator/adaptor proteins, XRCC1 and MDC1, and increase cisplatin induced DNA damage in ovarian tumors (Figure3, upper). Afterwards, it investigated the antitumor effect of CX-4945 on cholangiocarcinoma (CCA), and found that CX-4945 reduced tumor growth and increased mice survival rate in CCA PDX model (Figure3, lower). Moreover, CX-4945 had a synergistic effect when combined with the standard therapy, gemcitabine and cisplatin, of CCA through inhibiting activation of DNA repairing enzymes XRCC1 and MDC1 (Figure 3; lower).

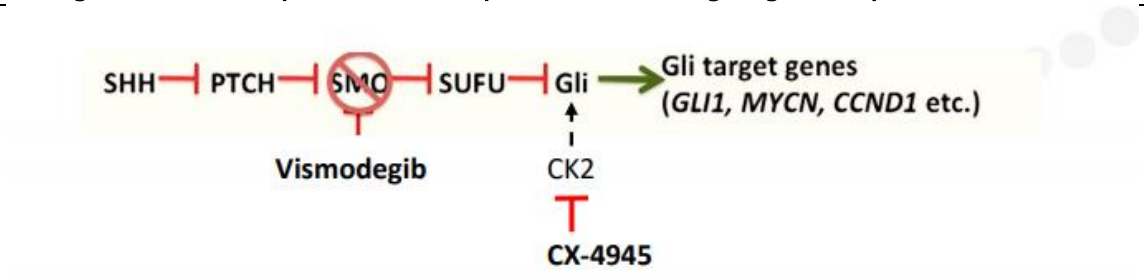
Figure 3: CX-4945 could augment efficacy of DNA-targeted chemotherapies by suppressing DNA repair response



Source: Company data, Yuanta Investment Consulting

- For CCA, Silmitasertib combined with chemotherapy has shown safety and preliminary clinical efficacy in phase I clinical trials, and mgmt expects to discuss with US FDA to change clinical design of the phase II clinical trials.
- **CK2 regulates the activity of downstream proteins in the Hedgehog Pathway:** Hedgehog (Hh) signaling is a critical developmental regulator and its aberrant activation, due to somatic or germline mutations of genes encoding pathway components, causes Basal Cell Carcinoma (BCC) and medulloblastoma (MB). As a result, the company plans to evaluate the efficacy of CX-4945, a potent CK2 inhibitor, in treatment of BCC.

Figure4: CK2 regulates the activity of downstream proteins in the Hedgehog Pathway



Source: Company data, Yuanta Investment Consulting

- For BCC, mgmt plans to recruit 3-6 patients to determine maximum tolerated dose (MTD), after which it expects to perform an expansion cohort study, including 2 cohorts of BCC patients, with 20 patients in total. Because 85% of all SMO-treated patients harbor SMO mutations post-treatment and that SMOi-resistant tumors maintain a high level of Gli expression, which is thought to be the terminal end of the HH pathway, as well as the target of silmitasertib, mgmt expects to accelerate silmitasertib development for treatment of BCC through expansion cohort study.

Accelerated approval for targeted therapies- tissue agnostic therapies

Tissue agnostic therapies to become the trend for oncology new drug development

Tissue agnostic therapies are targeted therapies with approval based on a common biomarker across different kinds of tumors rather than the location in the body where the tumor originated. The intent of approval for tissue agnostic therapies is to accelerate orphan drug approval and to implement precision medicine. Orphan drug approvals accounted for approximately 40% of the New Molecular Entities and Therapeutic Biologic Products in Center for Drug Evaluation and Research over the last several years. The US FDA provides incentives to manufacturers for orphan drug development by granting eligible requests for orphan drug designation (ODD), which may qualify the sponsor of the drug for a waiver of the prescription drug application user fee, tax credits for qualified clinical trials, and potential marketing exclusivity upon approval. When reviewing a request for ODD, the FDA considers the mechanism of action of the drug to determine what specific disease or condition the drug is to treat, diagnose or prevent. Historically, FDA has used a histology based approach to designate and approve oncology drugs to treat cancers based on a single anatomic site.

However, as knowledge of oncogenesis has evolved, oncologists have begun categorizing organ-specific cancers based on molecular markets, which has examples in breast cancers and in non-small-cell lung cancers. The molecular markers may be prognostic indicators and may be the targets for drug development and treatment. As a result, many targeted therapies have been approved for cancer treatment. Approval of a tissue agnostic therapy also accelerates the approval of the targeted therapy in different types of cancers, which saves time and money for the manufacturer and makes the patients accessible to the therapy faster.

Figure5: Tissue-agnostic cancer therapy overview

Generic name	Brand name (Company)	Indication	Status
Pembrolizumab	Keytruda (Merck)	Adult and pediatric patients with unresectable or metastatic solid tumors with MSI-H or dMMR	Approved by the FDA in May 2017
Larotrectinib	Vitrakvi (Loxo Oncology/Bayer)	Adult and pediatric patients with locally advanced or metastatic solid tumors harboring NTRK gene fusions	Approved by the FDA in Nov 2018
Loxo-195	TBD (Bayer)	Patients with TRK fusion-positive solid tumors	Drug under development; early clinical data available
Entrectinib	Rozlytrek (Ignyta/Roche)	Pediatric and adult patients with recurrent or refractory extracranial solid tumors harboring NTRK1/2/3, ROS1, or ALK gene fusions	Approved by the FDA in Aug 2019
BLU-667	TBD (Blueprint Medicines)	Solid tumors with RET alterations	Drug under development; Phase I clinical data available
Loxo-292	TBD (Loxo Oncology)	Solid tumors with RET alterations	The FDA granted breakthrough therapy designation on Sept 5, 2018
Anti-ERBB3 antibody		Solid tumors with NRG1-rearranged cancers	Preliminary clinical proof-of-practice data published

Source: American Association for Cancer Research; Yuanta Investment Consulting

There are three new oncology drugs approved by the US FDA through tissue agnostic trials, namely Keytruda®, Larotrectinib (Vitrakvi®), and entrectinib (Rozlytrek®). The key to entering the tissue agnostic approval pathway is to have a predictable biomarker that can be measured and can predict the prognosis of the treatment. According to the recent approval timeline for tissue agnostic therapies, if it starts tissue agnostic trials of Pidnarulex, Senhwa expects it will take only 3-4 years for approval of Pidnarulex for the treatment of patients with HRD in various cancers.

Targeted therapies a focus for international big pharmaceutical companies to compete in oncology market

7 out of top 10 M&A deals in pharmaceutical industry from 2015 to 2019 were related to small molecule targeted therapies. Combined with the success in the approval of agnostic tissue therapies, targeted therapies have accounted for a large portion of oncology M&A deals in the past five years, with the largest merger a US$74 bn buyout of Celgene by BMS. In terms of tissue agnostic therapy, LOXO had a rich pipeline for tissue agnostic therapies, having licensed out its product, Vitrakvi®, to Bayer and merging with Eli Lilly for US$8 bn in cash.

.

Figure6: Tissue agnostic therapy deal case

Tissue agnostic therapy license deal

Product	Licensor	Licensee	Deal	Date	Remark
Larotrectinib (LOXO-101) & LOXO-195	Loxo Oncology	Bayer	•Ex-US market rights • Deal Size US$8.5 bn • Upfront US$400 mn • License options US$750 mn • Milestone of US$450 mn for larotrectinib and another milestone of US$200 mn for LOXO-195 • The commercial costs and profits were shared equally for the US market	2017/11/14	• Both of the drugs highly selective tropomyosin receptor kinase (TRK) inhibitors intended for patients with TRK fusion cancers. • Bayer exercised its option and got full US market right of the two compounds on 18 Feb, 2019.

Tissue agnostic therapy - M&A deal

Product	Target	Acquirer	Deal	Date	Remark
Entrectinib	Ignyta Pharmaceuticals	Roche	• Deal Size: US$1.8 bn (Cash) • Price to Book ratio: 20.8x	2017/12/21	• Entrectinib is a selective CNS-active tyrosine-kinase inhibitor targeting tumors that harbor ROS1 or NTRK fusions.

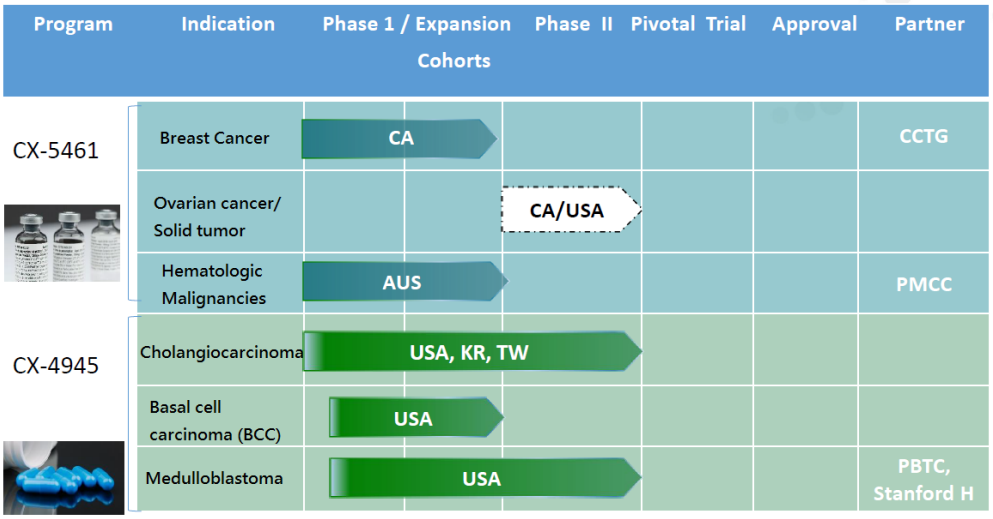
LOXO-292	Loxo Oncology	Eli Lilly	Deal Size: US$8.0 bn (Cash)	2019/2/14	• LOXO-292 is a first-in-class oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA for three indications.

Source: Company data, Yuanta Investment Consulting

Company profile

Founded in 2012, Senhwa Bioscience focuses on development of first-in-class targeted therapies for cancer treatment, walking in the trend of precision medicine for cancer treatment. Its cooperating partner, CCTG, presented the phase I clinical data of Pidnarulex (CX-5461)at the the spotlight presentation of SABCS on Dec 12, 2019, displaying a good safety profile and positive preliminary clinical efficacy. Looking forward, proven safety data of its two drug candidates supports clinical tests for different indications. Moreover, it will leverage regulatory shortcut to accelerate new drugs' time to market.

Figure 7: Product pipeline



Source: Company data, Yuanta Investment Consulting

Figure 8: Peer valuation comparison table

Company	Ticker	Price	Mkt Cap (US$ mn)	EPS			PER (x)			EPS growth (%)		
				2018A	2019F	2020F	2018A	2019F	2020F	2018A	2019F	2020F
Senhwa Biosciences	**6492 TT**	**NT$64.00**	**158**	**-5.05**	**-6.70**	**-6.63**	**NA**	**NA**	**NA**	**NA**	**NA**	**NA**
Global peers												
AstraZeneca	AZN LN	£7,714	131490	1.70	3.59	4.27	44.03	27.94	23.50	-28.27	3.67	18.90
Takeda	4502 JP	¥4,338	62421	239.35	124.58	398.12	21.65	34.82	10.90	62.66	-52.58	250.77
GSK	GSK LN	£1,817.6	117828	0.74	1.23	1.21	20.23	14.83	15.08	134.71	2.68	-1.71
Bayer	BAYN GR	€ 73.8	80384	1.80	6.45	7.38	33.64	11.44	10.01	-35.94	8.59	14.34
Eli Lilly	LLY US	US$131.11	125883	3.14	5.81	6.76	22.44	22.55	19.40	NA	4.74	16.26
Blueprint	BPMC US	US$82.59	4064	-5.39	-7.70	-8.97	NA	NA	NA	NA	NA	NA
Global Average							**28.40**	**22.32**	**15.78**	**19.13**	**-12.63**	**47.02**
Local peers												
Aslan Pharma	6497 TT	NT$9.08	57	-8.49	NA	NA	NA	NA	NA	NA	NA	NA
Pharmaengine	4162 TT	NT$67.40	330	0.88	2.24	3.51	128.41	30.05	19.22	-66.54	154.89	56.35
Polaris Group	6550 TT	NT$19.52	200	-3.78	NA	NA	NA	NA	NA	NA	NA	NA
OBI Pharma	4174 TT	NT$135.50	847	-7.00	-7.93	-8.71	NA	NA	NA	NA	NA	NA
Taiwan Liposome	4152 TT	NT$85.60	211	-14.34	-11.82	-9.75	NA	NA	NA	NA	NA	NA
Local Average							**128.41**	**30.05**	**19.22**	**-66.54**	**154.89**	**56.35**

Source: Company data, Yuanta Investment Consulting, Bloomberg

Notes: EPS figures are denominated in local currency

Figure 9: Peer valuation comparison table (continued)

Company	Ticker	Price	Mkt Cap (US$ mn)	ROE (%)			BVPS			PBR (x)		
				2018A	2019F	2020F	2018A	2019F	2020F	2018A	2019F	2020F
Senhwa Biosciences	**6492 TT**	**NT$64.00**	**158**	**-27.06**	**-70.30**	**-227.93**	**16.24**	**8.84**	**NA**	**4.43**	**7.24**	**NA**
Global peers												
AstraZeneca	AZN LN	£7,714	131490	15.71	23.71	25.65	9.84	11.15	11.35	7.61	8.99	8.83
Takeda	4502 JP	¥4,338	62421	9.60	3.84	-4.48	2556.51	3719.57	3225.97	2.03	1.17	1.34
GSK	GSK LN	£1,817.6	117828	NA	121.28	86.80	0.88	0.92	1.24	16.98	19.67	14.69
Bayer	BAYN GR	€73.8	80384	4.10	10.93	12.68	49.30	48.27	50.31	1.23	1.53	1.47
Eli Lilly	LLY US	US$131.11	125883	30.18	63.15	88.41	9.30	8.49	8.32	12.45	15.44	15.75
Blueprint	BPMC US	US$82.59	4064	-45.38	-81.62	-99.83	9.51	8.79	7.90	5.67	9.40	10.46
Global Average				**2.84**	**23.55**	**18.21**				**7.66**	**9.37**	**8.76**
Local peers												
Aslan Pharma	6497 TT	NT$9.08	57	-127.80	NA	NA	5.84	NA	NA	4.32	NA	NA
Pharmaengine	4162 TT	NT$67.40	330	3.40	3.41	2.85	25.30	24.58	24.81	4.47	2.74	2.72
Polaris Group	6550 TT	NT$19.52	200	-125.22	NA	NA	2.23	NA	NA	13.45	NA	NA
OBI Pharma	4174 TT	NT$135.50	847	-25.98	-22.10	NA	24.89	28.24	NA	6.23	4.80	NA
Taiwan Liposome	4152 TT	NT$85.60	211	-108.85	-170.29	NA	10.43	4.87	NA	8.58	17.58	NA
Local Average				**-76.89**	**-62.99**	**2.85**				**7.41**	**8.37**	**2.72**

Source: Company data, Yuanta Investment Consulting, Bloomberg

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