

Cantargia

Company update

Buoyant on CANFOUR and CANOPY interims

Cantargia has provided updated interim data from its Phase IIa CANFOUR trial, reporting new efficacy data from the combination arms of the study investigating CAN04 (anti-IL1RAP) in first-line NSCLC and PDAC. These new Phase IIa data, combined with initial interim data reported in December 2019, continue to support the hypothesis that CAN04 has a synergistic benefit with chemotherapy, in our view. Another tailwind is increasing positive sentiment on Novartis's canakinumab (anti-IL1beta) progressing in its Phase III trials in NSCLC. We have revised our rNPV model, increasing success probability for CAN04 and revising deal terms, upgrading our valuation to SEK65.1/share (vs SEK38.2/share previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	0.0	(91.2)	(1.38)	0.0	N/A	N/A
12/19	0.0	(110.8)	(1.56)	0.0	N/A	N/A
12/20e	0.0	(138.0)	(1.69)	0.0	N/A	N/A
12/21e	0.0	(138.5)	(1.52)	0.0	N/A	N/A

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

Phase IIa CANFOUR interim data

Cantargia has reported updated interim datasets from its ongoing Phase IIa CANFOUR trial investigating CAN04 in first-line NSCLC and PDAC. Overall, these data are positive and broadly in line with those reported in [December 2019](#). Recruitment has now completed in the PDAC arm of the study, while in the NSCLC combination arm, recruitment continues to experience disruptions from the COVID-19 pandemic. However, Cantargia has now guided that with the data to hand there is no longer a need to fully recruit this arm. Final analysis and key efficacy data are expected in 2021. Cantargia is preparing to engage with regulators to discuss Phase III development plans.

CANOPY-1 passes interim efficacy analysis

Novartis reported that the Phase III CANOPY-1 trial for its anti-IL-1beta canakinumab (plus pembrolizumab and chemo) in first-line NSCLC passed interim analysis during Q320, but the efficacy threshold to warrant an early stoppage was not met. During its Q320 results call, Novartis guided that the data remain blinded and the study will continue until final analysis, expected in H221. Another interim analysis is planned before then, but guidance was not provided on timing. The CANOPY studies have significant read-across for Cantargia's anti-IL-1RAP CAN04, as positive efficacy data would validate targeting the IL-1 axis in oncology. Phase III CANOPY-2 data in second/third-line NSCLC are also expected in H121.

Valuation: SEK5.93bn or SEK65.1/share

We value Cantargia at SEK5.93bn or SEK65.1/share vs SEK3.48bn or SEK38.2/share previously. Rolling the model forward was balanced by a lower net cash position. Based on the new data, we increase the success probability for CAN04 to 25% (from 18%). We also update the list of comparable deals (Exhibit 4) used as benchmarks in our model, which increased the assumed upfront payment to \$250m (from \$123m) and total milestone payments to \$1.4bn (from \$844m).

Pharma & biotech

30 October 2020

Price SEK56
Market cap SEK5.1bn

Net cash (SEKm) at end Q220	458.3
Shares in issue	91.0m
Free float	90%
Code	CANT
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



Business description

Cantargia is a clinical-stage biotechnology company based in Sweden, established in 2009 and listed on the Nasdaq Stockholm main market. It is developing two assets against IL1RAP, CAN04 and CAN10. CAN04 is being studied in a Phase IIa clinical trial, CANFOUR, in solid tumours focusing on NSCLC and pancreatic cancer.

Next events

Phase IIa CANFOUR efficacy data for CAN04 in PDAC & NSCLC	2021
Final analysis from Novartis's Phase III CANOPY-2 trial in 2/3L NSCLC	H121
Final analysis from Novartis's Phase III CANOPY-1 trial in 1L NSCLC	H221

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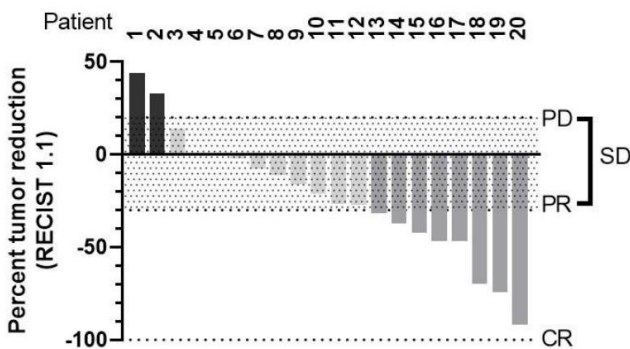
Updated interim data from CANFOUR trial

Cantargia has provided updated interim datasets from its [Phase IIa CANFOUR trial](#), reporting new efficacy data from the combination arms of the study investigating CAN04 in first-line NSCLC and PDAC in combination with chemotherapy or monotherapy. These new Phase IIa data, combined with initial interim data reported in [December 2019](#), continue to support the hypothesis that CAN04 has a synergistic benefit with chemotherapy regimens, which strengthens Cantargia’s position as it nears discussions with regulators on potential Phase III development plans for CAN04 (and any potential partnering discussions). Key efficacy readouts (progression-free survival and overall survival) from the combination arms are still likely to be available during 2021.

As a reminder, the CANFOUR study is an open-label, three-arm Phase I/IIa trial with CAN04 in NSCLC and PDAC as monotherapy and in combination with first-line chemotherapy regimens (more details on trial design in [our last report](#)). In addition to direct cell killing via antibody-dependent cellular cytotoxicity, CAN04 can inhibit IL1RAP and block the IL-1 signalling pathway which tumours can exploit as a defence strategy against immune system attack. Phase I data presented at ASCO 2019 showed that CAN04 was generally safe and well tolerated, and inflammatory biomarkers were reduced, in line with the proposed mechanism of action.

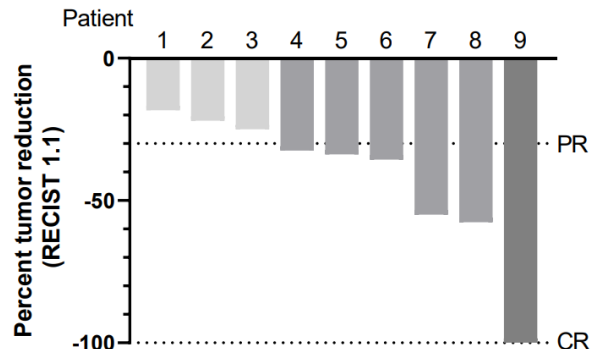
As of 8 October 2020, all 31 PDAC patients had been recruited into the study cohort being treated with a first-line regimen of CAN04 with gemcitabine plus nab-paclitaxel. As shown in Exhibit 1, partial responses (PR) were observed in 8/20 (40%) evaluable patients, of which this PR was durable out to c one year in two patients. Stable disease was achieved in 10/20 (50%) patients, with 2/20 having progressive disease. These data imply a 40% objective response rate (ORR) and 90% disease control rate (DCR) at this analysis. In our view, this is promising compared to historical control data ([Von Hoff et al, 2013](#)), which show a 23% ORR and 48% DCR in PDAC patients treated solely with first-line gemcitabine plus nab-paclitaxel. As per the previous interim data, these imply that CAN04 is having a synergistic effect, albeit with the usual cross-trial comparison caveats.

Exhibit 1: PDAC combination arm waterfall plot



Source: Cantargia

Exhibit 2: NSCLC combination arm waterfall plot



Source: Cantargia

No major new side effects were reported. A full analysis of biomarker data was not released but Cantargia noted that two patients, who initially had progressive disease at two months, subsequently responded with tumour shrinkage of 39% and 24% and a corresponding 95% and 71% reduction in CA19-9, a biomarker for pancreatic cancer tumour burden. An additional 20–40 PDAC patients will be recruited into an extension phase of the study to obtain complementary data, but this interim dataset is expected to be presented in full at a conference during 2021.

Cantargia also provided an update from the NSCLC combination arm of CANFOUR on 23 September, at which point 13/31 patients had initiated treatment with a first-line regimen of CAN04 with gemcitabine plus cisplatin. As shown in Exhibit 3, of the nine patients treated for at least two

months who were evaluable at this analysis, one complete response (CR) had been observed (durable for c one year) and five partial responses, implying a 67% ORR. Putting this into context, historical control data show 22–28% ORRs for first-line intervention with gemcitabine plus cisplatin in NSCLC ([Schiller et al, 2002](#); [Scagliotti et al, 2008](#)), again the normal cross-trial comparison caveats apply.

Recruitment has continued to be slow in this arm of the trial and is unlikely to improve in Q420. This partly due to the current pandemic, but has ultimately been compounded by the paradigm shift in the treatment of first-line NSCLC, which has seen broad uptake and use of anti-PD-(L)1s such as Merck's Keytruda (pembrolizumab) and Roche's Tecentriq (atezolizumab) in conjunction with chemotherapy. Patients will still be allowed to enrol into the NSCLC combination arm of the CANFOUR trial, but management has now guided that with the data to hand, there is no longer a need to reach the target of 31 patients. Preparations are now underway to develop CAN04 in both first- and second-line NSCLC as part of a triple combination with approved regimens that use checkpoint inhibitors and chemotherapy, potentially initiating in 2021.

First patient treated in CPI combination trial

Following IND approval from the FDA in May 2020, Cantargia has now enrolled the first patient in its [Phase Ib trial](#) investigating CAN04 in combination with pembrolizumab across a range of solid tumours. This is a major R&D expansion as the combination will involve checkpoint inhibitors (CPIs). The rationale is based on several observations:

- Myeloid suppressive cells, such as tumour-associated macrophages or myeloid-derived suppressor cells, express IL-1RAP and play a substantial role in PD-1 resistance.
- IL-1 upregulates PD-L1 on macrophages and induces downstream factors, such as IL-6, which add to immunosuppression in the tumour microenvironment.
- IL-1beta blockade has been shown to reverse tolerance to anti-PD-1 in an in vivo setting.

The indications (NSCLC, head and neck cancer and urothelial cancer or malignant melanoma) were selected because the tumours express IL1RAP and are relatively immunogenic, therefore suitable for treatment with CPIs. In addition, the checkpoint inhibitor, Keytruda, is a standard therapy in these indications. The patients in the trial will be eligible if they have progressed on prior PD-(L)1 antibody therapy (second-line positioning). The trial plans to include up to 18 patients.

Novartis's CANOPY data could define IL-1 landscape

These updated interim data from CANFOUR are broadly in line with what was previously communicated. In our view, the recent rally in Cantargia's share price at least in part reflects growing sentiment in anticipation of upcoming pivotal data from Novartis's CANOPY studies for anti-IL-1beta canakinumab in NSCLC. Of particular relevance to Cantargia are the Phase III CANOPY-1 study in first-line NSCLC, which investigated canakinumab as part of a triple combination with anti-PD-1 pembrolizumab and chemotherapy, and the Phase III CANOPY-2 study in second-/third-line NSCLC, which investigated canakinumab combined with docetaxel.

On 27 October 2020, Novartis reported that CANOPY-1 passed interim efficacy analysis (Q320), with the Data and Safety and Monitoring Board (DSMB) recommending continuation to final analysis, expected in H221. We understand that both progression-free survival (PFS) and overall survival (OS) were assessed at this analysis and that stoppage criteria would apply if overwhelming efficacy (PFS or OS) was seen. This could have enabled filing in 2021, but continuation of the study until final analysis implies that these criteria were not met. In our view, this could indicate that the DSMB noted an efficacy signal, but this was either not yet statistically significant or had a magnitude of benefit required to trigger an early stoppage. We anticipate unblinding of the data at

final analysis when sufficient events might have accrued. Novartis has guided that an additional interim analysis is planned for CANOPY-1 before then, but has not provided any guidance on the timing.

Our focus is now on the upcoming Phase III CANOPY-2 data expected in H121. Either of these final analyses will likely define sentiment around modalities targeting the IL-1 axis and invariably have significant read-across for development of CAN04. We note that positive data from either trial would likely spark interest in CAN04 from external partners, particularly given Cantargia is now planning discussions with regulators on Phase III trial design. Conversely, negative data would significantly affect current very strong sentiment, in our view, but would not fully invalidate the IL-1 hypothesis. This is based on the fact that Novartis's canakinumab targets IL-1beta, while CAN04 targets the downstream IL-1RAP, which means it blocks signalling from both IL-1beta and IL-1alpha. CAN04 is therefore clearly differentiated from canakinumab and allows for more comprehensive IL-1 pathway signalling control. Ultimately, irrespective of the results from Novartis's CANOPY studies, the lessons learnt could shape Cantargia's Phase III trial plans and/or more clearly define CAN04's potential positioning.

Exhibit 3: Summary of clinical trials with Novartis' canakinumab and Cantargia's CAN04

Pharmacological class/target	Product (generic name)	Current development status of oncology indications	Notes
Anti-IL-1 β Mab Novartis	Ilaris (canakinumab)	Phase III in 1L NSCLC (+pembrolizumab+chemo) (CANOPY-1, NCT03631199 , n=673)	Fully enrolled (Jan 2020), interim efficacy analysis passed Q320. DSMB recommended that trial continue to final analysis in H221, another interim analysis planned but timing has not been provided.
		Phase III in 2/3L NSCLC (+docetaxel) (CANOPY-2, NCT03626545 , n=245)	Fully enrolled, events have been accruing at a slower rate than expected. Final analysis expected in H121 with filing potentially in 2021.
		Phase III in adjuvant NSCLC (CANOPY-A, NCT03447769 , n=1,500)	Trial c 40% enrolled in June 2020, expected to be fully enrolled in 2022. Interim analysis expected in 2022 ahead of final analysis in 2023.
		Phase II in neoadjuvant NSCLC (+pembrolizumab) (CANOPY-N NCT03968419 , n=110)	Trial c.20% enrolled in June 2020.
		Phase II in 2L melanoma (+spartalizumab) (PLATforM, NCT03484923 , n=195)	Recruiting, interim analysis planned for H122 ahead of final in 2024.
		Phase I in neoadjuvant RCC (+spartalizumab) (SPARC-1, NCT04028245 , n=14)	Recruiting.
		Phase Ib in mTNBC (+spartalizumab) (NCT03742349 , n=220)	Recruiting.
		Phase Ib in CRC, TNBC & NSCLC (NCT02900664 , n=290)	Active, not recruiting.
		Phase Ib in NSCLC, active not recruiting (ElevatION, NCT03064854 , n=112)	Active, not recruiting.
		Gevokizumab	
Phase I in pancreatic cancer (+Onivyde and 5-FU) (OnFX, NCT03207724 , n=16)	Active, not recruiting.		
Anti-IL1RAP Mab Cantargia	CAN04	Phase I/IIa in 1L NSCLC & PDAC (+SoC chemo) (CANFOUR, NCT03267316 , n=100)	Positive interim data reported in Sep/Oct 2020, efficacy readouts (OS & PFS) expected during 2021.
		Phase Ib in NSCLC, HNSCC, urothelial cancer and melanoma (+pembrolizumab) (NCT04452214 , n=15)	FPPD in Oct 2020.

Source: EvaluatePharma, company websites, clinicaltrials.gov. Notes: Ordered by most pharmacological target and most advanced asset.

New entrant in the IL-1 pathway for cancer space

The interest in targeting the IL-1 pathway in cancer has been growing lately. In late September 2020, private biotech company Flame Biosciences revealed its R&D plans for the first time and raised \$100m. Flame Biosciences' lead programme FL-101, an IL-1beta neutralising antibody, is expected to enter clinical testing in H121 in patients with NSCLC. The funding round was led by

Rock Springs Capital and several other well-known institutional investors participated. FL-101 has the same target as canakinumab and it appears that Flame Biosciences was formed in response to Novartis's Phase III canakinumab trial results (the same trial provided a tailwind for Cantargia as well; details in our [Cantargia initiation](#)). It is somewhat striking that a company in a much earlier stage than Cantargia raised such a sum of money for an antibody that has the same target as canakinumab (albeit Flame claims it is more potent). In our view, this is yet another indication that the interest in Cantargia's CAN04, which is differentiated, will not subside any time soon.

Valuation

Our updated valuation of Cantargia is higher at SEK5.93bn or SEK65.1/share vs SEK3.48bn or SEK38.2/share previously (Exhibit 4). The changes include rolling the model forward, which was balanced by a lower net cash position. We have also increased the success probability for CAN04 to 25% from 18% based on the data update. Lastly, we have revised the list of comparable deals that we use as benchmarks in our rNPV model. We have benchmarked against more recent and relevant deal terms than those used in our initiation in 2018.

Given the progress Cantargia has made since our initiation and increasing visibility of CAN04's potential, we have expanded comparable deal criteria to include Phase II-stage assets and so that the deal terms explicitly include more than one indication. Based on deals that have occurred since 2015 for Phase III-ready immunoncology assets, we now assume an upfront payment of c \$250m (from \$123m) and milestones totalling up to c \$1.4bn (from \$844m). The updated list includes fairly high-value deals, but we keep the 70% deal term adjustment in our rNPV model, which we had included to capture inherent uncertainties in the partnering process and due to a lack of directly comparable deals in the IL-1 pathway for cancer treatment.

Exhibit 4: SOTP Cantargia valuation							
Product	Launch	Peak sales (\$m)	NPV (SEKm)	NPV/share (SEK)	Technology probability (%)	rNPV (SEKm)	rNPV/share (SEK)
CAN04 – NSCLC	2026	3,100	8,437.5	92.6	25.0%	2,352.4	25.8
CAN04 – PDAC	2024	2,100	8,798.7	96.6	25.0%	3,123.4	34.3
Net cash (end-Q220)			458.3	5.0	100%	458.3	5.0
Valuation			17,694.5	194.2		5,934.1	65.1

Source: Edison Investment Research; Note: WACC = 12.5% for product valuations.

Exhibit 5: Comparable Phase II oncology deals						
Date	Licensor	Licensee	Product (s)	Pharmacological class / Target	Upfront (\$m)	Milestones (\$m)
04/09/2020	AbbVie	I-Mab	lemzoparlimab (TCJ4)	anti-CD47 mAb	200	1,740
27/05/2020	Gilead	Arcus Biosciences	zimberelimab (AB122) domvanilimab (AB154)	anti-PD-1 mAb anti-TIGIT mAb*	175	1,225
05/02/2019	GSK	Merck KGaA	bintrafusp alfa (M7824)	TGF-βxPD-L1 bsAb	354	4,012
05/07/2017	Celgene	BeiGene	tislelizumab (BGB-A317)	anti-PD-1 mAb	263	980
10/02/2017	Seattle Genetics	Immunomedics	sacituzumab govitecan (Trodelvy)	TROP2 ADC	250	1,700
15/10/2015	BMS	Five Prime	Cabiralizumab (FPA008)	CSF-1R mAb	350	1,390
24/04/2015	AstraZeneca	Innate	Monalizumab (IPH2201)	anti-NKG2A mAb	250	1,025
Median					c 250	c 1,390

Source: Edison Investment Research, EvaluatePharma; Notes: *Gilead/Arcus deal includes options for additional assets not listed; we had excluded the licensing deals signed between [BMS/Nektar](#) and [AstraZeneca/Daiichi Sankyo](#) as an outlier (given the upfronts alone exceed Cantargia's current EV).

Financials

With its Q220 results, Cantargia reported an operating loss of SEK37.7m vs SEK25.2m in Q219. R&D costs were SEK333.7m vs SEK20.8m in Q219, an increase due to the Phase IIa CANFOUR study advancing, higher spending on CAN04 production development (CMC) and the maturing preclinical pipeline (CAN10 and CANxx). The results are largely in line with our expectations, so our estimates are unchanged. We note that until the outcome of the COVID-19 pandemic is known, spending visibility is decreased due to multiple possible effects. The reported cash position at end Q220 was comfortable at SEK458m (including short-term investments).

Exhibit 6: Financial summary

	SEK'000s	2018	2019	2020e	2021e
December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of Sales		0	0	0	0
Gross Profit		0	0	0	0
Research and development		(76,951)	(97,477)	(123,478)	(123,478)
EBITDA		(93,306)	(111,590)	(138,015)	(138,451)
Operating Profit (before amort. and except.)		(93,306)	(111,590)	(138,015)	(138,451)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(93,306)	(111,590)	(138,015)	(138,451)
Net Interest		2,145	780	0	0
Profit Before Tax (norm)		(91,161)	(110,810)	(138,015)	(138,451)
Profit Before Tax (reported)		(91,161)	(110,810)	(138,015)	(138,451)
Tax		0	0	0	0
Profit After Tax (norm)		(91,161)	(110,810)	(138,015)	(138,451)
Profit After Tax (reported)		(91,161)	(110,810)	(138,015)	(138,451)
Average Number of Shares Outstanding (m)		66.2	71.1	81.9	91.0
EPS - normalised (SEK)		(1.38)	(1.56)	(1.69)	(1.52)
Dividend per share (SEK)		0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		2,957	6,868	6,868	6,868
Intangible Assets		0	6,868	6,868	6,868
Tangible Assets		0	0	0	0
Investments		2,957	0	0	0
Current Assets		168,486	159,189	411,686	274,698
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		76,528	39,870	292,367	155,379
Other*		91,958	119,319	119,319	119,319
Current Liabilities		(16,398)	(23,785)	(23,785)	(23,785)
Creditors		(16,398)	(23,785)	(23,785)	(23,785)
Short term borrowings		0	0	0	0
Long Term Liabilities		0	0	0	0
Long term borrowings		0	0	0	0
Other long-term liabilities		0	0	0	0
Net Assets		155,045	142,272	394,769	257,781
CASH FLOW					
Operating Cash Flow		(105,165)	(111,853)	(138,015)	(138,451)
Net Interest		478	597	1,463	1,463
Tax		0	0	0	0
Capex		0	(6,880)	0	0
Acquisitions/disposals		0	0	0	0
Financing		0	98,037	389,048	0
Other		31,434	(16,559)	0	0
Dividends		0	0	0	0
Net Cash Flow		(73,253)	(36,658)	252,497	(136,988)
Opening net debt/(cash)		(149,781)	(76,528)	(39,870)	(292,367)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(76,528)	(39,870)	(292,367)	(155,379)

Source: Cantargia accounts, Edison Investment Research

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