EDISON

# Cantargia

R&D update

## CANFOUR interim Phase I presented at ESMO

Pharma & biotech

**On 20 October 2018, Cantargia presented interim data from part I of its Phase I/IIa CANFOUR trial with nidanilimab (IL1RAP antibody) at the ESMO congress in Munich, Germany, demonstrating a good safety/tolerability profile so far. The maximum tolerated dose has not been reached and so a final dose (10mg/kg) cohort is being recruited. The Phase IIa part of the study is expected to start in Q418 as planned. Meanwhile, on 25 September Cantargia's shares were up-listed to the Nasdaq Stockholm main market, which will expose the company to a wider investment community. Our valuation is virtually unchanged at SEK1.80bn or SEK27.2/share with the success probability rate subject to revision once the final Phase I data are published in Q418.**

| Year end | Revenue (SEKm) | PBT* (SEKm) | EPS* (SEK) | DPS (SEK) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/16 | 0.0 | (47.5) | (2.72) | 0.0 | N/A | N/A |
| 12/17 | 0.0 | (60.3) | (1.86) | 0.0 | N/A | N/A |
| 12/18e | 0.0 | (83.3) | (1.47) | 0.0 | N/A | N/A |
| 12/19e | 0.0 | (93.5) | (1.41) | 0.0 | N/A | N/A |

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

## Nidanilimab well tolerated so far

Phase I of the CANFOUR trial is testing nidanilimab in patients with solid cancers: non-small cell lung (NSCL), pancreatic, colorectal or triple negative breast cancers. Phase I was designed to establish the recommended dose for Phase IIa and to assess initial safety and tolerability (Exhibit 1). The data reported at ESMO were gathered from 16 patients. The patients received weekly infusions of between 1mg/kg and 6mg/kg and, in general, tolerated nidanilimab well with no treatment discontinuations or grade 4 or 5 adverse events. Infusion-related reactions were the most common adverse event (44%), as is often seen with other biologicals. The safety profile looks beneficial so far, in our view. Data from the higher dose cohort are expected in Q418, which is when the recommended dose will be selected.

## Early efficacy insights

Although Phase I of the trial was not designed for efficacy, initial clinical findings were also presented at ESMO. Of the 16 patients, five had stable disease by immune-related response criteria at eight weeks follow up, eight patients had progressive disease and three could not be evaluated. One patient with NSCLC had stable disease at six months. These patients received an average of 3.9 lines of treatment before receiving nidanilimab, so even though no conclusions about efficacy can be made at this early stage, the fact that clinical response was seen in such heavily pre-treated patients is welcomed.

## Valuation: SEK1.80bn or SEK27.2/share

We value Cantargia at SEK1.80bn (SEK213m in cash at end-H118) or SEK27.2/share, marginally higher than our previous SEK1.79bn or SEK27.1/share due to rolling forward our model. Cantargia is enrolling the last cohort in Phase I with the highest dose and still plans to initiate the Phase IIa part of the study in Q418. As previously, results from Phase IIa are expected in early 2020.

**30 October 2018**

| | |
|---|---|
| **Price** | **SEK18.10** |
| **Market cap** | **SEK1198m** |
| | US$:SEK9.05 |
| Net cash (SEKm) at end Q218 | 213 |
| Shares in issue | 66.2m |
| Free float | 90% |
| Code | CANT |
| Primary exchange | Nasdaq Stockholm |
| Secondary exchange | N/A |

### Share price performance


| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (20.3) | (6.2) | 104.3 |
| Rel (local) | (11.6) | 1.3 | 120.3 |
| 52-week high/low | SEK23.3 | | SEK6.4 |

### Business description

Cantargia is a clinical stage biotechnology company based in Sweden, established in 2009 and listed on Nasdaq Stockholm main market. It is developing two antibodies against IL1RAP, nidanilimab (CAN04) and CANxx. Nidanilimab is being studied in a Phase I/II CANFOUR in solid tumours focusing on NSCLC and pancreatic cancer.

### Next events

| | |
|---|---|
| Final cohort results from Phase I of CANFOUR | Q418 |
| Start of Phase IIa CANFOUR | Q418 |
| Q318 results | 15 November 2018 |
| Preclinical data | H218 |

### Analysts


Jonas Peciulis +44 (0)20 3077 5728

Alice Nettleton +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

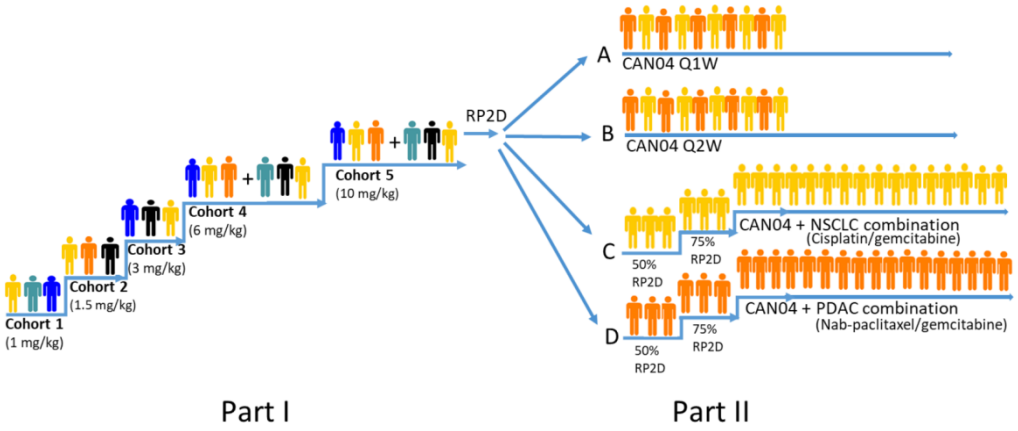
## Phase I/IIa CANFOUR design

**Exhibit 1: Phase I/IIa CANFOUR design, total n=65**

| Trial | Stage | Trial status, design and upcoming events |
|---|---|---|
| CANFOUR | Phase I | ■ Study ongoing (started September 2017)<br>■ Patients with relapsed or refractory NSCLC, pancreatic cancer, breast cancer or colorectal cancer<br>■ Design – open label, non-randomised, dose escalation followed by dose expansion, safety and tolerability study. Dose escalation: patients receiving intravenous nidanilimab once weekly in cohorts of three<br>■ **Well tolerated by the first 16 patients; findings from the highest dose cohort (10mg/kg) in Q418** |
| | Phase IIa | ■ Patients with advanced NSCLC or pancreatic cancer<br>■ Design – open label, non-randomised, three treatment arms: monotherapy; combinations in NSCLC; and pancreatic cancer<br>■ **Results early 2020**<br>■ Primary endpoint – safety and tolerability as monotherapy or in combination with standard chemotherapy regimen<br>■ Secondary end points – pharmacokinetic parameters, preliminary signs of efficacy (tumour response, health-related quality of life)<br>■ Study sites in EU |

Source: Edison Investment Research, Cantargia, clinicaltrials.gov.

**Exhibit 2: Phase I/IIa**




Source: Cantargia. Note: RP2D – recommended dose for Phase II; PDAC - pancreatic ductal adenocarcinoma.

The 16 patients that have been evaluated so far received weekly infusions of between 1mg/kg and 6mg/kg. There were three grade 3 adverse events in the higher dose cohorts, and no grade 4 or 5 adverse events. The most common treatment-related adverse event was an infusion-related reaction (44% of patients) during the first infusion, which resolved within a few hours. Only one patient experienced an infusion-related reaction during the second administration. One patient from the cohort receiving the highest dose at the time of analysis (6mg/kg, cohort 4) showed a dose-limiting toxicity leukopenia/neutropenia, which was reversible. Overall, nidanilimab appears to be well tolerated at dose 6mg/kg. The infusion-related reactions are common with antibody therapies and accepted as part of the treatment, as long as these are manageable.

## Next steps

Since the maximum tolerated dose has not been reached, patients are being enrolled at present into cohort 5 to assess a 10mg/kg dose. As previously, Cantargia expects to start the Phase IIa part of the CANFOUR trial by the end of 2018. By then the safety/tolerability findings from all the cohorts and recommended dose should be known. Cantargia will also report mature pharmacokinetics data

and biomarker analysis, which may provide further insights. For example, at the ESMO congress the company reported that after two doses of nidanilimab a decrease in IL-6 in 11 of 14 patients (versus baseline, p=0.06) and a decrease in CRP in nine of 11 patients (p=0.04) were observed, which is consistent with the nidanilimab's mode of action and indicates target engagement.

The Phase IIa part of the CANFOUR trial will evaluate nidanilimab as monotherapy as well as in combination with standard of care therapy in the target indications NSCLC (first line and second line) and pancreatic cancer (first line) (Exhibit 2). As previously, the results are expected in early 2020. We leave our assumptions in our model unchanged, as described in our initiation report. We will review our success probability for nidanilimab once the recommended dose has been established successfully.

## Exhibit 3: Financial summary

| SEK'000s | 2016 | 2017 | 2018e | 2019e |
|---|---|---|---|---|
| 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 | (35,493) | (44,819) | (65,219) | (77,699) |
| EBITDA | (47,557) | (60,010) | (85,845) | (93,815) |
| Operating Profit (before amort. and except.) | (47,557) | (60,010) | (85,845) | (93,815) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Exceptionals | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 |
| Operating Profit | (47,557) | (60,010) | (85,845) | (93,815) |
| Net Interest | 67 | (243) | 2,500 | 360 |
| Profit Before Tax (norm) | (47,490) | (60,253) | (83,345) | (93,455) |
| Profit Before Tax (reported) | (47,490) | (60,253) | (83,345) | (93,455) |
| Tax | 0 | 0 | 0 | 0 |
| Profit After Tax (norm) | (47,490) | (60,253) | (83,345) | (93,455) |
| Profit After Tax (reported) | (47,490) | (60,253) | (83,345) | (93,455) |
| Average Number of Shares Outstanding (m) | 17.5 | 32.4 | 56.6 | 66.2 |
| EPS - normalised (ore) | (2.72) | (1.86) | (1.47) | (1.41) |
| EPS - normalised fully diluted (ore) | (2.72) | (1.86) | (1.47) | (1.41) |
| EPS - reported (SEK) | (2.72) | (1.86) | (1.47) | (1.41) |
| Dividend per share (ore) | 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 | 2,662 | 2,957 | 2,957 | 2,957 |
| Intangible Assets | 0 | 0 | 0 | 0 |
| Tangible Assets | 0 | 0 | 0 | 0 |
| Investments | 2,662 | 2,957 | 2,957 | 2,957 |
| Current Assets | 35,636 | 271,126 | 173,196 | 79,741 |
| Stocks | 0 | 0 | 0 | 0 |
| Debtors | 0 | 0 | 0 | 0 |
| Cash | 25,904 | 149,781 | 61,496 | 78,041 |
| Other* | 9,732 | 121,345 | 111,700 | 1,700 |
| Current Liabilities | (9,494) | (27,957) | (14,600) | (14,600) |
| Creditors | (9,494) | (27,957) | (14,600) | (14,600) |
| 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 | 28,804 | 246,126 | 161,553 | 68,098 |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (42,405) | (40,860) | (100,787) | (93,815) |
| Net Interest | 67 | (243) | 2,500 | 360 |
| Tax | 0 | 0 | 0 | 0 |
| Capex | 0 | 0 | 0 | 0 |
| Acquisitions/disposals | 0 | 0 | 0 | 0 |
| Financing | 56,225 | 304,479 | 0 | 0 |
| Other | 2,376 | (139,499) | 10,002 | 110,000 |
| Dividends | 0 | 0 | 0 | 0 |
| Net Cash Flow | 16,263 | 123,877 | (88,285) | 16,545 |
| Opening net debt/(cash) | (9,641) | (25,904) | (149,781) | (61,496) |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | (0) |
| Closing net debt/(cash) | (25,904) | (149,781) | (61,496) | (78,041) |

Source: Cantargia's accounts, Edison Investment Research. Note: *Mainly short-term investments.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia