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Corporate Research

Fluoguide

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Trial part 1 complete with apparently good safety profile for FG001

Management announced Friday afternoon that lead product FG001 was found safe and to have lit up brain tumours in 25 of 27 pts in part 1 of its phase 1/2 trial. With an optimal dose now selected, the next step will be to optimise dose timing, so management expects part 2 (the efficacy part) of the trial to begin in Q1/22, as previously guided. We have yet to see safety data, but, overall, it appears to be about as good a result as one could hope for. Small positive.

An important step in the right direction

We note that the two patients whose cancers did not light up were treated with the lower doses, so in our view, this is not of concern. Indeed, it is promising that of the two brain cancers that were not glioblastoma, both also lit up, suggesting broader utility of FG001 in brain cancers than we had initially anticipated.

Overview of data from part 1 of the phase 1/2 trial of FG001

Safety and tolerability overview								
Cohort	Dosing	Dose (mg/pt)	Patients (#)	GBM ^{*)} (#)	Non-GBM (#)	Light seen (#)	Light Seen (%)	Safe
1	morning	1	3	3	0	2	67%	Yes
2	morning	2	3	3	0	3	100%	Yes
3	morning	4	3	3	0	2	67%	Yes
4	morning	8	4	3	1	4	100%	Yes
5	morning	16	3	3	0	3	100%	Yes
5a	evening	16	5	4	1	5	100%	Yes
6	morning	24	3	3	0	3	100%	Yes
7	morning	36	3	3	0	3	100%	Yes
Total			27	25	2	25	NA	Yes

^{*)} High grade glioma

Source: Company data

We note that, as a rule, adverse events will always have been reported in clinical trials, so although it may have been determined that FG001 is safe, investors should hold off on full judgement on the trial results until they have at least been published.

Key figures				
(DKKm)	2020	2021E	2022E	2023E
Revenues (m)	3	6	0	0
Adj. EBIT	(22)	(34)	(65)	(78)
PTP (m)	(22)	(34)	(65)	(78)
EPS	(1.75)	(2.40)	(4.26)	(5.09)
EPS (adjusted)	(1.75)	(2.40)	(4.26)	(5.09)
DPS	0.00	0.00	0.00	0.00
Revenue growth (%)	0.0	0.0	0.0	0.0
EPS growth (%)	n.a.	n.a.	n.a.	n.a.
Operating margin (%)	0.0	0.0	0.0	0.0
ROCE (%)	(495.1)	(118.8)	(81.7)	(102.5)
Net Debt/EBITDA (x)	0.5	1.7	1.8	0.8
PER (adjusted)	(50.4)	(29.5)	(16.6)	(13.9)
Dividend yield (%)	0.0	0.0	0.0	0.0
Free Cash Flow Yield (%)	(1.0)	(3.7)	(5.5)	(6.6)
P/BV (x)	210.7	15.1	7.9	18.5
EV/EBIT (x)	(41.5)	(21.8)	(11.2)	(10.1)
EV/Sales (x)	n.m.	n.m.	n.m.	n.m.

Source: SEB

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