

**O** Outperform • Long term (3 years)**B** Buy • Short term (3 months)

# Photocure

## Phase 3 abstract for Cevira shows impressive response rate

- Abstract shows more details from Phase 3 trial (n=402) of out-licensed asset Cevira...
- ... shows 19% placebo-adjusted clearance of pre-cancerous cervical lesions (p=0.0001)
- Positive – but more details due at the EUROGIN presentation on March 16

### Cevira delivers 19% placebo-adjusted response – in-line with 20% 'expectation'

In September 2023, we provided our [first-take](#) on the Phase 3 top-line results of Photocure's outlicensed asset Cevira, which contained very limited details. Today, we received another piece of the puzzle with an [abstract](#) providing additional data points. As illustrated below, in a 402 patient Phase 3 trial from eight countries (including Germany and the Netherlands), Cevira showed a response rate of 41.1% versus placebo of 21.7%, a ~19% placebo-adjusted response rate. According to the [study protocol](#), the trial was powered to show a ~20% placebo-adjusted response rate, with a 60% response from Cevira and 40% from placebo. We believe the lower response rate in the Phase 3 trial is explained by it treating higher-grade and more difficult-to-treat tumours compared to the Phase 2b trial, which the protocol was based on. Treatment emergent adverse events (TEAEs) in the Cevira and PBO groups were 57% and 56%, respectively. The majority of TEAEs were mild, and the incidence of serious adverse events were 1.5% in both treatment groups. The abstract did not specify error rates or drop-out rates, but based on the Phase 2b results, an 8% error rate of pathological assessment and 10% dropout rate was expected. Overall, we view the results as strong and they appear to be clinically meaningful. We do however hope to get more details on how many patients followed the trial protocol and the share of patients with CIN 2 and CIN 3 tumours, respectively.

### Next step – oral presentation at the EUROGIN congress on March 16

The study will be presented for the first time in the form of an oral presentation at the 2024 European Research Organization on Genital Infection and Neoplasia (EUROGIN), according to partner [Asieris](#). We will attend the presentation scheduled for Saturday, March 16 at 11:15-11:24 CET in Stockholm. We also note that the results have been selected for late breaking oral presentation at the 2024 Society of Gynecologic Oncology (SGO) congress in San Diego, to be held on March 16-18. We will try to get feedback on the data from key opinion leaders, and whether it is perceived to be practice-changing data, and whether additional data will be needed to achieve European market approval.

### Attractive deal economics with Chinese regulatory filing likely next step

In July 2019, Photocure signed a [global licensing agreement](#) with Chinese specialty pharma company Jiangsu Yahong Meditech (also known as "Asieris") to develop and commercialise Cevira. Photocure has the rights of up to USD 200m in milestone payments (mostly related to sales thresholds) as well as tiered sales royalties ranging from 10-20%. Photocure would receive USD 13m upon potential Chinese regulatory approval (expected 2025) and USD 31m upon potential EU/US approval. The partner Asieris IPO'd in China in early 2022, with two of three of its late-stage pipeline assets coming from Photocure (Cevira and Hexvix). We have translated and studied Asieris' IPO prospectus and have made two key findings: 1) following its registrational trials, it expected commercial launches of both Cevira and Hexvix during 2024, and 2) Asieris guides for USD 500-800m in sales for Cevira by 2030 in China alone based on 15-25% penetration rates and a price of CNY 7,500 per treatment in a ~2.6 million addressable patient population. This would translate into NOK 800m-1bn annual royalty potential for Photocure. Our risk-adjusted stand-alone valuation of Cevira points to NOK 35 per share (NOK 89 de-risked).

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Company data

NOKm	2021	2022	2023	2024e	2025e
Sales	361	393	501	482	559
Sales growth (%)	40.6	8.9	27.5	-3.8	16.1
Gross margin (%)	93.3	94.3	94.8	94.0	94.0
EBIT adj margin (%)	-5	-43	28	1	67
EBT	-31.1	-65.4	9.8	-13.9	52.8
EPS rep (NOK)	-1.14	-2.65	0.01	-0.40	1.52
EPS adj (NOK)	-1.14	-2.65	0.01	-0.40	1.52
P/E adj (x)	n.m	n.m	>99	n.m	35.6
P/BV (x)	5.5	6.3	3.8	3.1	2.9
ROE adj (%)	-6.1	-14.9	0.06	-2.3	8.4
EV/EBIT (x)	n.m	n.m	57.2	>99	18.0
EV/EBITDA (x)	>99	n.m	28.7	39.6	12.3
EV/sales (x)	7.0	6.8	3.2	2.6	2.2
FCF adj yield (%)	0.72	-0.19	2.0	-0.02	3.0
Tot DPS	0.00	0.00	0.00	0.00	0.00
Net debt/equity (%)	-50.2	-48.4	-48.9	-47.9	-50.6
Target price (NOK)	125				

Source: Handelsbanken Capital Markets

Cevira uses the same active ingredient as Hexivix for its HAL gel (2030 patent)



Cevira drug delivery device

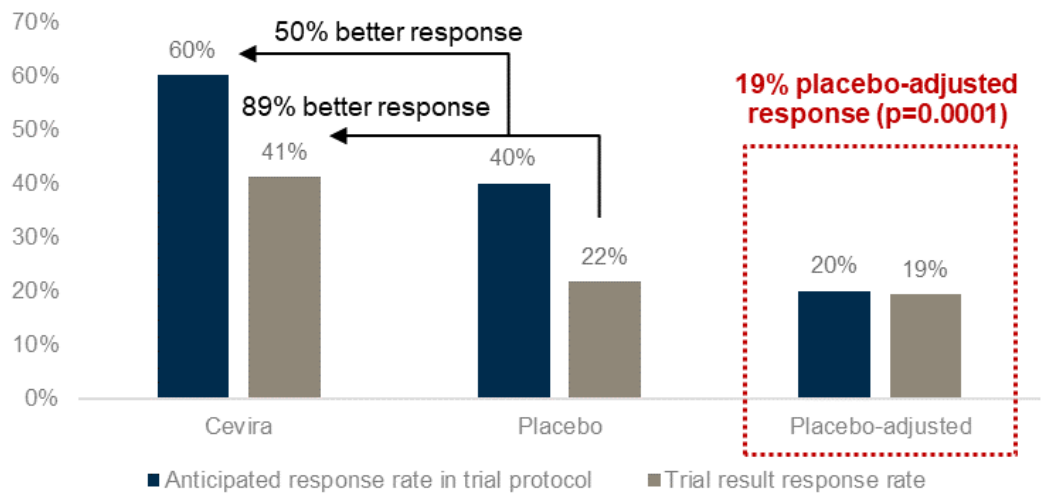
HAL gel is applied to the device

Cevira drug delivery device is administrated locally in the cervix

Source: Handelsbanken Capital Markets

Response Rate - comparing the trial protocol expectations versus the outcome

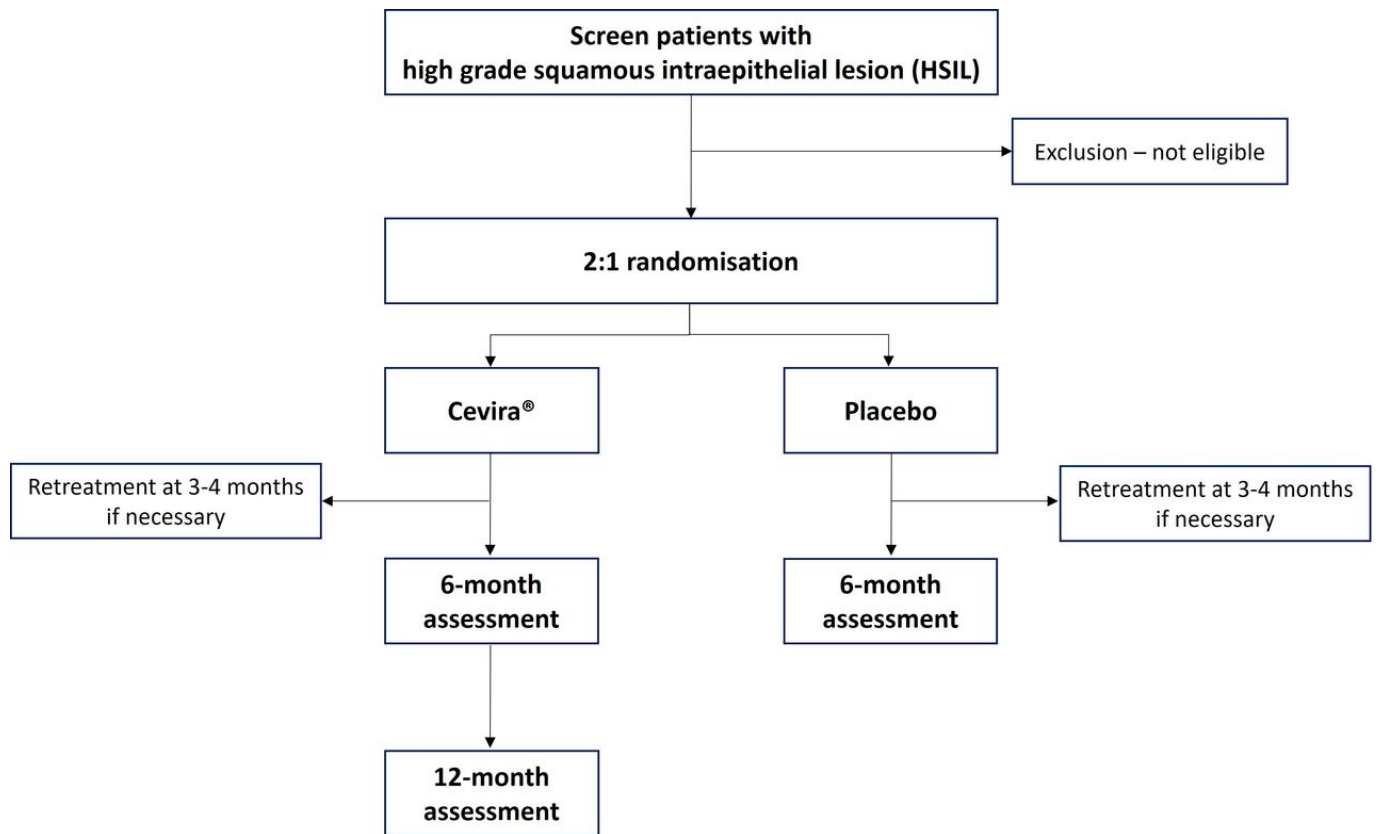
Based on the Ph2 trial, the study protocol expected a 60% reponse rate for Cevira and 40% for placebo, we believe the lower response rate was due to the Ph3 trial including tougher higher-grade tumours - but ~20% placebo-adjusted response rate for Cevira was spot-on



Source: Handelsbanken Capital Markets

Note: Abstract: [https://agenda.euromedicom.com/pdf/abstract.php?id\\_manifestation=363&id\\_abstract=6939](https://agenda.euromedicom.com/pdf/abstract.php?id_manifestation=363&id_abstract=6939)

APRICITY Phase 3 study design: 402 patients enrolled (target was 'at least' 384)



Source: Handelsbanken Capital Markets

Partner Asieris guided for CNY 3-5bn Cevira sales by 2030

峰值渗透率为 15%。在 15%~25% 峰值市场渗透率区间内进行弹性测算, APL-1702 到 2030 年在国内市场空间可达 29.38~48.97 亿元; 即使在最终未被纳入医保目录的很小概率悲观情形下, 按照仅 10% 的峰值市场渗透率测算, APL-1702 的市场空间也可达到 19.59 亿元。因此, APL-1702 市场空间较为广阔。具体弹性分析测算结果如下表所示:

年度	2023 年	2024 年	2025 年	2026 年	.....	2030 年
<b>情形 1: APL-1702 被纳入医保, 市场渗透率乐观</b>						
市场渗透率	-	0.63%	6.25%	11.25%	.....	25.00%
治疗费用 (万元/次)	-	0.75	0.75	0.75	.....	0.75
市场销售规模 (亿元)	-	1.24	12.35	22.20	.....	48.97
<b>情形 2: APL-1702 被纳入医保, 市场渗透率中性</b>						

Source: Handelsbanken Capital Markets, Jiangsu Yahong Meditech IPO Prospectus 2021

## Photocure

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13 Mar 2024: Photocure - Handelsbanken's analysts Rickard Anderkrans and Mattias Häggblom have no positions in Photocure or a related instrument.

Handelsbanken beneficially owns one percent or more of any class of common equity securities of the company that is the subject of this research report.

The short-term recommendation Buy was set on 25 Mar 2022 as the first short-term recommendation for the company at the share price of NOK 111.1.

The long-term recommendation Outperform was set on 25 Mar 2022 as the first long-term recommendation for the company at the share price of NOK 111.1.

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