

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

Photocure

Sure looks approvable to us

- We attended the EUROGIN HPV Congress for a presentation of the Cevira Phase 3 data...
- ...with solid response rates across all relevant subgroups which should support approval...
- ...where Chinese regulatory filing in Q2 2024 and approval 2025 could bring USD 13m

Solid response rates across all relevant subgroups

We attended the EUROGIN 2024 Congress in Stockholm to see the first-ever presentation of Cevira's Phase 3 trial 'APRICITY', Photocure's out-licensed asset to Chinese partner Asieris (see our previous commentary from the [top-line announcement](#) and the [abstract publication](#)). The trial was presented by the European Principal Investigator Prof. Peter Hillemanns from the prestigious CCC Hannover - where we note that the trial included 44 Chinese recruiting sites, and 17 in Europe. Of the 382 analysed patients, 80% were from China, and 20% from Europe. Looking at pathology, 48% of patients were classified as CIN 2, and 52% as CIN 3. The CIN 3 lesions are generally more aggressive and tougher to treat. We already knew Cevira met the primary endpoint 41% response rate and 19% placebo-adjusted response after six months ($p=0.0001$). However, we also view the subgroup analysis as highly encouraging, as illustrated below. We highlight three key points: 1) Solid 20% placebo-adjusted response in Chinese patients, which will likely be an important finding for the Chinese regulators; 2) strong absolute and relative response in patients <30 years, a key patient group with Cevira's benign safety profile to preserve fertility and 3) a 49% absolute and 27% placebo-adjusted response rate in CIN 2 patients, another key patient cohort as physicians are more likely to opt for non-invasive treatments given the lesions are less aggressive and more likely to regress naturally. All in all, we continue to view the data as solid, with an encouraging safety and efficacy profile. We look forward to the 12-month follow-up data, to see how long the responses last. It caught our interest that one of the first questions from the audience following the presentation was whether this product was available on the market yet.

Congress feedback: Robust trial that should support approval and sales uptake

Feedback from the congress suggests that it is viewed as a robust, well-balanced, 'western grade' trial (designed according to EU/US standards), which should be enough for a regulatory approval – at least in China to begin with. The 19% placebo-adjusted response rate was generally viewed as strong, and enough to promote a good uptake in CIN 1 and CIN 2 patients (~80% of the patient volume). One physician suggested Imiquimod could be a reasonable commercial analogue for Cevira, a topical treatment for external genital warts with similar placebo-adjusted response rates which reached USD >340m sales in the US alone, before facing generic competition in 2011. The physician did, however, note that Cevira appears to have a superior safety profile. We discussed the potential for Cevira to become a 'first line treatment' for CIN 1 and 2 patients, as it appears far superior to the 'wait and see' approach often applied for these patients. It is still unclear whether the trial will be enough to support a European approval, but feedback was clear that an additional trial would likely be needed for US approval. The trial was also [presented at the SGO Congress](#) in San Diego on March 17 as a 'late-breaking abstract', which we believe could be an excellent opportunity for Asieris to find a partner to help develop and commercialise Cevira for the US market. Photocure will retain its rights to Cevira even if it is sub-licensed to another partner for the US market.

Chinese approval would lift rNPV valuation to NOK 63 per share for Cevira alone

We expect that Photocure's partner Asieris will file for Chinese regulatory approval in Q2 2024. With a 12-18 months review time, this could imply a regulatory approval in 2025. Photocure is due to receive a milestone payment of USD 13m following regulatory filing and regulatory approval in China (split not disclosed). While vaccines are reducing the rates of cervical lesions and cancer, the market remains significant, particularly in emerging markets. According to Frost & Sullivan, the number of HSIL patients is projected to reach 16.6m globally and 2.2m in China by 2030. At the IPO, Asieris guided 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 (significantly above our USD ~190m 2030 estimate for Cevira sales in China). This would translate into NOK 800m-1bn annual royalty potential for

Photocure. Our risk-adjusted NPV valuation of Cevira stands at NOK 35 per share, and at NOK 89 per share removing all risk-adjustments. However, our stand-alone valuation of the asset would rise to NOK 63 per share if we apply a 100% probability of success in China, which is above the current company valuation of NOK 60 per share. Our forecasts currently assume a 45% probability of success in China, and 25% for both Europe and the US. Photocure has the right to tiered royalties between 10-20% on global sales of Cevira, and up to USD 200m in milestones.

Rickard Anderkrans, +46 73 337 4501, rickard.anderkrans@handelsbanken.se

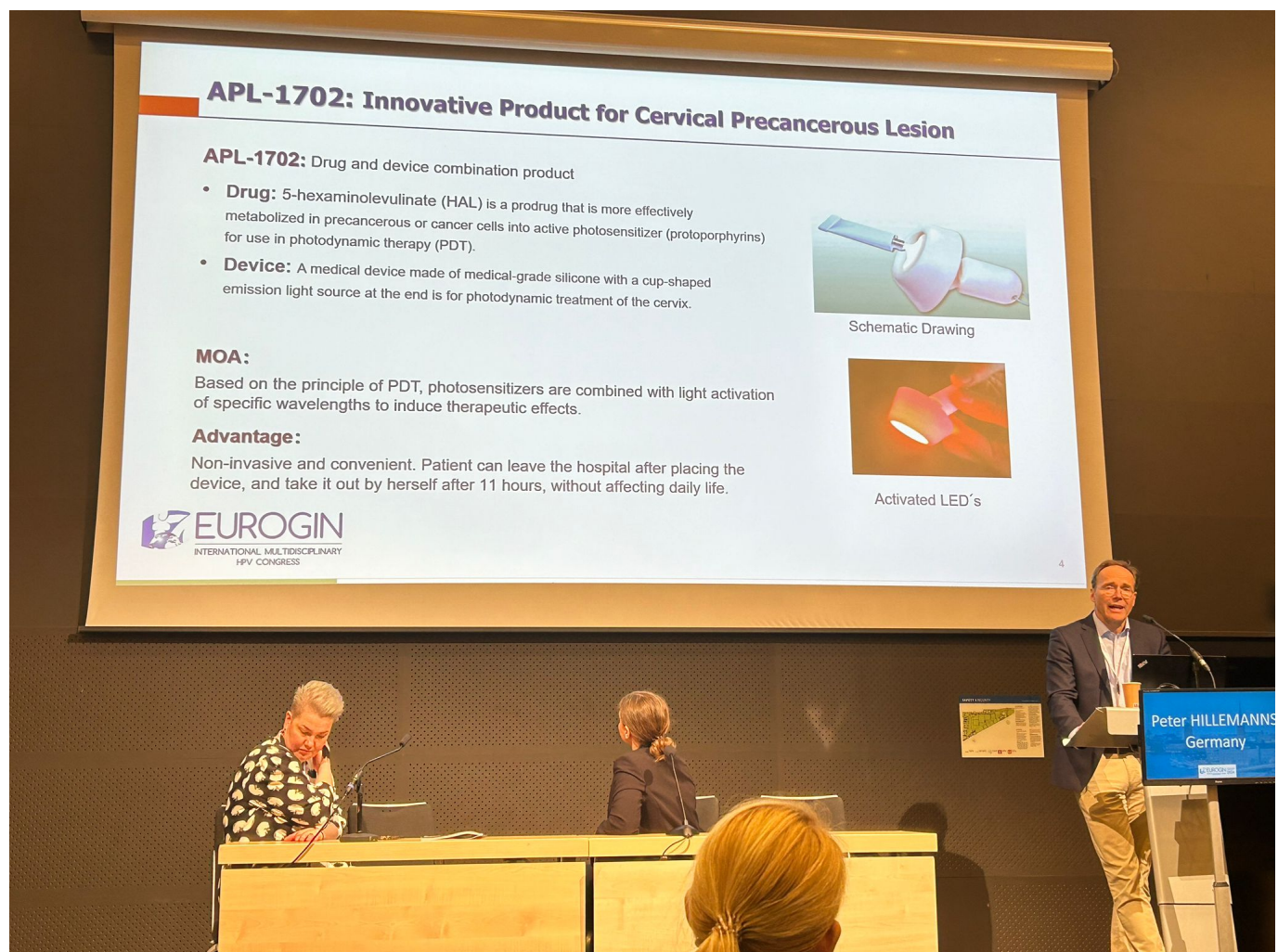
Mattias Hägglom, +46 70 204 4078, mattias.haggblom@handelsbanken.se

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	-5	-43	28	1	67
margin (%)	-1.5	-11.0	5.6	0.24	11.9
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	39.4
P/BV (x)	5.5	6.3	3.8	3.4	3.2
ROE adj (%)	-6.1	-14.9	0.06	-2.3	8.4
EV/EBIT (x)	n.m	n.m	57.2	>99	20.4
EV/EBITDA (x)	>99	n.m	28.7	44.6	13.9
EV/sales (x)	7.0	6.8	3.2	2.9	2.4
FCF adj yield (%)	0.72	-0.19	2.0	-0.02	2.7
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 (APL-1702) Phase 3 data was presented by Dr. Hillemanns from CCC Hannover



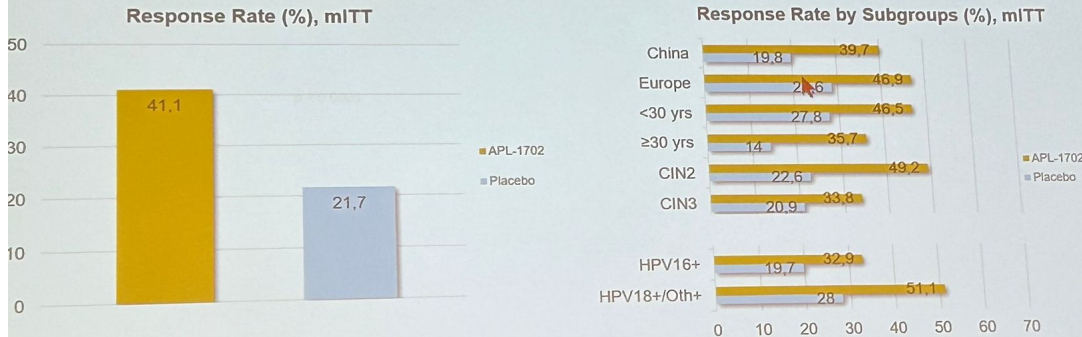
Source: Handelsbanken Capital Markets

Cevira showed 41.1% response rate, significantly above placebo 21.7% (p=0.0001)

Outcome of Primary Endpoint

Response rate: Response rates in APL-1702 group and placebo group are **41.1%** and 21.7% respectively (p = 0.0001) in mITT population. The study has achieved its primary endpoint.

PP population, the response rate in APL-1702 group and placebo group are **42.9%** and 22.9% respectively (p = 0.0002)



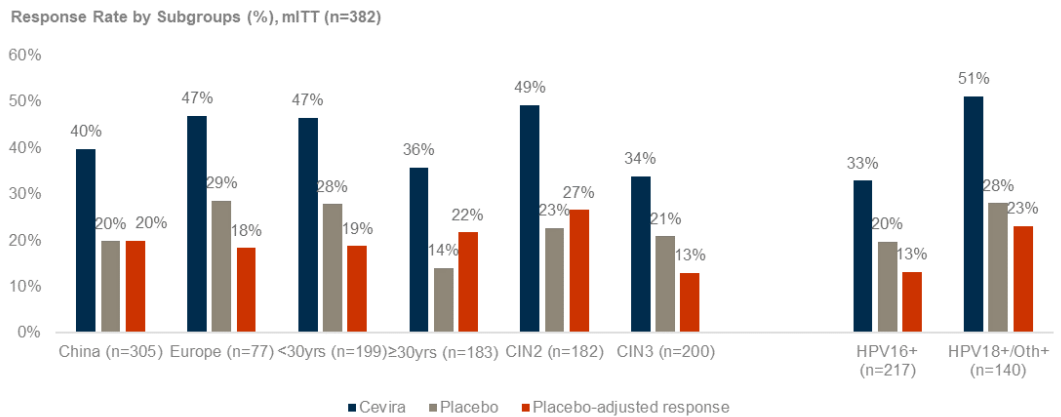
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Source: Handelsbanken Capital Markets

The result was solid across all relevant subgroups after six months

Strong response rate in Chinese patients (Chinese approval first priority), patients <30yrs (fertility key) and patients with CIN2 tumors (key patient group for commercialisation)



Source: Handelsbanken Capital Markets

Key secondary endpoint: Successfully clearing high-risk HPV-types 16 and 18

Secondary Endpoint: HPV16+ /18+ Clearance

- **HPV16+ clearance Rate: 31.5%** of HPV 16 patients with clearance of baseline HPV16 positive in APL-1702 group and 16.9% in placebo group. The difference of two groups was 14.61% (95% CI: 0.55, 25.73).
- **HPV16+/18+ clearance Rate: 31.4%** of HPV 16 and/or HPV 18 patients with clearance of baseline HPV16+/18+ positive in APL-1702 group and 15.4% patients in placebo group. The difference of two groups was 16.03% (95% CI: 2.08, 26.52). The APL-1702 group was twice the value of the placebo group.

HPV16+ clearance Rate (%), mITT

Group	Clearance Rate (%)
APL-1702	31.5
Placebo	16.9

HPV16+/18+ clearance Rate (%), mITT

Group	Clearance Rate (%)
APL-1702	31.4
Placebo	15.4

EUROGIN INTERNATIONAL MULTIDISCIPLINARY HPV CONGRESS

Source: Handelsbanken Capital Markets

Main safety data - solid safety profile with no systemic toxicity risks

Main Safety Data

TEAEs in the APL-1702 group and placebo group are 56.8% and 56.0% respectively. The majority TEAEs are mild. TRAEs in the APL-1702 group and placebo group are only 31.6% and 26.1% respectively. **No discontinuation due to TRAE.**

SAEs: The incidence of SAEs are very low, 1.5% in both groups. (In APL-1702 group, 4 patients had 4 SAEs, 3 spontaneous abortion, 1 biochemical pregnancy, 1 femur fracture and 1 appendicitis. In placebo group, 2 patients had 3 SAEs, including spontaneous abortion, ectopic pregnancy and ankle fracture.)

Overview of All TEAEs (%), Safety population

Group	Total TEAEs (%)
APL-1702	56.8%
Placebo	56.0%

Top 10 TEAEs	APL-1702	Placebo	Total
Vaginal discharge	35 (13.2)	5 (3.7)	40 (10.0)
Vaginal infection	20 (7.5)	17 (12.7)	37 (9.3)
Abdominal pain	21 (7.9)	5 (3.7)	26 (6.5)
Vaginal hemorrhage	15 (5.6)	7 (5.2)	22 (5.5)
Abdominal pain lower	12 (4.5)	4 (3.0)	16 (4.0)
Upper respiratory tract infection	7 (2.6)	8 (6.0)	15 (3.8)
Abdominal discomfort	11 (4.1)	2 (1.5)	13 (3.3)
Vulvovaginal pain	8 (3.0)	4 (3.0)	12 (3.0)
COVID-19	7 (2.6)	4 (3.0)	11 (2.8)
Vulvovaginal discomfort	7 (2.6)	4 (3.0)	11 (2.8)

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Source: Handelsbanken Capital Markets

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18 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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