



Brilliance in photodynamic technology™

HAL PDT for HPV infection

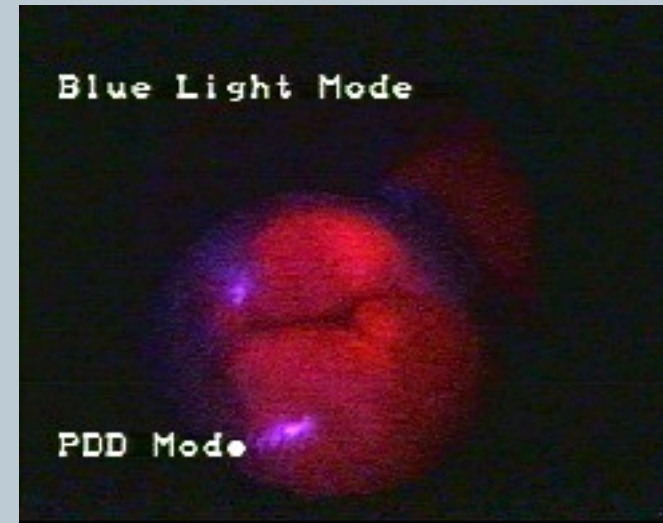
5 June 2007

HAL PDT – the first therapeutic for HPV infection

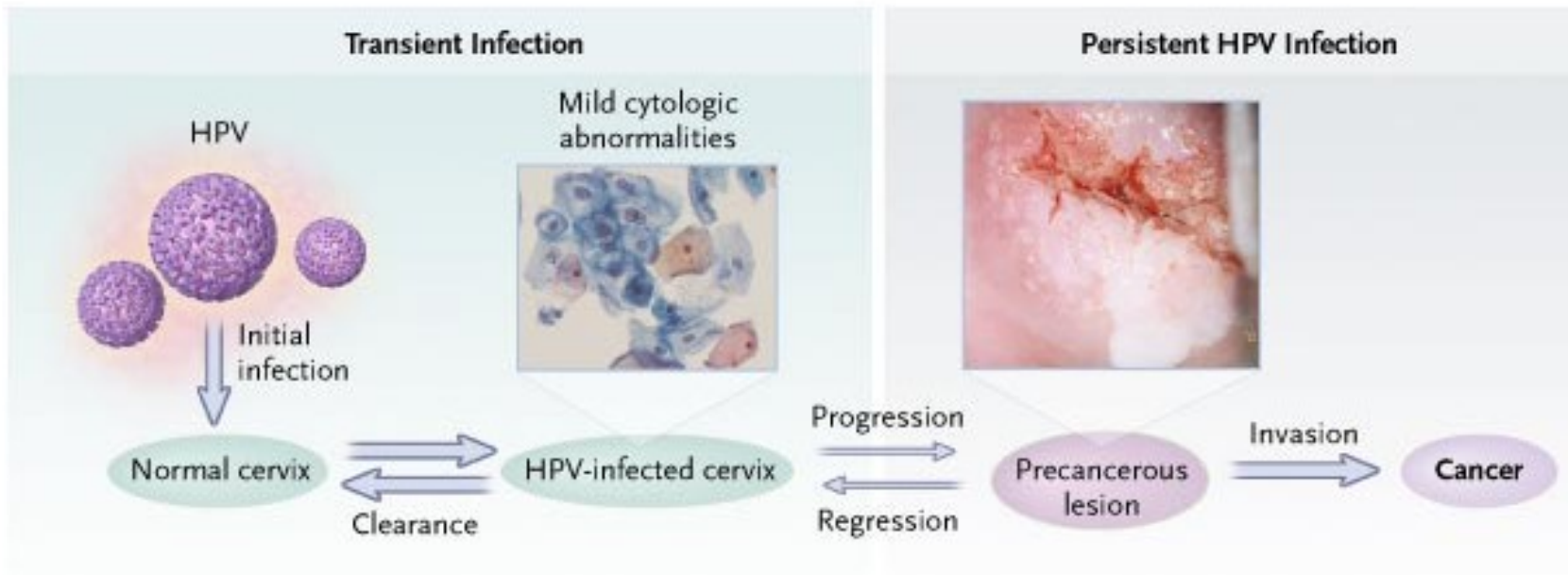


- HPV-related disease, a major global health problem
- HAL PDT preserves normal tissue
- Established technology
- Strong proof-of-concept (PoC) data
- Strong intellectual property

Red light on drug exposed tissue



Natural development from HPV infection to cervical cancer



ASCUS → CIN I → CIN II → CIN III → cancer
Mild abnormalities precancer

Wright and Schiffman, NEJM 2003

HPV infection - high prevalence and sexually transmitted



- HPV is a highly prevalent sexually-transmitted infection, which affects 80% of all women during their lifetime
- An estimated 30 million women in the US and EU have “persistent” HPV at a 10% risk of CIN II-III and cervical cancer
- HPV leads to 7 million diagnoses of ASCUS and CIN I-III every year in the US and EU

Our target market segments have a potential value close to €3bn



Persistent HPV
infection

€13bn

ASCUS / CIN I

€2.6bn

CIN II/III

€430m

NOTE: Estimates calculated from
prevalence data and Hexvix EU
floor price of €400

There is a high level of unmet need in our target patient segments



Patient profile

Unmet need

1. Women diagnosed with high-risk HPV infection with ASCUS/CIN I



Treatment that will prevent progression to CIN II/III and cancer

2. Women diagnosed with CIN II/III who are referred for excision surgery



Non-surgical treatment without side effects

1. Need for treatment of mild HPV-related abnormalities



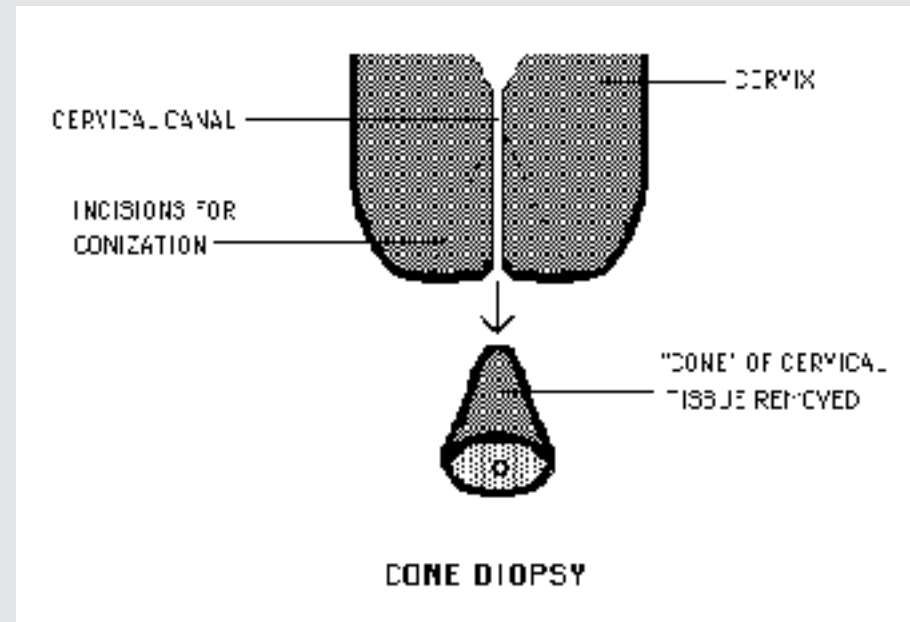
- HPV testing is identifying a large population of newly diagnosed women with high-risk HPV infection
- HPV diagnosis causes high levels of anxiety
 - Fear of disease progression to precancer/cancer
 - Anxiety over having a sexually-transmitted disease
- ~30% of patients with ASCUS/CIN I are misdiagnosed and have more severe lesions (CIN II/III)

“Women anxiety of a positive HPV-test is higher compared to having a positive cytology test” – Doctor, UK

2. Women with CIN II/III will demand a non-surgical treatment - if available



- Conisation surgery does not discriminate normal from dysplastic tissue
- Surgery causes patient anxiety because risk of cervical damage incl. preterm delivery, stenosis and reduced fertility

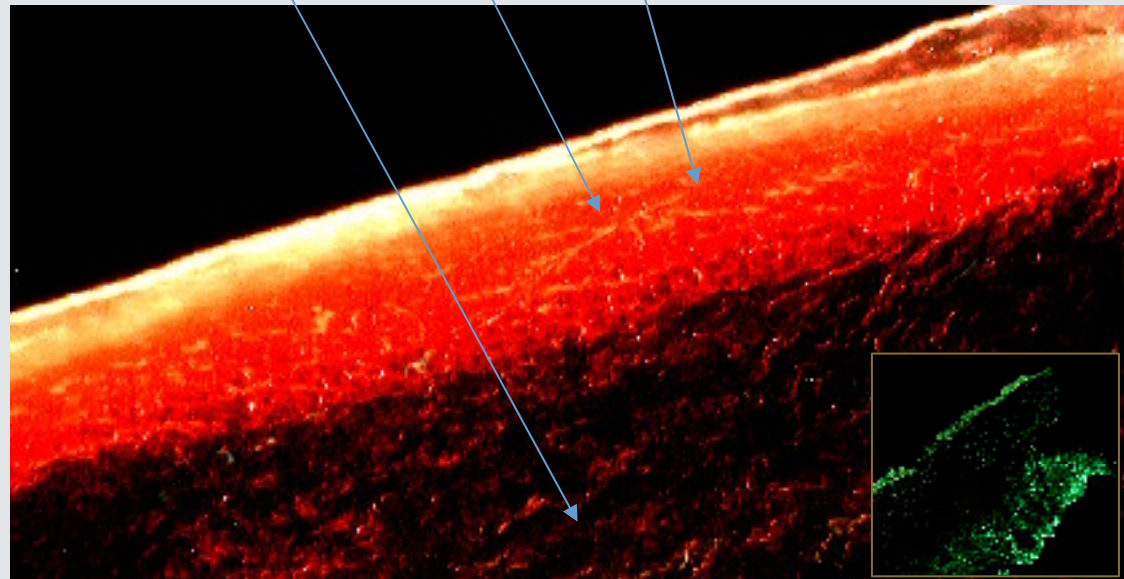


**“My heart hurts every time I perform a conisation on a young girl”
– Gynaecologist, Norway**

HAL PDT is effective and promising in HPV infection



- HPV infects and transforms the epithelium
- PDT destroys infected tissue, but
- Preserves normal tissue
- No severe side effects



Courtesy: Hillemanns, Hannover



Clinical proof-of-concept study

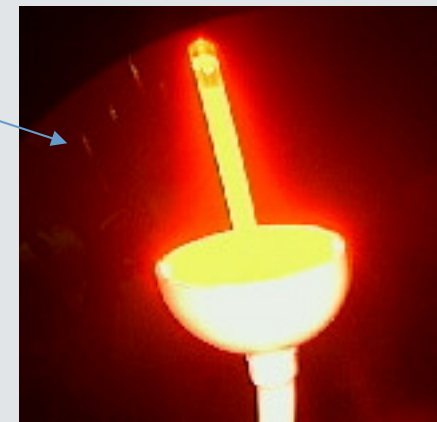
Rationale

- Show HAL PDT feasibility
- 24 women with HPV and CIN I-III
- HAL gel application
- Red 633nm light (PDT)



Endpoint

- Biopsy confirmed removal of HPV infection and dysplasia





PDT removes HPV and CIN lesions

	Number patients	Patients in complete remission	
CIN I	7	5	71%
CIN II/III	17	10	59%
Total	24	15	63%

100% correlation of HPV and precancer removal



HAL PDT is safe

Systemic adverse events:

- None

Local adverse events:

- Mild vaginal discharge for 2 days
- One patient with minor uterine cramping



Phase IIa study in progress...

Design

- Randomised and double blind
- HAL dose-finding to improve efficacy
- ~100 women eligible for conisation (CIN II/III)
- Ullevål and Hannover University Hospitals

So far...

- 50 patients included
- No serious side effects
- Results expected 1Q 2008

HPV vaccines are not treatments for HPV infections



- Today's HPV vaccines will only offer protection against approximately 50% of cancer-causing infections
- The first vaccination effects on the incidence of precancerous lesions will not come until 15 years, with a maximum effect 50-60 years after full vaccination uptake
- Our business forecasts take into account the long-term uptake of vaccines

Development Plan



- **Confirmatory phase IIb study**

Planned Start	2008
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Planned Completion	2009
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- **Phase III studies:**

Planned Start	2010
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Planned Completion	2011
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- Development of **new drug formulation, lamp, light catheter** in progress - available for Phase II study 2008
- Select partner(s) to successfully commercialise the product

Target regulatory submissions US/EU in 2011

HAL PDT – the only therapeutic option for HPV infection



- Cervical surgery for CIN II/III causes anxiety and morbidity that may affect fertility and future pregnancy.
- There is no current treatment for women diagnosed with ASCUS/CIN I caused by HPV infection
 - 30% of ASCUS/CIN I diagnoses have CIN II/III
 - Anxiety of potential disease progression without treatment
- Our target market is conservatively valued at €3bn with a high potential upside in patients with persistent HPV infection only.
- HPV tests and vaccines will cause a huge increase in awareness of the link between HPV and cancer.

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