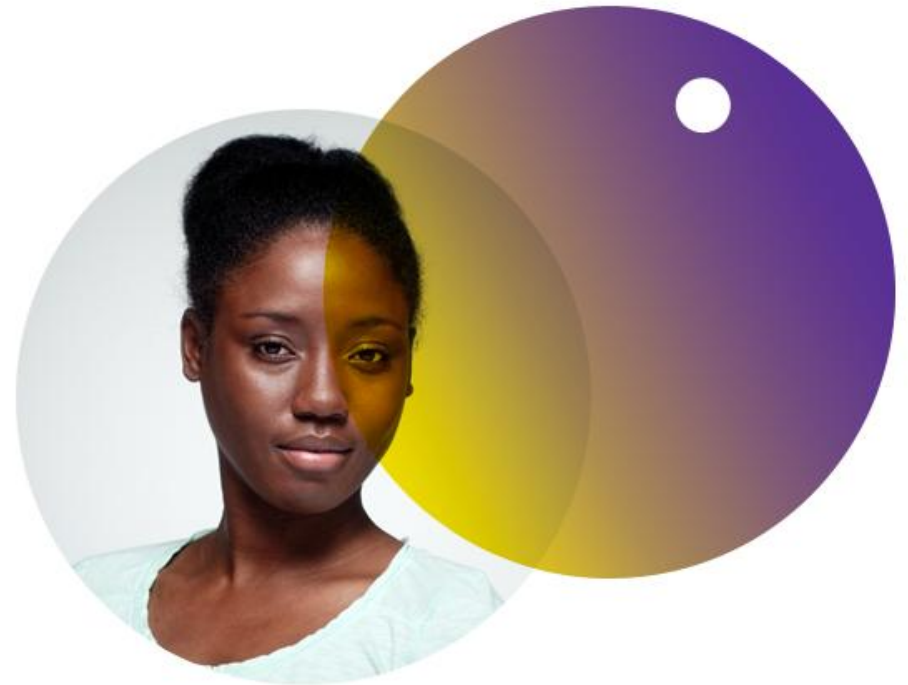


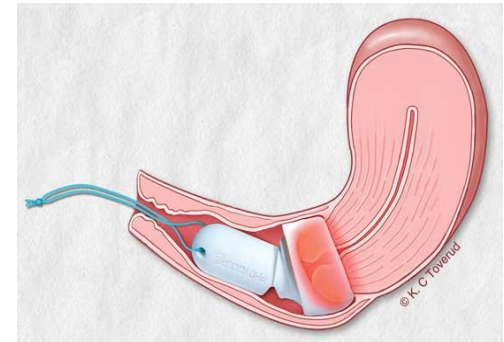
CEVIRA®  
Phase 2b  
Clinical Trial  
3 Month Results

DECEMBER, 2012



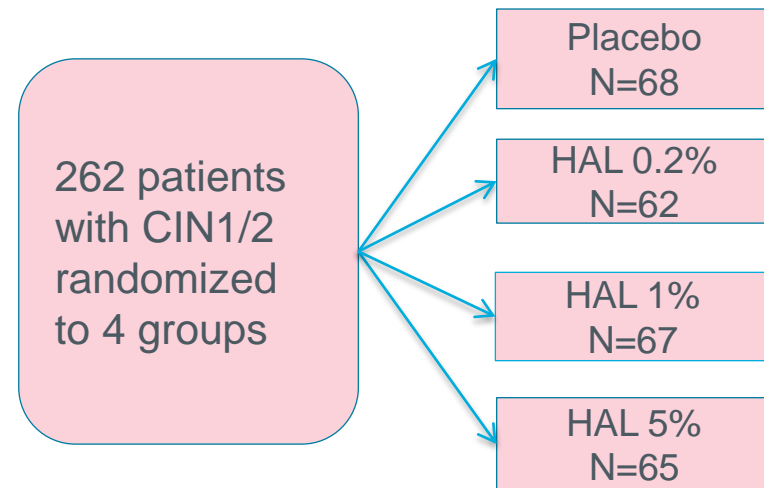
# Objective of Cevira Phase 2b study

- To verify feasibility, efficacy and safety of the new Cevira photodynamic treatment in a placebo controlled multicenter Phase 2b study in patients diagnosed with CIN1 or CIN2
  - Previous Photocure studies with laser showed excellent efficacy and safety signals in CIN1/2
  - Current study is the first multicenter with the new integrated drug device
- To define the optimal efficacy endpoint(s) and patient population(s) to enable design of further clinical program
- To assess the optimal dose of hexylaminolevulinate (HAL)



# Main Study Metrics

- Enrolled 262 patients (average age 29 years) with local histology confirmed CIN1 or CIN2 (safety population)
- 191 patients with CIN 1 and 2 verified by central blinded review (efficacy population)
- 128 CIN1/2 patients with positive HPV DNA status
- 50 CIN 1/2 patients with positive HPV 16/18 DNA status
- 1 or 2 treatments depending on results at 3 months
  - 50% of the patients received two treatments
- Patients enrolled at 23 centres in EU and US



# Clinical Trial End Points



- **Primary efficacy /overall response**

- Histology (central review)
- Cytology
- HPV DNA genotyping

- **Safety assessments**

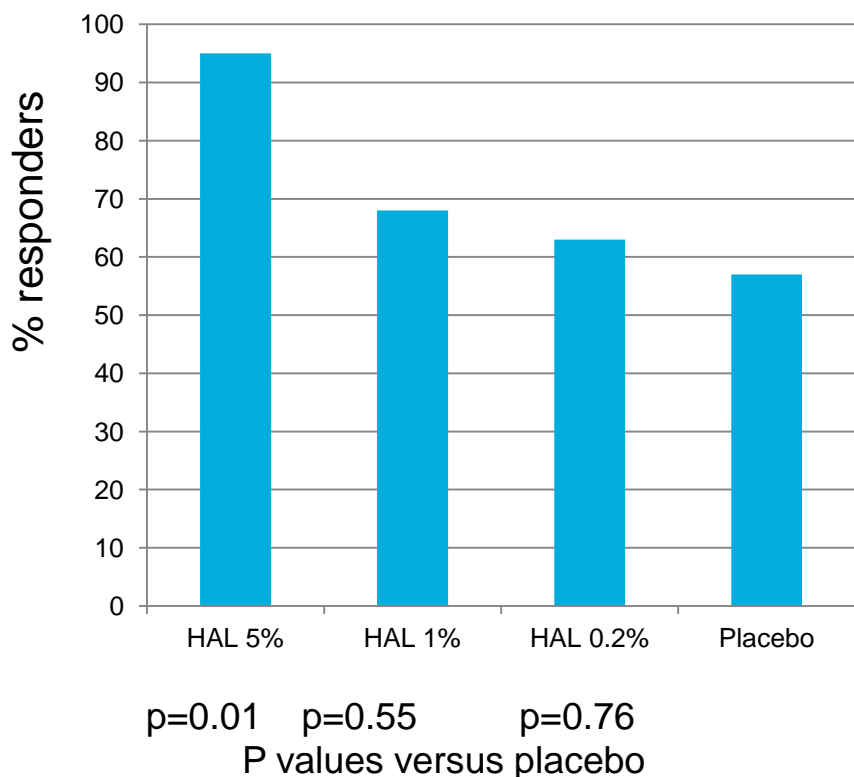
- Local tolerance
- Systemic toxicity
- Adverse events

- **Secondary efficacy**

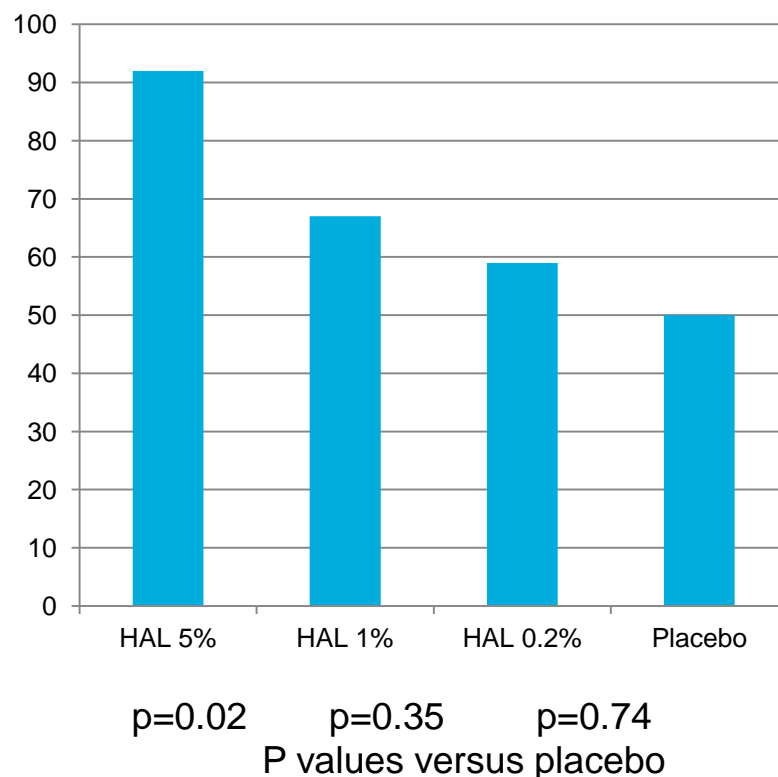
- Cytology
- HPV DNA genotyping

# Cevira Showed a Significant Efficacy in CIN2 Patients

Overall response\* in CIN2 patients  
(N= 87)



Overall response\* in CIN2 HPV positive\*\* patients (N= 72)



\*Combination of histology, cytology and HPV

\*\* Twelve HPV oncogenic subtypes



# Cevira Demonstrated a Strong Efficacy in Eradication of the Leading Cause of Cervical Cancer (HPV16/18)

- Several human papilloma virus (HPV) strains can cause precancerous lesions which lead to cervical cancer
  - HPV strain 16 and 18 has the highest risk for causing cancer
- Cevira showed significant eradication of high risk HPV 16/18 in CIN 2 population vs placebo
  - Cevira showed a clear trend towards higher eradication of HPV 16/18 in the overall study population vs placebo
- Cevira showed a clear trend towards higher eradication of the oncogenic HPV strains in CIN2 and in the overall study population vs placebo

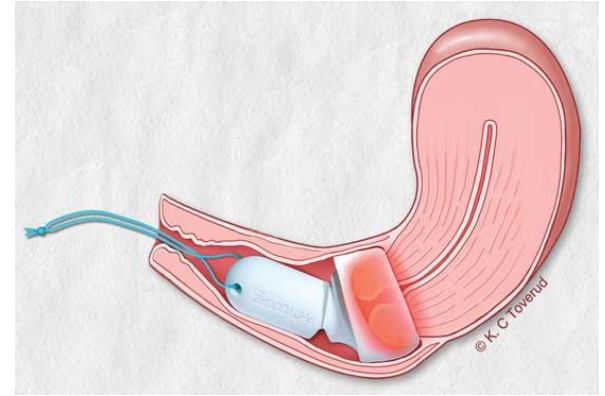
HPV CLEARANCE RATE			
	Cevira*	Placebo	P value
<b>CIN 2 PATIENTS</b>			
HPV 16/18 (n=33)	83%	0%	0.02
HPV OVERALL** (n=72)	62%	28%	0.08
<b>CIN 1/2 PATIENTS</b>			
HPV 16/18 (n= 50)	54%	11%	0.07
HPV OVERALL** (n=128)	58%	38%	0.13

\*Cevira at 5%

\*\* Twelve Oncogenic HPV strains (16,18,31,33,35,39,45,51,52,56,58,59)

# Tolerability

- No serious or systemic treatment related events were reported
- Treatment was well tolerated by the patients at all doses
  - 38% of the patients reported self-limiting local related events (e.g. discharge, discomfort, bleeding)
- Five pregnancies reported during study
  - 4 normal deliveries
  - 1 delivery due Jan 2013



# Summary of Initial Results at 3 Months

- Cevira at the optimal dose demonstrated significant efficacy in the CIN2 patients
  - Significant overall response
  - Significant clearance of high risk HPV16/18
- Cevira at the optimal dose showed a clear effect in overall response and HPV clearance in the overall CIN1/2 study population, though not statistically significant
- The study confirmed the strong patient and gynecologist acceptability and safe use of Cevira
- The study supports results seen in previous studies and forms an excellent basis for selecting patient populations and endpoints for further clinical development
- Final study results will be reported 1H 2013
- 8. Partnership discussions ongoing







THE  
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Thank you for your attention