



Brilliance in photodynamic technology™

# MAL PDT for the Treatment of Acne

5 June 2007

# MAL PDT for Acne will apply Photocure's proven technology in a new and large market



- Acne affects 85% of young people
- Left untreated, Acne can have serious physical and psychological consequences
- Current therapies have major safety issues, leading to significant unmet needs
- Photocure is developing a new topical MAL PDT product for the treatment of moderate to severe acne



# Acne is highly prevalent and has a major impact on quality of life



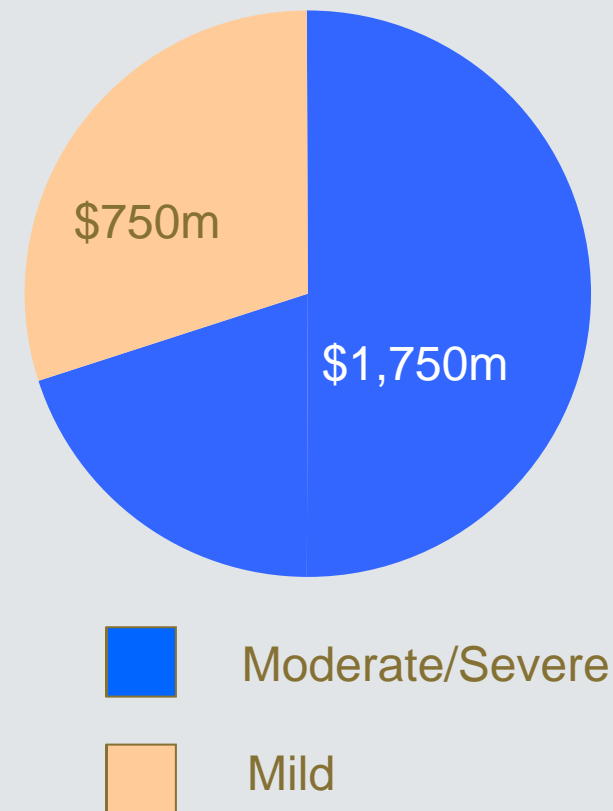
- Acne has a prevalence of 120 million sufferers in the US and the big 5 European markets
- 85% of all young people experience some form of acne between ages 12-24
- Clinical studies show that acne has a greater impact on emotional state and social function than other serious diseases (e.g. asthma, epilepsy)

# Our target segments represent 70% of the \$2.5bn global pharmaceutical acne market



- The global pharmaceutical Rx market for acne was worth \$2.5bn in 2006
- Acne patients are typically segmented into Mild (30%), Moderate (50%), and Severe (20%)
- Our target segments are patients with Moderate and Severe acne

Global acne market, \$2.5bn



# MAL PDT will provide a novel first line treatment for moderate and severe acne



|                            | <b>Mild (30%)</b>                           | <b>Moderate (50%)</b>   | <b>Severe (20%)</b> |
|----------------------------|---|---|---------------------|
| <b>1st line</b>            | Topical retinoid<br>+ topical antimicrobial | <b>Oral antibiotics</b><br>+ Topical retinoids<br>+/- Benzyl peroxide | <b>Isotretinoin</b> |
| <b>2<sup>nd</sup> line</b> | Alt. retinoid + antimicrobial               | Alt. Oral antibiotic  |                     |
| <b>3<sup>rd</sup> line</b> |   | Isotretinoin  |                     |

# Isotretinoin has severe side effects and the FDA has imposed restrictions on prescribing



- Isotretinoin is a highly teratogenic agent which cannot be used in females who are pregnant or at risk of pregnancy
- Last year the FDA introduced tight controls on prescribing (iPLEDGE) and patients are now much more aware of the risks and side effects
- US dermatologists are prescribing less isotretinoin as patients and parents demand alternatives

**“When we explain the side effects of isotretinoin many patients these days ask for an alternative” – US Dermatologist**

# Antibiotics require long treatment times and there is risk of increased resistance



- Antibiotics typically have a slow onset which can lead to poor patient compliance
- Treatment course is long and acne recurrence rate is high
- Dermatologists in the US estimate that 30% of their moderate/severe patients do not respond adequately and have to be moved to isotretinoin

**“I try antibiotics first line but often end up having to recommend isotretinoin ” – US Dermatologist**

# MAL PDT addresses the underlying causes of acne



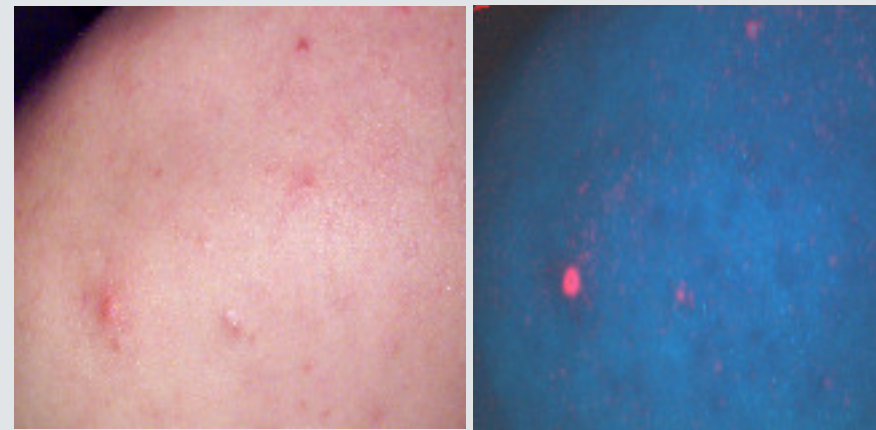
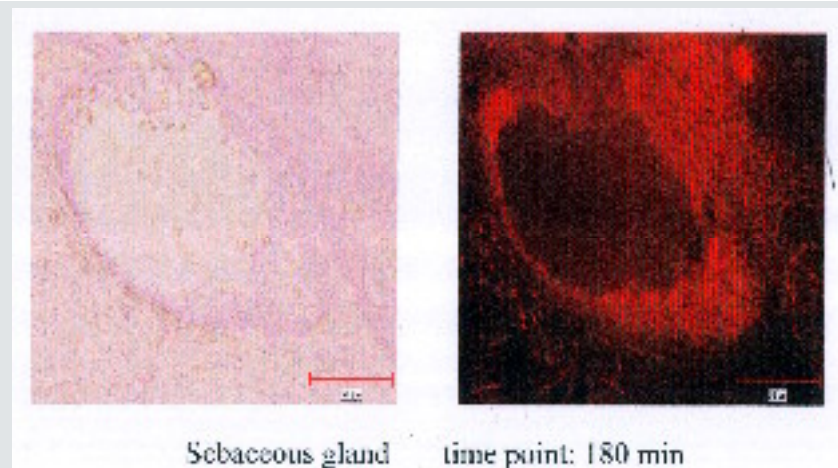
Primary pathophysiologic factors in acne:

- Sebum production
- Abnormal desquamation of follicular epithelium
- *P acnes* proliferation
- Inflammation

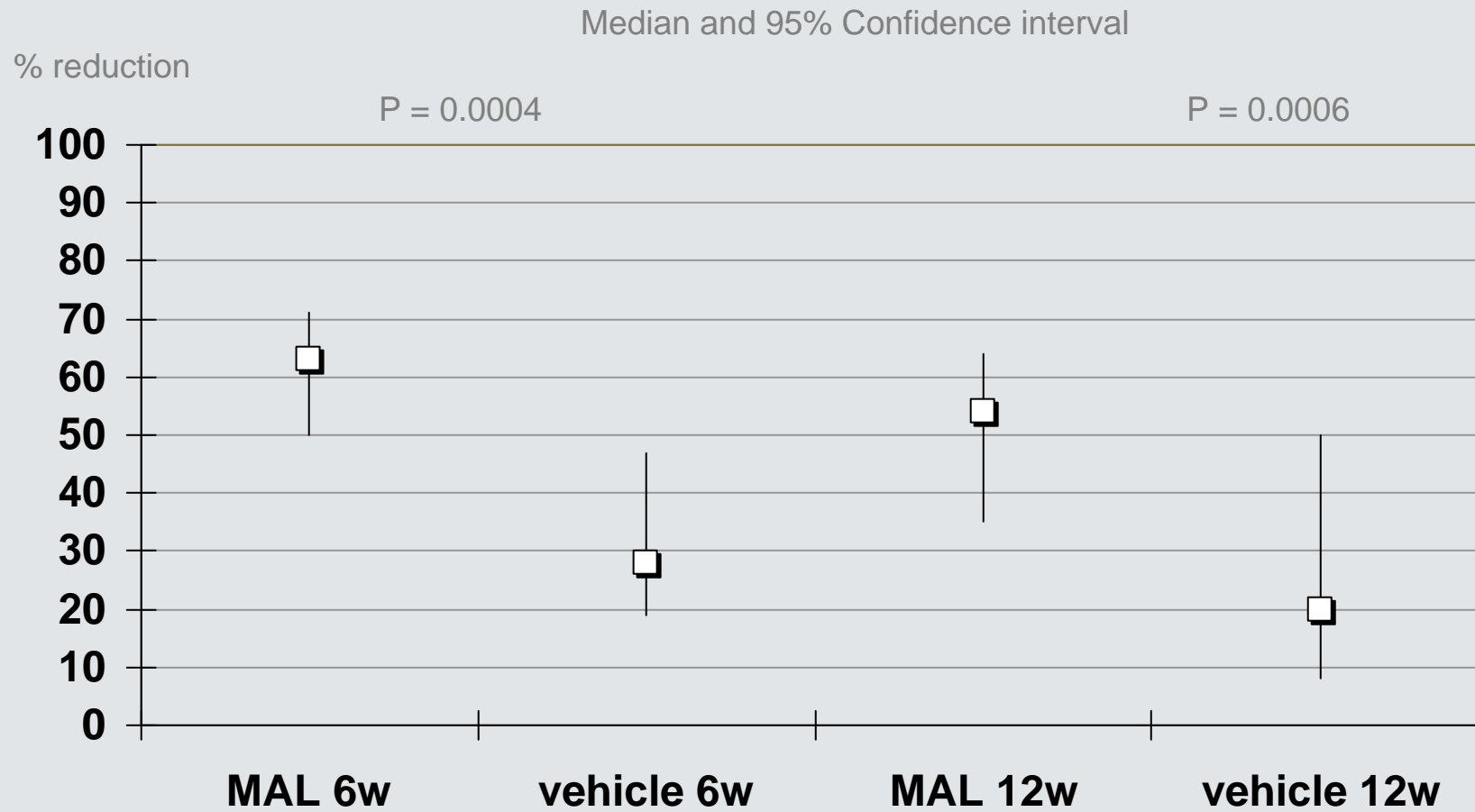
# MAL PDT is clinically proven to act on at least two of the primary causal factors



- Preclinical experience shows that MAL PDT kills *P.acnes* bacteria
- Clinical study showed mean reduction in "*P.acnes*" bacteria of 23 % after MAL PDT (Cunliffe, Leeds, UK)
- Clinical experience shows a build-up of photoactive porphyrins in sebaceous glands after MAL PDT (Bissonnette, Canada)
- Clinical experience shows a selective build-up of photoactive porphyrins in acne affected skin (Bissonnette, Canada)
- PDT decreases sebum production and the size of sebaceous glands (Rox Anderson, MIT, US 2000)

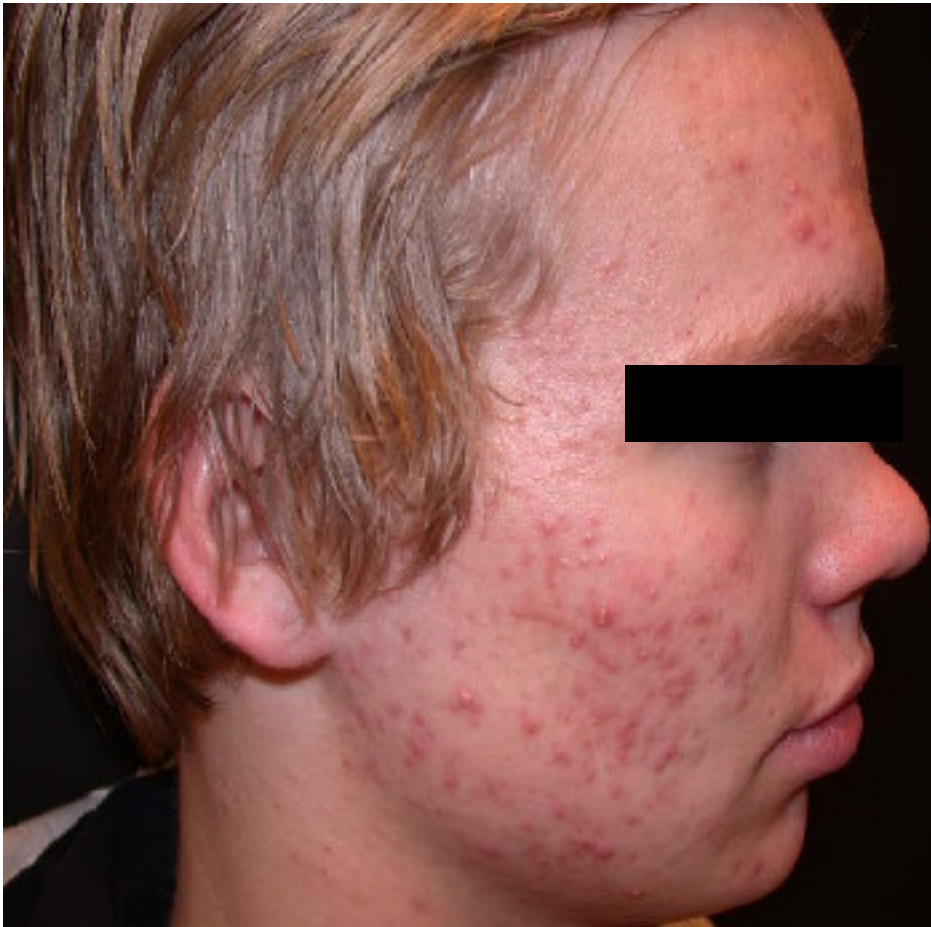


# 64% reduction in number of inflammatory acne lesions after MAL PDT\*



\*C. Hörfelt Br J Dermatol September 2006

# Effective treatment can dramatically improve a patient's quality of life

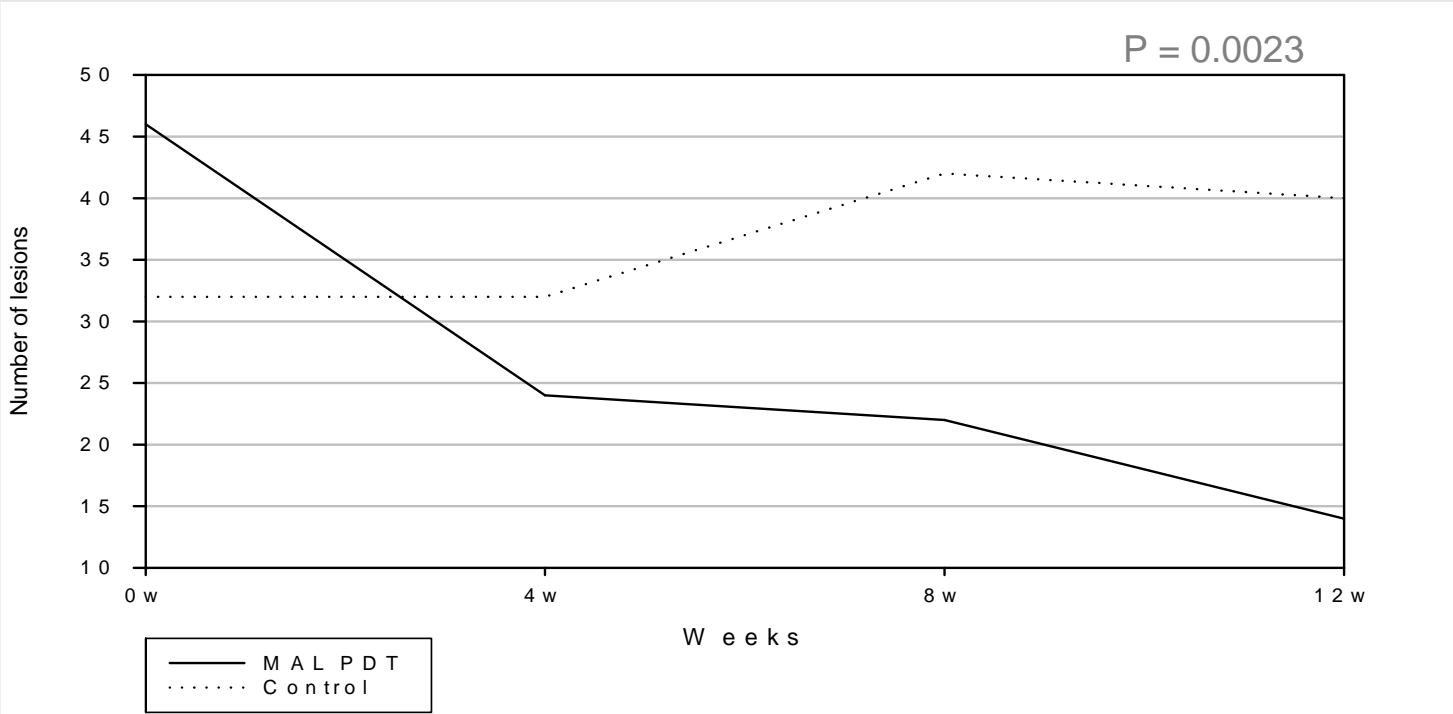


Before treatment



12 week post treatment

# 68% reduction in number of inflammatory acne lesions after MAL PDT\*



One year data shows sustained response\*\*

\*S.R. Wiegell Br J Dermatol May 2006  
\*\* Publication in progress

# Development Plan



- **Confirmatory phase II** study with 200 patients at 10 sites in US  
Started Q1 2007 (David Pariser)  
Planned Completion: Recruitment completed end 2007
- **Phase III studies:**  
Planned Start 2008.  
Planned Completion Recruitment completed 2009  
1 year follow-up completed 2010
- Development of **3rd generation field lamp** in progress - available for Phase 3 studies end 2007
- Select Partner(s) to successfully commercialise the product

Target regulatory submissions US/EU in 2010

# Acne is an exciting new indication for our proven MAL PDT technology



- Offers severe acne patients an effective and safer option than Isotretinoin
- Offers moderate acne patients a faster onset and longer term therapeutic effect than antibiotics
- Our target market is valued at \$1.75bn
- We have excellent Proof of Concept data and strong patent protection

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