



A treatment option that combines  
efficacy with excellent  
cosmetic outcomes  
& patient acceptability

## PRESS RELEASE

For medical press

January 2006

New 5 year Metvix<sup>®</sup> data demonstrate long-term efficacy and reliability of treatment for non-melanoma skin cancers (NMSC)

Patient compliance and cosmetic benefits indicate positive role of this novel therapy

New five year clinical trial results have demonstrated the high efficacy and long-term response rates of Metvix<sup>®</sup> photodynamic therapy (MAL-PDT) in NMSC compared to current standard treatments cryotherapy and surgery. As NMSC is the most common form of skin cancer in Caucasians and, like all skin cancers, has been increasing over recent decades, new methods to effectively treat are essential to prevent extensive damage and further skin cancer developing.

“This is an exciting step forward in the treatment of NMSC, including superficial and nodular basal cell carcinomas. MAL-PDT has shown consistent efficacy in previous trial results, however, the newly available five year data confirm that MAL-PDT is a reliable treatment option, with the added cosmetic benefits which are so important to patients.” said Dr Peter Foley, Department of Medicine, University of Melbourne, Australia.

Long-term measurement of the response rates for any new cancer treatment is necessary to demonstrate high efficacy and reliability. Several ongoing Metvix<sup>®</sup> clinical trials in basal cell carcinoma have reached the 60 month follow up mark demonstrating reliable long term efficacy within the range of standard treatments.<sup>1</sup> In addition Metvix<sup>®</sup> not only meets the efficacy standards of current treatments but also has significant benefits in relation to compliance, re-treatment, high selectivity, cosmetic aspects including healing.<sup>2, 3, 4, 5, 6, 7</sup>

The 60 month data in two of the main forms of NMSC showed:

- In superficial basal cell carcinomas (sBCC) similar recurrence with Metvix<sup>®</sup> to cryotherapy of 22% vs 19% (with no additional recurrences from 36 months). This was despite using only one Metvix<sup>®</sup> treatment session for most patients instead of the recommended standard protocol of two sessions seven days apart. Superior cosmesis including healing were demonstrated compared to cryotherapy
- In nodular basal cell carcinomas (nBCC) Metvix<sup>®</sup> was non-inferior to surgery in relation to initial response rates with recurrence rates at 60 months being only slightly higher at 14% vs 4% respectively, however, with overall cosmetic outcome for patients being significantly superior after MAL-PDT compared to surgery (84% vs 36% excellent or good cosmetic outcome)<sup>8</sup>



A treatment option that combines  
efficacy with excellent  
cosmetic outcomes  
& patient acceptability

Commenting on the trial results, Dr Colin Morton, Department of Dermatology, Falkirk Royal Infirmary, Scotland said: "The potential for the use of MAL-PDT as a standard treatment for non-melanoma skin cancers has been closely monitored for some time by the medical community. The new five year data, combined with the original high clearance rates and good cosmesis, are welcomed as confirmation of its place in our therapeutic armamentarium. Recurrence rates are comparable to current non-surgical treatments, but given its safety and lesion selectivity, MAL-PDT can be safely repeated if necessary. As a non-invasive, easy to use therapy, that can be carefully delivered under physician control using standardised procedures, MAL-PDT appears set to become a much more widely used therapy."

An important consideration of treatment is the potential for scarring and the healing process which is integral to patient satisfaction. In a combined analysis of 404 patients treated with MAL-PDT, 68% of BCC subjects indicated a preference for MAL-PDT compared to previous treatment with surgery and 62% of subjects preferred MAL-PDT to previous treatments such as cryotherapy, 5-FU, surgery or other (pooled analysis from 6 phase III studies in AK & BCC).<sup>9</sup>

With increasing incidence of skin cancers it is important that all members of the medical community are aware of potential skin cancer cases and are kept informed of the range of treatment options available. Metvix<sup>®</sup> now has the supporting evidence that confirms the long term efficacy of the treatment and its place as a standard treatment for NMSC.

For further information please contact:

Mary Barrington-Ward  
Shire Health International  
Tel: +44 207 108 6066  
E-mail: [mary.barringtonward@shirehealthlondon.com](mailto:mary.barringtonward@shirehealthlondon.com)

#### **Notes to editors:**

##### **Non-melanoma skin cancers (NMSC)**

Skin cancers are divided into two general types: non-melanoma and melanoma. Non-melanoma skin cancers are the most common cancers of the skin. They are called non-melanoma because this group of cancers includes all skin cancers except one – malignant melanoma. There are a number of different types of NMSC, the most common types being squamous cell carcinoma (SCC) and basal cell carcinomas (BCCs). NMSC is rarely life-threatening but if left untreated can cause extensive damage to surrounding organs and structures and increase the chances of developing new skin cancers in later years.

BCC is the most common human cancer and is locally destructive. Basal cell carcinoma is slow growing and accounts for about 70% to 80% of all skin cancers in men and 80% to 90% in women. They usually develop on sun-exposed areas, especially the head and neck. There are two main sub-types of BCC known as superficial and nodular BCCs.

SCC accounts for about 10% to 30% of all skin cancers and tend to be more aggressive than basal cell cancers. They commonly appear on sun-exposed areas of the body such as the face, ear, neck,



A treatment option that combines  
efficacy with excellent  
cosmetic outcomes  
& patient acceptability

lip, and back of the hands. Squamous cell carcinomas tend to be more aggressive than basal cell cancers. They are more likely to invade tissues beneath the skin, and slightly more likely to spread to lymph nodes and/or distant parts of the body, although this is still uncommon.

### **Metvix<sup>®</sup>**

Metvix<sup>®</sup> -- MAL-PDT -- is a novel skin cancer treatment that combines local application of a cream (Metvix<sup>®</sup> - methyl aminolevulinate), selectively absorbed into the cancer cells, and illumination with a proprietary red light source (Aktilite<sup>®</sup>) to activate the photosensitiser. The resulting photodynamic reaction leads to the selective destruction of the tumour cells. Metvix<sup>®</sup> with Aktilite<sup>®</sup> is an approved and standardised procedure that is relatively easy to perform and physician-controlled ensuring effective delivery and patient compliance. Metvix<sup>®</sup> is approved for pre-cancerous skin lesions (actinic keratosis, AK) and non-melanoma skin cancer (superficial and nodular basal cell carcinoma, BCC unsuitable for other available therapies due to possible treatment related morbidity and poor cosmetic outcome) in most European countries, New Zealand and Australia, and for AK in the US. The Bowens indication was recently approved in Europe. Market authorisation applications are pending in other countries.

Metvix<sup>®</sup> and Aktilite<sup>®</sup> are registered trademarks of PhotoCure ASA who developed Metvix<sup>®</sup> and are responsible for the marketing and sales of Metvix<sup>®</sup> in Nordic countries, while Galderma is responsible for the marketing and sales of Metvix<sup>®</sup> in the rest of the world.

### **Galderma**

Galderma is the world's leading pharmaceutical company in dermatology, focusing exclusively on meeting the needs of dermatology patients and physicians by providing therapeutic solutions for the diagnosis, prevention and treatment of dermatological conditions. Its expertise spans a broad spectrum of skin, hair and nail diseases.

Created in 1981, Galderma is a joint venture between Nestlé and L'Oréal with its parent company based in Switzerland. The company has wholly-owned subsidiaries in 33 countries and a worldwide network of exclusive sales agents. Corporate Services offices are in Paris-La Défense. Galderma's ongoing development is anchored in its portfolio of highly successful dermatological products that are today marketed in more than sixty five countries. The company had global revenues of 586.2 million euros in 2004.

Committed to the future of dermatology Galderma's mission is to offer innovative therapeutic solutions that improve the quality of life of dermatology patients.



A treatment option that combines  
efficacy with excellent  
cosmetic outcomes  
& patient acceptability

## References

1. Foley, P (2005). Long-term outcomes (five-year data) with MAL-PDT (abstract). Presented at 14th Congress of the European Academy of Dermatology and Venereology, London, October 2005.
2. Szeimies, RM *et al* (2002). Photodynamic therapy using topical methyl 5-aminolevulinate compared with cryotherapy for actinic keratosis: a prospective randomized study. *J Am Acad Dermatol* **47**:258-262
3. Horn M *et al* (2003). Topical methyl aminolevulinate therapy in patients with basal cell carcinoma prone to complications and poor cosmetic outcome with conventional treatment. *Brit J Dermatol* **149**:1242-1249
4. Peng Q *et al* (1996). Build up of esterified aminolevulinic-acid-derivative-induced porphyrin fluorescence in normal mouse skin. *J Photochem Photobiol B* **34**:95-96
5. Kloek J *et al* (1996). Prodrugs of 5-aminolevulinic acid for photodynamic therapy. *Photochem Photobiol* **64**:994-1000
6. Fritsch C *et al* (1998). Preferential relative porphyrin enrichment in solar keratoses upon topical application of  $\delta$ -aminolevulinic acid methylester. *Photochem Photobiol* **68**:218-221
7. Parisier DM *et al* (2003). Photodynamic therapy with topical methyl aminolevulinate for actinic keratosis: results of a prospective multicenter trial. *J Am Acad Dermatol* **48**:227-232
8. Rhodes LE *et al* (2005). A randomized European comparison of excision surgery and MAL-PDT in nodular basal cell carcinoma. *Arch Dermatol* **140**:17-23
9. Vinciullo C *et al* (2005). Patient satisfaction after treatment of basal cell carcinoma and actinic keratoses with MAL-PDT compared to previous other therapies (poster). Presented at 14th Congress of the European Academy of Dermatology and Venereology, London, October 2005.