

## **Mirvaso® (Brimonidine) the first and only Treatment targeting the Facial Redness of Rosacea approved by the European Commission**

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### **- Galderma portfolio expands to offer a fast onset and Long-acting alpha-2 adrenergic receptor agonist -**

**Lausanne, Switzerland, 26 February 2014** – Galderma, a leading global pharmaceutical company exclusively focused on dermatology, today announced that the European Commission has granted Marketing Authorisation in Europe for Mirvaso® (brimonidine) 3 mg/g gel.

<http://www.multivu.com/mnr/65011-mirvaso-first-and-only-treatment-rosacea>

Mirvaso® is an alpha-2 adrenergic receptor agonist that acts rapidly and can last for up to 12 hours.<sup>1</sup> It is indicated for the symptomatic treatment of facial erythema (redness) of rosacea in adult patients.

*“Mirvaso® is the only approved medicinal product that directly targets the facial redness of rosacea and provides an innovative therapy for the condition. Applied once-daily, Mirvaso® works quickly to reduce the redness of rosacea.” said Humberto C. Antunes, President and CEO of Galderma. “This is yet another milestone in Galderma’s continued R&D commitment to address the unmet needs of patients with skin conditions.”*

The European Commission decision to grant Marketing Authorisation in Europe for Mirvaso® is based on data collected from 553 patients enrolled in two phase 3 clinical trials of one-month duration.<sup>1</sup> The results from both studies showed that adults with rosacea erythema who used Mirvaso® demonstrated significantly greater reduction of the facial redness than the ones who applied vehicle gel only.<sup>1</sup> In addition, a long-term study in 449 subjects who used Mirvaso® for up to 12-months demonstrated that Mirvaso® was effective and well tolerated.<sup>2</sup>

*“Rosacea is a chronic, inflammatory and vascular disorder affecting the face, with facial erythema (redness) being a prominent characteristic. If left untreated the condition often has a severe impact on patients’ quality of life.” said Dr Alison Layton (MB, ChB, MRCP, FRCP) Consultant Dermatologist at Harrogate and District NHS Foundation Trust in the United Kingdom. “Up until now there has*

*been no clinically approved treatment targeting the facial erythema of rosacea and Mirvaso® can play a key role in the treatment of facial redness. Mirvaso® offers patients an easy to apply, long acting treatment with visible reductions in facial redness within 30 minutes of application – potentially giving them a better quality of life.”*

Marketing Authorisation in Europe for Mirvaso® is applicable to the 28 Member States of the European Union, as well as Iceland, Lichtenstein and Norway.

For further information about the company, please visit [www.galderma.com](http://www.galderma.com) and follow @galderma on [Twitter](#) and [LinkedIn](#).

### **About Mirvaso® (brimonidine)**

Mirvaso® (brimonidine) 3 mg/g gel is an alpha-2 adrenergic agonist indicated for the symptomatic treatment of facial erythema of rosacea in adult patients. Mirvaso® is the proprietary name endorsed by the European Medicines Agency (EMA) for brimonidine.

### **Galderma – a global company exclusively dedicated to dermatology**

Galderma is a global company founded in 1981 committed to delivering innovative medical solutions to meet the dermatological needs of people throughout their lifetime while serving healthcare professionals around the world. The company has 33 wholly-owned affiliates with a worldwide network of distributors and more than 5,000 employees. Galderma’s extensive product portfolio is available in 80 countries and treats a range of dermatological conditions including: acne, rosacea, onychomycosis, psoriasis & steroid-responsive dermatoses, pigmentary disorders, skin cancer and medical solutions for skin senescence.

With approximately 19% of revenues invested each year to discover and develop new products and access innovative technologies, the company is one of the world’s leading investors in dermatology R&D. Five state-of-the-art R&D centers and five manufacturing sites are dedicated to providing a wide range of innovative medical solutions which meet the highest standards of safety and efficacy.

Strategic brands include Epiduo, Oracea, Clobex, Differin, Mirvaso®, Rozex/MetroGel, Silkis/Vectical, Tri-Luma, Loceryl, Cetaphil, Metvix, Azzalure, Restylane and Emervel.

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**References**

1. Fowler J, Jackson M, Moore A et al. Efficacy and safety of once-daily topical brimonidine tartrate gel 0.5% for the treatment of moderate to severe facial erythema of rosacea: results of two randomized, double-blind, vehicle-controlled pivotal studies. *J Drugs Dermatol* 2013; 12 (6): 650–656.
2. Moore A, Kemper S, Murakawa G et al. Long-term safety and efficacy of once-daily topical brimonidine tartrate gel 0.5% for the treatment of moderate to severe facial erythema of rosacea: results of a 1-year open-label study. *J Drugs Dermatol* 2014; 13 (1): 56–61.

<http://www.galderma.com/Media/Press-releases/ArticleType/ArticleView/ArticleID/57>