



NEWS RELEASE

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**Media Contact: Twist Mktg
Erin Bittner, 212-301-7226**

**Galderma Announces the Publication of Positive Results of the Long-Term Study
of Mirvaso[®] Gel for Treatment of Persistent Erythema of Rosacea**

***Efficacy and Safety Results from One-Year Study Published in Journal of Drugs in
Dermatology***

FT. WORTH, Texas – January 29, 2014 – Galderma Laboratories, L.P. today announced the publication of the long-term efficacy and safety results of a one-year, open-label, non-comparative study of Mirvaso[®] (brimonidine) Topical Gel, 0.33%* in patients with moderate to severe facial erythema (redness) of rosacea. Mirvaso was approved by the U.S. Food and Drug Administration in August 2013 as the first and only topical treatment indicated for the persistent facial erythema of rosacea in adults 18 years of age or older.¹ The results of this study, in which 276 subjects applied Mirvaso for at least one year, demonstrate that Mirvaso is safe and effective when used once-daily for up to 12 months.² The study results were published in the January issue of *Journal of Drugs in Dermatology*.

In addition to the long-term study, the approval of Mirvaso was also based on results from two identical randomized, vehicle-controlled pivotal 8-week studies in a total of 553 subjects, 269 of those treated once daily with Mirvaso for 29 days followed by a 4-week follow-up period. These studies demonstrated that Mirvaso was safe and effective for the treatment of persistent, non-transient facial erythema of rosacea when applied once daily.²

“The positive results of this long-term study provide additional evidence of the efficacy and safety of Mirvaso for patients with the persistent facial redness of rosacea,” said Humberto Antunes, President and CEO, Galderma Laboratories. “Since we launched Mirvaso commercially in the United States in September 2013, we have seen widespread adoption by dermatologists, underscoring the important need for an effective topical prescription treatment for this most common symptom of rosacea.”

Long-Term Study Design

The study was conducted at 27 centers in the United States.² Subjects with moderate to severe erythema of rosacea were instructed to apply topical Mirvaso once daily for up to 12 months, during which the

severity of erythema and adverse events were evaluated.² In this study, subjects were allowed to use other rosacea therapies (oral and topical) in addition to Mirvaso. A total of 449 subjects were enrolled and 276 subjects applied Mirvaso for at least one year.²

Long-Term Study Results

With regard to efficacy, the results showed that Mirvaso was effective in reducing the persistent facial erythema of rosacea on day 1 of treatment and consistent results were observed throughout the 12 month study. In addition, no evidence of tachyphylaxis (a sudden decrease in response after drug administration compared to prior usage) was reported.² With regard to safety, no new major safety findings were observed in this study as compared to the vehicle-controlled pivotal studies. The most common adverse events ($\geq 4\%$ of subjects) were flushing (10%), erythema (8%), worsening of rosacea (5%), nasopharyngitis (5%), skin burning sensation (4%), increased intraocular pressure (4%) and headache (4%).²

About Mirvaso

Mirvaso is a topical gel that may work by constricting the dilated facial blood vessels to reduce the redness of rosacea.¹ Mirvaso should be applied in a pea-sized amount, once daily to each of the five regions of the face: the forehead, chin, nose and each cheek.¹ Applied once-daily, Mirvaso works quickly to reduce the redness of rosacea and lasts up to 12 hours before the redness returns.¹

Mirvaso is safe and well-tolerated.² In controlled clinical trials the most common adverse reactions (incidence $\geq 1\%$) included erythema, flushing, skin burning sensation, and contact dermatitis.¹

About Rosacea

Rosacea is a chronic, inflammatory and vascular disorder affecting the face. Redness⁴, visible blood vessels⁴, bumps, and blemishes⁴ typically appear in the middle of the face (forehead, nose, cheeks) after age 30 in men and women.⁴ Rosacea affects an estimated 16 million Americans.⁵

Triggers for the condition may include spicy foods, alcohol, emotional stress, sun exposure, and hot baths.⁶ Because of the physical manifestation of rosacea on the face, the condition can cause embarrassment⁷, anxiety and frustration,⁸ and can have a negative impact on the patients' social life.⁹ Stinging, burning⁶, sensitivity of the skin is common⁶, and in some cases, the eyes can become red, dry and itchy.⁶ If left untreated, rosacea may worsen. If people suspect that they might have rosacea, they should visit their dermatologist or healthcare provider for diagnosis and treatment.



Important Safety Information for Mirvaso Gel

Indication: Mirvaso[®] (brimonidine) topical gel, 0.33%* is an alpha adrenergic agonist indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older.

Adverse Events: In clinical trials, the most common adverse reactions ($\geq 1\%$) included erythema, flushing, skin burning sensation and skin irritation. **Warnings/Precautions:** Mirvaso Gel should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Alpha-2 adrenergic agents can lower blood pressure. Mirvaso Gel should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease. Serious adverse reactions following accidental ingestion of Mirvaso Gel by children have been reported. **Keep Mirvaso Gel out of reach of children.** Not for oral, ophthalmic, or intravaginal use.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Galderma

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 31 wholly-owned affiliates and a worldwide network of distributors, more than 4,200 employees and an extensive product portfolio available in 70 countries.

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. Four state-of-the-art R&D centers and four manufacturing sites are dedicated to providing a wide range of innovative medical solutions which meet the highest standards of safety and efficacy.

Brands in the U.S. include *Cetaphil[®]*, *Epiduo[®]*, *Oracea[®]*, *Clobex[®]*, *Differin[®]*, *MetroGel[®]*, *Vectical[®]*, *Tri-Luma[®]* and *Pliaglis[®]*.

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*Each gram of gel contains 5 mg of brimonidine tartrate, equivalent to 3.3 mg of brimonidine free base



¹ Mirvaso.com

² Moore A., 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. *Journal of Drugs in Dermatology*. 2014; 1:56-61.

³ Mirvaso Prescribing Information.

⁴ National Rosacea Society. All About Redness. <http://www.rosacea.org/patients/allaboutrosacea.php>. Accessed January 28, 2014.

⁵ National Rosacea Society. Patient Home Page. <http://www.rosacea.org/patients/index.php>. Accessed January 28, 2014.

⁶ National Rosacea Society. Frequently Asked Questions. <http://www.rosacea.org/patients/faq.php>. Accessed January 28, 2014.

⁷ Drummond P et al. Blushing in Rosacea Sufferers. *Journal of Psychosomatic Research*. 2012; 72:153-158.

⁸ National Rosacea Society. Essential Steps Help Keep Rosacea at Bay. http://rosacea.org/rr/2009/spring/article_2.php. Accessed January 28, 2014.

⁹ Drummond P et al. Blushing Propensity and Psychological Distress in People With Rosacea. *Clinical Psychology and Psychotherapy*. 2011;19(6): 488-95.