Galderma Receives FDA Approval of Mirvaso®

AUGUST 26, 2013

The First and Only FDA-Approved Topical treatment Specifically Developed and Indicated for the Facial Erythema of Rosacea
Mirvaso Works Quickly and Lasts for up to 12 Hours[2]

FT. WORTH, Texas – August 26, 2013 – Galderma Laboratories, L.P. today announced that the U.S. Food and Drug Administration (FDA) has approved Mirvaso® (brimonidine) topical gel, 0.33%* for the topical treatment of the facial erythema (redness) of rosacea in adults 18 years of age or older.[1] Applied once-daily, Mirvaso works quickly to reduce the redness of rosacea and lasts up to 12 hours.[2] Galderma expects Mirvaso to be available in pharmacies September 2013.
"Facial redness is the most common symptom of rosacea, but until now, physicians have been without prescription treatment options to specifically address this patient need," said Mark Jackson, M.D., Clinical Professor of Medicine at the University of Louisville, dermatologist and a principal investigator for the phase 3 studies of Mirvaso. "The FDA approval of Mirvaso marks a turning point in rosacea treatment: we are now able to provide patients that deal with the daily frustrations caused by the redness of rosacea with an effective therapy."

The approval of Mirvaso was based on data collected from more than 550 patients enrolled in two phase 3 clinical studies of one-month duration.[1] The results from both studies showed that adults who used Mirvaso demonstrated significantly greater improvement in the facial redness of rosacea than vehicle gel.[1,2] In addition, a long-term study in 276 subjects that used Mirvaso for up to 12-months was also conducted. 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]

"The FDA approval of Mirvaso provides a first-in-class therapy for facial redness of rosacea, that we are proud to add to our existing rosacea portfolio, that includes Oracea® and MetroGel® 1% pump, said Francois Fournier, President of North American Operations, Galderma Laboratories. "This milestone exemplifies Galderma's continued two decades R&D commitment to address the unmet needs of rosacea patients and clinicians."
Mirvaso is safe and well-tolerated. In controlled clinical trials the most common adverse reactions (incidence ≥ 1%) included erythema, flushing, skin burning sensation, and contact

dermatitis. In the long-term study, the most common adverse events (≥ 4% of subjects) included flushing (10%), erythema (8%), rosacea (5%), nasopharyngitis (5%), skin burning sensation (4%), increased intraocular pressure (4%), and headache (4%).[2,1]
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What is Rosacea?
Rosacea is a chronic, inflammatory and vascular disorder affecting the face. Redness[3], visible blood vessels[3], bumps and blemishes[3] typically appear in the middle of the face (forehead, nose, cheeks) after age 30 in men and women.[3] Rosacea affects an estimated 16 million Americans.[4] Triggers for the condition may include spicy foods, alcohol, emotional stress, sun exposure, and hot baths.[5] Because of the physical manifestation of rosacea on the face, the condition can cause embarrassment[6], anxiety and frustration[7] and can have a negative impact on the patients' social life.[8] Stinging, burning[5], sensitivity of the skin is common[5], and in some cases, the eyes can become red, dry and itchy.[5] 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 - Mirvaso® Gel
Indication: Mirvaso® (brimonidine) topical gel, 0.33% is an alpha-2 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 (≥1%) included erythema, flushing, skin-burning sensation and contact dermatitis.**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

Important Safety Information - ORACEA®
Indication: ORACEA® is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with ORACEA were nasopharyngitis,

sinusitis, diarrhea, hypertension and aspartate aminotransferase increase.**Warnings/Precautions:** ORACEA should not be used to treat or prevent infections. ORACEA should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA treatment beyond 16 weeks and safety beyond 9 months have not been established.

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Important Safety Information - MetroGel® 1% Pump

Indication: METROGEL® 1% is indicated for the topical treatment of the inflammatory lesions of rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with METROGEL 1% were nasopharyngitis, upper respiratory tract infection, and headache. Other adverse experiences reported when using topical metronidazole include skin irritation, transient redness, metallic taste, tingling or numbness of the extremities and nausea. **Warnings/Precautions:** METROGEL 1% should not be used by patients who are allergic to metronidazole or any ingredient in METROGEL 1%. Avoid contact of METROGEL 1% with the eyes as it may cause tearing. METROGEL 1% should be used with caution in patients with evidence of, or a history of, blood dyscrasia, and with patients taking blood thinning agents as they may experience prolonged prothrombin times. METROGEL 1% treatment should be discontinued if numbness or paresthesia of any extremity should occur.
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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 33 wholly-owned affiliates and a worldwide network of distributors, more than 5,000 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.

Strategic 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® Prescribing Information

[2] Fowler J 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. Journal of Drugs in Dermatology. 2013; 12:650-656.

[3] National Rosacea Society. All About Redness.http://www.rosacea.org/patients/allaboutrosacea.php. Accessed June 26, 2013

[4] National Rosacea Society. Patient Home Page. http://www.rosacea.org/patients/index.php. Accessed July 16, 2013

[5] National Rosacea Society. Frequently Asked Questions.http://www.rosacea.org/patients/faq.php. Accesed July 16, 2013

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

[7] National Rosacea Society. Essential Steps Help Keep Rosacea at Bay.http://rosacea.org/rr/2009/spring/article_2.php. Accessed August 1, 2013

[8] Dummond P et al. Blushing Propensity and Psychological Distress in People With Rosacea. Clinical Psychology and Psychotherapy. 2011:19 (6): 488-95.

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