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# Promius Pharma Launches Sernivo™ (betamethasone dipropionate) Spray, 0.05% New Product For Mild to Moderate Plaque Psoriasis

Hyderabad, India and Princeton, NJ, USA. June 1, 2016: Dr. Reddyc Laboratories announced today that its US subsidiary, Promius Pharma, LLC, U.S. (BSE: 500124, NSE: DRREDDY, NYSE: RDY), launched Sernivoï (betamethasone dipropionate) Spray, 0.05% in the U.S. Sernivo Spray, a prescription topical steroid approved by the Food and Drug Administration (FDA) in February of 2016, is indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older.

We are proud to bring Sernivo Spray to patients across the U.S.,+said Raghav Chari, Executive Vice President, Proprietary Products Group at Dr. Reddyc Laboratories, ‰his is another significant milestone for Promius Pharma. As an emerging leader in the dermatology space, we are committed to developing innovative treatment options.+

Promius has conducted two multi-center, randomized, double-blind, vehicle-controlled clinical trials in subjects aged 18 years and older with moderate plaque psoriasis to evaluate the safety and efficacy of Sernivo Spray. In both trials, randomized subjects applied Sernivo Spray or vehicle spray to the affected areas twice daily for 28 days. Enrolled subjects had body surface area of involvement between 10% to 20% and an Investigator Global Assessment (IGA) score of 3 (moderate). Efficacy was assessed as the proportion of subjects who were considered a treatment success (defined as having an IGA score of 0 or 1 [clear or almost clear] and at least a 2-scale reduction from baseline). Treatment success was achieved in significantly more subjects using Sernivo Spray than vehicle at both Day 15 and Day 29 across both studies. At Day 29 in Studies 1 and 2, Sernivo Spray achieved treatment success of 42.7% and 34.5% compared to vehicle success rates of 11.7% and 13.6%, respectively (p<0.001).

Relaque psoriasis can be a frustrating condition for patients and physicians alike. For patients, it is not only itchy and painful, but depending on where on the body it occurs, it can be embarrassing for them and decrease their quality of life,+said Leon H. Kircik, M.D., clinical associate professor of dermatology at Indiana University School of Medicine. % so one of the researchers for Sernivo Spray, Iqn excited to see this new treatment option added to our tool chest. With Sernivo Spray, I will now have a versatile option for patients that is easy to use in difficult to treat areas, like elbows and knees.+

### Important Safety Information for SERNIVO™ (betamethasone dipropionate) Spray, 0.05%

#### Indication

SERNIVO Spray is indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older. It is not known if SERNIVO Spray is safe and effective in children under 18 years of age. SERNIVO Spray is not recommended for use in patients under 18 years of age.

### Important Safety Information

Important: SERNIVO Spray is for use on the skin only. Do not get SERNIVO Spray near or in your eyes, mouth, or vagina.

## What should I tell my healthcare provider before taking SERNIVO Spray?

# Before you take SERNIVO Spray, tell your healthcare provider about all of your medical conditions, including if you:

- are allergic to any of the ingredients in SERNIVO Spray. have thinning of the skin (atrophy) at the treatment site.
- are pregnant or plan to become pregnant. It is not known if SERNIVO Spray will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SERNIVO Spray passes into breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription and overthe-counter medicines, vitamins, and herbal supplements. **Especially tell your healthcare provider** if you take other corticosteroid medicines by mouth or use other products on your skin that contain corticosteroids.

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

### How should I use SERNIVO Spray?

- Use SERNIVO Spray exactly as your healthcare provider tells you to use it.
- Your healthcare provider should tell you how much SERNIVO Spray to use and where to apply it.
- Apply SERNIVO Spray 2 times a day.
- Use SERNIVO Spray for the shortest amount of time needed to treat your plaque psoriasis. Tell
  your healthcare provider if your skin condition is not getting better after 4 weeks of using
  SERNIVO Spray.
- Do not use SERNIVO Spray for longer than 4 weeks.
- Wash your hands after applying SERNIVO Spray.
- Do not use SERNIVO Spray on your face, scalp, underarms (armpits), groin, or areas where your skin may touch or rub together.
- Do not bandage, cover, or wrap the treated skin area, unless your healthcare provider tells you to.

### What are the possible side effects of SERNIVO Spray?

 SERNIVO Spray can pass through your skin. Too much SERNIVO Spray passing through your skin can cause your adrenal glands to stop working. Your doctor may do blood tests to check for adrenal gland problems.

The most common side effects of SERNIVO Spray include itching, burning, stinging, pain and thinning of skin (atrophy) at the treated site. These are not all the possible side effects of SERNIVO Spray. Call your doctor for medical advice about side effects.

To report SUSPECTED SIDE EFFECTS, call Promius Pharma at 1-888-966-8766 or contact the FDA at 1-800-FDA-1088.

To learn more about SERNIVO Spray, go to www.sernivo.com. Please also see <u>Full Prescribing</u> <u>Information</u> at www.sernivo.com.

**About Dr. Reddy's**: Dr. Reddy**s** Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products. Dr. Reddy**s** offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastro-intestinal,

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