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# **Sonoma Pharmaceuticals Announces Results from SebuDerm™ Gel Study in Treatment of Seborrheic Dermatitis**

- **Evaluation of SebuDerm (hypochlorous acid) Gel on Mild to Moderate Facial and Scalp Seborrheic Dermatitis**
- **Investigator Global Assessment (IGA) Scores Showed a 33% Improvement at Day 14 and a 52% Improvement at Day 28**
- **Clinical Poster being Presented at the 13<sup>th</sup> Annual Maui Dermatology Conference on March 20-24**

PETALUMA, Calif., March 16, 2017 (GLOBE NEWSWIRE) -- Sonoma Pharmaceuticals, Inc. (NASDAQ: SNOA, warrants SNOAW), a specialty pharmaceutical company that develops and markets unique and effective solutions for the treatment of dermatological conditions and advanced tissue care, today announced the results of a clinical study evaluating the impact of SebuDerm™ (topical hypochlorous acid) gel in the treatment of mild to moderate facial and scalp seborrheic dermatitis.

In a 25-patient study, conducted by Zoe Draelos, MD; and president of Dermatology Consulting Services in High Point, North Carolina, two key metrics were utilized in assessing efficacy of SebuDerm; the first being the investigator's global assessment (IGA) of efficacy improvement in appearance and symptoms from baseline; and secondly, the subject global assessment (SGA) of improvement in itching, burning and stinging. No adverse effects were reported and overall treatment was well tolerated by the subjects.

Author of the study, Zoe Draelos, MD, commented, "Seborrheic dermatitis is a common condition afflicting men and women of all ages that is challenging for dermatologists to treat. While treatment options exist, recurrence is common and few options exist for disease maintenance. A new addition to the dermatologist's armamentarium will be welcomed."

The IGA of efficacy improvement from baseline was 33% at day 14 and 52% at day 28. The SGA of efficacy improvement from baseline was 62% through day 28.

Dr. Draelos' clinical study poster is being presented at 13<sup>th</sup> Annual Maui Dermatology Conference in Maui, Hawaii on March 20-24, 2017. The company received a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the company's SebuDerm™ Gel as a prescription product, intended to manage and relieve the burning, itching, erythema, scaling and pain experienced with seborrhea and seborrheic dermatitis in December 2015.

U.S. commercialization is underway via Sonoma's dermatology division IntraDerm Pharmaceuticals' 30-plus-person direct sales team. Sonoma is also in discussions with prospective international distributors and partners to bring this advanced technology to dermatology patients throughout the globe, including Asia, Latin America and the Middle East.

"Our new SebuDerm gel adds a valuable tool to the dermatologist's bag when it comes to combatting both seborrhea and seborrheic dermatitis," said Jeffrey Day, president of IntraDerm Pharmaceuticals. "Nearly a quarter of the general population is afflicted with seborrheic dermatitis and we hope to impress our physician customers with our terrific new treatment option in SebuDerm."

### **Seborrheic Dermatitis Market Size**

It is estimated that 25% of the general population has seborrheic dermatitis. Although the etiology of seborrheic dermatitis is not entirely understood, most experts share the belief of Bruce Strober, M.D., Ph.D., co-director of the psoriasis and psoriatic arthritis center at New York University Medical Center, who says, "The disease may be triggered by environmental factors, but there is a strong immune predisposition." The disease is far more prevalent in patients with HIV, neurologic disorders, elderly patients and infants.

According to *JAMA Pediatrics*, an industry healthcare journal, seborrheic dermatitis is a common complaint brought to pediatricians. Also known as "cradle cap" in infants, "dandruff" in adolescents, seborrheic dermatitis is also found in the face, scalp and chest areas in adults. It is believed this condition is triggered by *Malassezia* yeasts. Treatment has supported a billion dollar market for over-the-counter treatments.

### **Current Treatment Options**

Studies have also shown a causative role of the yeast-like fungus *Pityrosporum* in the development of seborrheic dermatitis, notes Joel Schlessinger, M.D., a dermatologist in private practice in Omaha, Nebraska, and president emeritus of the American Society of Cosmetic Dermatology & Aesthetic Surgery.

Dr. Schlessinger advocates the use of both oral ketoconazole (weekly for six to eight weeks) and a topical foam to treat the underlying *pityrosporum* infection. In addition, newer formulations of corticosteroids, like clobetasol and betamethasone, he says, "have markedly changed the treatment of scalp psoriasis and seborrheic dermatitis. Before these were available there were few palatable options for these conditions, but now the treatments are quite 'patient friendly.' Older treatments such as Derma-Smoother F/S and other tar-based shampoos are clearly a challenge for patients and often result in poor results due to compliance issues."

Current therapies include the use of a topical ketoconazole-containing agent. If that is not effective, then dermatologists may step up to a topical corticosteroid, with lower potency on the face, higher potency on the scalp. Another popular option is the use of topical immunomodulatory drugs, like tacrolimus and pimecrolimus. These agents have been found to be safe and effective for seborrheic dermatitis on the face. The downside is that they burn and sting. If there is not a reimbursement issue, dermatologists often prescribe these drugs as first-line therapy.

### **About Sonoma Pharmaceuticals, Inc.**

Sonoma is a specialty pharmaceutical company that develops and markets unique and effective solutions for the treatment of dermatological conditions and advanced tissue care. The company's products, which are sold throughout the United States and internationally, have improved outcomes for more than five million patients globally by reducing infections, itch, pain, scarring and harmful inflammatory responses. The company's headquarters are in Petaluma, California, with manufacturing operations in the United States and Latin America. European marketing and sales are headquartered in Roermond, Netherlands. More information can be found at [www.sonomapharma.com](http://www.sonomapharma.com).

### **Forward-Looking Statements**

Except for historical information herein, matters set forth in this press release are forward-looking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about the commercial and technology progress and future financial performance of Sonoma Pharmaceuticals, Inc. and its subsidiaries (the "Company"). These forward-looking statements are identified by the use of words such as "believe," "achieve," and "strive," among others. Forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including such risks that regulatory clinical and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the Company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be as large as expected, the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, the Company may not meet its future capital needs, as well as uncertainties relative to varying product formulations and a multitude of diverse regulatory and marketing requirements in different countries and municipalities, and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission including its annual report on Form 10-K for the fiscal year ended March 31, 2016. The Company disclaims any obligation to update these forward-looking statements, except as required by law.

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