TOPIX PHARMACEUTICALS INTRODUCES NEW BACKBAR LINE

Topix Pharmaceuticals, Inc. is rolling out its Backbar Line, a collection of 10 professional products that allows physicians to use their own branding. The collection features:

- Gentle Antioxidant Soothing Cleanser: The soap-free formula cleanses and soothes with antioxidants and botanicals like pro-vitamin B and chamomile and cucumber extracts.
- Clarifying Brightening Polish: Glycolic and salicylic acids and natural biocellulose beads exfoliate, while arbutin improves clarity. The formula helps skin retain moisture.
- Restorative Moisturizer: The cream contains ceramides, antioxidants, stem cells, peptides, emollients, and humectants to hydrate.
- Hyaluronic Acid Serum: An antioxidant- and humectant-rich booster that provides all-day moisture retention and visibly reduces the signs of aging.
- Vitamin C Pro-Collagen Brightening Serum: Contains 20 percent Vitamin C Active Complex to brighten, support collagen production, and protect against free radicals.
- Triple Antioxidant Cream: A triple antioxidant blend (green tea polyphenols, resveratrol and caffeine) soothes the skin, visibly reduces redness and guards against aging free radical damage.
- Sheer Physical Sunscreen SPF 50+: Suitable for sensitive and acne-prone skin, this sunscreen provides broad-spectrum SPF protection.
- Tinted Physical SPF 50+: Universal pigments deliver a touch of color while concealing imperfections and hiding fine lines, wrinkles, and enlarged pores.
- Neck Firming Cream: Packed with anti-aging ingredients like a ceramide complex, peptides, and niacinamide, this treatment firms and rejuvenates skin and evens texture and tone.
- All-trans-Retinol Smoothing Body Lotion: Developed with a unique retinol delivery system, stem cell technology and the PWR3+ Antioxidant Complex fights against sagging and damaging free radicals.

Only available for sale direct to offices, the line is designed to support procedures and non-invasive treatments. *topixpharm.com*

ALASTIN LAUNCHES TRANSFORM BODY TREATMENT

Alastin Skincare, Inc. launched TransFORM Body Treatment with TriHex Technology at the recent American Society for Dermatologic Surgery (ASDS) Annual Meeting in Phoenix. When this product is applied after non-surgical body fat reduction and energy-based body skin tightening procedures, it is intended to help accelerate outcomes by supporting the body's natural repair processes. It also helps to support the production of elastin and collagen to enhance the results of body skin tightening procedures. It provides benefits as a stand-alone skin tightening treatment to address lax, sagging skin and the crepey texture that often accompanies aging.

A blend of peptides including Hexapeptide-11 is encapsulated in a proprietary LipoDRONE Delivery System, which helps shuttle the peptide through the skin to the dermal fat around the hair follicle, to naturally signal the process of fat debris clearance post-treatment. At the same time, Alastin's patented TriHex Technology works to support the increase of elastin and collagen production and help boost the body's natural hyaluronic acid production.

Initial split-body evaluations utilizing the TransFORM product in conjunction with energy-based devices for non-surgical fat reduction have demonstrated enhanced results in subjects on the side treated with TransFORM. Moreover, daily application of TransFORM with no energy device treatment yielded an 11 percent improvement in skin roughness and crepiness at week 4 and 38 percent improvement by week 8. *alastin.com*

NEW FROM NEOVA: RETINOL SPRAY

Neova's new Intensive Retinol Spray is a regenerating, concentrated leave-on exfoliant with AHA, BHA, and retinol that gently peels back accumulated dullness, visible photodamage, and loss of elasticity to improve the appearance of texture, luminosity, firmness, and elasticity. The company says the product is good for all skin types, even the sensitive, with photodamage. But the product may cause sun sensitivity, and those using it should also use a broad-spectrum sunscreen with SPF 30 or higher. *Neova.com* ■

Therapeutics Focus: Acne

ORTHO DERMATOLOGICS' ALTRENO NOW AVAILABLE IN THE US

Ortho Dermatologics launched Altreno (tretinoin) Lotion, 0.05% for the topical treatment of acne vulgaris in patients 9 years of age and older. Altreno Lotion is the first and only tretinoin available in a lotion for acne. Altreno Lotion has been shown to be effective and generally well-tolerated, and is provided in a formulation with known moisturizers hyaluronic acid, glycerin and collagen, according to the company.

"Many acne patients struggle using acne medications because they can cause irritation to the skin," says Joshua Zeichner, MD, director, Cosmetic and Clinical Research in Dermatology, The Mount Sinai Hospital, New York City. "Altreno Lotion has demonstrated the efficacy of a tretinoin with a proven tolerability profile. Greater tolerability may help improve adherence to skin care regimens, which may ultimately lead to better patient outcomes."

The FDA approved Altreno Lotion in August, based on data from two identical multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies that demonstrated Altreno Lotion resulted in statistically significant reductions in both inflammatory and non-inflammatory lesions compared to vehicle. Results were published in the *Journal of Drugs in Dermatology*.

In the studies, Altreno Lotion was shown to have significantly greater efficacy compared to vehicle in achieving treatment success, which was defined as at least a two-grade improvement from baseline in a global severity by Evaluator Global Severity Score (EGSS) and 'clear' or 'almost clear' skin. By week 12, 17.7 percent of Altreno Lotion patients had achieved treatment success, compared to 9.3 percent of patients receiving vehicle. Altreno Lotion also demonstrated statistically significant reductions in both inflammatory and noninflammatory lesion counts (both P<.001) at week 12 compared to vehicle (52.1 percent versus 41.0 percent for inflammatory lesion counts and 46.1 percent versus 29.9 percent in noninflammatory lesion counts). The most common adverse reactions were application site pain (3.1 percent), dryness (3.7 percent) and erythema (1.4 percent). Altreno Lotion was found to be generally well-tolerated among treatment groups.

"Extensive clinical data have shown that topical retinoids are highly effective in acne and are recommended as the cornerstone of topical therapy; however, retinoids are perceived to have limited efficacy in inflammatory acne and that tolerability issues are barriers to their use. The results from the two Phase 3 clinical trials demonstrated that Altreno can provide physicians and their patients a new treatment option that significantly reduces inflammatory and noninflammatory acne lesions along with a favorable tolerability profile," says Sabrina Fabi, MD, a dermatologist and dermatologic cosmetic surgeon from Cosmetic Laser Dermatology, San Diego, and assistant clinical professor, University of California, San Diego.

Patient satisfaction was also shown to be significantly greater with Altreno Lotion compared to vehicle, increasing from baseline to week 12 by 53 percent compared to 43 percent with vehicle (P<.001), and with nine out of 10 patients reporting satisfaction with their treatment. Patient satisfaction was measured using the acne-specific quality of life (Acne-QoL) questionnaire. The 19-item Acne-QoL is a validated psychometric instrument designed for use in clinical trials.

"We are proud to make Altreno Lotion available as a new option for acne patients, providing the trusted efficacy of a tretinoin, but in a lotion formulation that is generally well-tolerated and helps hydrate and moisturize the skin," says Bill Humphries, president, Ortho Dermatologics. "Millions of Americans are affected by acne, and the launch of Altreno Lotion underscores our commitment to expanding the treatment possibilities for this community."

ALMIRALL'S SEYSARA SET TO SHAKE UP US ACNE MARKET

The FDA's approval of Almirall's Seysara (sarecycline) for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ages nine and older is set to shake up the currently stagnant acne market due to its ease of administration and once-daily formulation, predicts GlobalData, a data and analytics company.

Seysara was originally developed by Paratek Pharmaceuticals. The company exclusively licensed US development and commercialization rights to Allergan and retains the development and commercialization rights to Seysara for the rest of the world. Almirall recently acquired the bulk of Allergan's Medical Dermatology portfolio, and now has the rights to Seysara in the US. Seysara is a once-daily, oral, narrow spectrum tetracycline-derived antibiotic with anti-inflammatory properties.

"Seysara will provide an alternative treatment to target *P. acnes* colonization and inflammation to those acne patients whose strains of *P. acnes* have already developed antibiotic resistance to clindamycin and erythromycin. As a once-daily oral tablet, Seysara should make treatment easier for patients," says Pavan Kottamasu, MBA, MSc, Senior Pharma Analyst at GlobalData.

The efficacy and safety of Seysara were observed in two replicative, randomized, multicenter, double-blind, placebo-controlled Phase III studies that compared sarecycline to placebo. The primary outcome measures were absolute change in inflammatory lesion count and Investigator Global Assessment (IGA) success from baseline to Week 12. Seysara was found to be statistically, significantly superior ($p < 0.004$) to placebo, with respect to both primary efficacy endpoints.

The most common adverse events reported were nausea, nasopharyngitis, and headache. The rate of discontinuation due to adverse events among sarecycline-treated patients in the two studies combined was 1.4%.

"Although the clinical trial evidence suggest that Seysara is efficacious and safe to use, the use of any antibiotic can lead to antibiotic resistance via pump efflux or ribosomal protection. Tetracycline-derived antibiotics are also well known to cause adverse effects such as hyperpigmentation in teeth, gastrointestinal irritation, and photosensitivity," says Mr. Kottamasu.

In addition, Seysara will potentially face competition from FMX101, Foamix Pharmaceuticals' Phase III drug with antibiotic properties that is also in development for the treatment of moderate to severe acne vulgaris. In September 2013, Foamix announced positive topline results for their Phase III trial evaluating FMX101 in moderate to severe acne patients. The study met both co-primary endpoints of absolute change from baseline in inflammatory lesion count at Week 12, and IGA treatment success at Week 12.

"The acne vulgaris pharmaceutical landscape has been stagnant for the past five years. Innovative novel products can challenge the treatment paradigm, such that compliance, the greatest unmet need for acne vulgaris patients, is improved and allows patients to receive the full benefit of a drug's efficacy," says Mr. Kottamasu.

PRE-CONDITIONING ADDED TO SEBACIA MICROPARTICLES ENHANCES OUTCOMES

Using pre-conditioning in conjunction with Sebacia Microparticles for treatment of acne leads to enhanced outcomes, new data suggest. In fact, results from a real-world, pre-conditioning registry trial in Europe demonstrate that the combination of pre-conditioning followed by Sebacia Microparticles leads to an average 79 percent improvement in facial acne through six months of follow-up.

For the ongoing single-arm registry study being conducted at nine commercial practices in Europe patients (n=71) with mild to moderate inflammatory facial acne undergo a short skin pre-conditioning period consisting of two to four weeks of daily topical application of a gel containing 0.1% adapalene and 2.5% benzoyl peroxide. Patients are then administered three weekly in-office treatments of Sebacia Microparticles.

Ashish Bhatia, MD presented the interim findings during the American Society for Dermatologic Surgery (ASDS) 2018 Annual Meeting. Key results include:

- At three months, the mean acne inflammatory lesion count (ILC) improvement was 66 percent from baseline and at six months, ILC further improved to 79 percent from baseline. Historically-reported ILC reduction at three months is 49 percent and at six months is 65 percent without pre-conditioning.
- 63 percent of patients had in Investigator Global Assessment (IGA) score of clear or almost clear at six months.
- 76 percent of patients were acne medication-free at three months; 61 percent at six months.
- 29 percent of patients received a topical prescription and only 10 percent received a systemic drug during six-month follow-up.
- Transient erythema (redness of the skin typical with laser use) was reported and patients were able to return to school or work immediately after the procedure. There were no serious or unanticipated adverse events. ■