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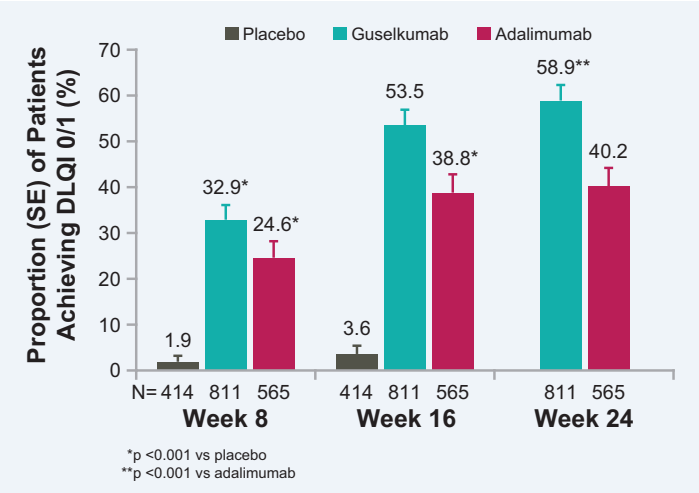
Psoriasis Research to Improve Patient Care: A Treasure Trove of Critical Questions

Psoriasis is a chronic, debilitating, inflammatory systemic skin disease with negative psychosocial impact, and is associated with multiple significant comorbidities. In the U.S. alone, this diagnosis affects more than 8 million people—roughly 3.2% of the population. Globally, 1%–4% of the population are affected. Moderate to severe disease especially has a profound impact on function and quality of life (QOL). Although the probability of successful treatment has improved dramatically with the advent of biological drugs (see box on page 5), this has turned out to be only a start toward achieving the often elusive goal of restoring patients' skin, lives—and psyches—to normal. The need to identify and understand the complex of factors that are pivotal in maximizing control of this disease and QOL for each patient remains urgent.

The roadmap for mastering this multifaceted challenge has now begun to emerge, much of it by way of the many perceptive and far-ranging questions articulated and productively explored by psoriasis specialist and patient advocate April W. Armstrong, MD, MPH,* at the University of Southern California (USC). She has become one of the leading voices in psoriasis research and treatment, and the constantly expanding knowledge base she produces is immediately applicable in clinical care.



Guselkumab superior to adalimumab. In patients with a baseline DLQI score >1, the proportion achieving a score of 0/1 was significantly greater in the guselkumab-treated group at all assessment intervals. (Reprinted from AW Armstrong et al. *Am J Clin Dermatol*. See *Suggested Readings* for citation.)

Finding Her Focus

Armstrong had actually planned to become a gastroenterologist—"until I stumbled onto dermatology late in my medical school rotations," she recalls. "I was fascinated by the variety of skin diseases, I really liked the full age range of the patients we see, and my mentors at Harvard inspired me—they were thoughtful, happy, extremely capable people who really made a difference in their patients' lives." Once in her residency, Armstrong's initial interest in surgery was eclipsed as she found herself drawn to inflammatory skin diseases and their potentially life-altering impact—and most especially to psoriasis. "I had begun following patients with psoriasis in my clinics. I saw so clearly that this disease profoundly impacts them—and that dermatologists are in a position to make a profound difference in these patients' lives."

Armstrong's residency also coincided with a fundamental turning point in the understanding and treatment of psoriasis. "Biologic treatments for psoriasis were just becoming available," she recalls. "Even as a trainee, I began to see the transformation for patients." And convention-shattering research had begun to reveal that psoriasis is not a skin-limited condition but is associated with various comorbidities.

But there was a distressing dichotomy. Despite the significantly improved treatment options, too many patients were still not treated or inadequately treated. Medication with the potential to normalize their lives was not reaching them. Armstrong also began to realize that a great deal of critical information about these revolutionary new drugs was lacking, so dermatologists have been unable to determine which drug is best for a particular patient. And very little was

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known about how patients feel about their disease, their lives, or the treatment they have been prescribed.

As Armstrong became convinced that sound clinical practice needs to be rooted in evidence-based medicine, finding the facts that would enable thoughtful, effective, comprehensive care for psoriasis patients quickly became the driving force in her research. She pursued her MPH to gain the skill set that would equip her to do her best research—and then got down to work.

Combining dedication, insight, and cutting-edge skills, and taking advantage of newly emerging comprehensive databases when appropriate, Armstrong has covered extensive and varied ground. Within this, she points to two areas that she is particularly passionate about.

One is uncovering the spectrum of information needed to define the real-life impact and value of available treatments, especially through comparative effectiveness research. "With the extensive variety of available treatments for psoriasis now, it is paramount that clinicians understand the differences between therapies. Although traditional efficacy endpoints capture factors such as body surface area and morphology, these endpoints may not necessarily align with outcomes that are most important to the patient," Armstrong emphasizes. "The second area," she continues, "is using technology to substantially improve healthcare delivery for our patients with chronic skin diseases—psoriasis in this case." Her pilot program is designed to provide ongoing care—remotely—to the significant number of patients with barriers to accessing a dermatologist face-to-face.

This article will highlight much of what Armstrong has been documenting in her ongoing efforts to help clinicians provide the best possible care to their psoriasis patients.

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The World of Drugs: Oral vs Biologic

Using data from the almost 43,000 patients contained in the Truven MarketScan U.S. claims database from 2008–2015, Armstrong documented similar safety profiles between conventional systemic/topical therapies and the handful of biologics available at that time (adalimumab, etanercept, ustekinumab, infliximab). None of them were linked to higher risk, and several were actually associated with a slightly lower risk of infection.

Looking at efficacy came next, with data for these comparisons extracted from comprehensive national databases. The 2003–13 Medical Expenditure Panel Survey, for example, provided well over 2 million patients with moderate to severe psoriasis. Armstrong and her team consistently found the biologics to be significantly superior to oral treatments—and she emphasizes that "clinicians need to take this into account as they make treatment decisions."

Armstrong documented the superior efficacy of biologic therapy in reducing the destructive impact of psoriasis on various aspects of physical function and general health. But she was particularly concerned about the most helpful type of treatment for improving psychological functioning. The effects that lesions have on appearance carry a psychosocial toll that produces decrements in mental health equivalent to those found in patients with such chronic systemic diseases as myocardial infarction, diabetes, and cancer. More than 30% of psoriasis patients are estimated to show symptoms of depression and anxiety. Yet there was a dearth of studies assessing the relative effects of different systemic treatments on mental health outcomes in a nationally representative psoriasis population. Armstrong pursued this, and found that biologics are associated with significantly lower scores for psychological distress and depression, and with significantly higher scores for multiple dimensions of mental health functioning.

Earlier studies assessing the impact of psoriasis on a patient's work performance had shown that having clear skin reduces presenteeism (difficulty in focusing on the work at hand). When Armstrong did multivariate linear regression analyses to see if the different systemic treatments affect patients' wage earnings, the adjusted mean annual wage was $11,342 higher for patients on biologics compared to oral therapies, primarily reflecting the ability to put in more hours at work.

The superiority of biologicals came into play—quite unexpectedly—in a recent cross-sectional study in which Armstrong and her team looked at the four U.S. census regions (Northeast, South, Midwest, West) to see which one offers the best access to healthcare resources. Data from the 1996–2015 Medical Expenditure Panel Survey ranked each census region for access to biologics, ambulatory visits per patient per year (PPPY), proportion of patients with ≥1

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Progress in Patient Care Began With the DF

Each year, the Dermatology Foundation carefully identifies emerging investigators whose ideas hold the potential to impact patient care in significant ways, and who possess the abilities to make this a reality. April W. Armstrong, MD, MPH, was one of these young investigators when she applied for a Career Development Award (CDA), and then a Patient Directed Grant, just over a decade ago. Her progress since then has already given dermatologists tools for choosing knowledgeably among the many psoriasis therapeutics, and improved insight into the disease burden their patients experience. Further advances are on the horizon.

Dr. Armstrong has identified significant inadequacies in the clinical care of patients with moderate to severe psoriasis, and is well on her way to eliminating them. "I believe that good clinical practice needs to be rooted in evidence-based medicine," she emphasizes, and she has been hard at work carrying out the exceptional number and breadth of studies that will enable dermatologists to consistently arrive at optimal treatment choices for this complex, life-altering, chronic inflammatory disease.

Dr. Armstrong has already made substantial progress. She has documented the significant superiority of biologic treatments to oral therapies, is estabishing the long-term safety and efficacy of individual biologic therapies, and shows the newer biologics—the IL-23 inhibitors and IL-17 inhibitors—to be significantly superior to the earlier TNF-α inhbitors for improving both skin and quality of life. She is deeply involved in innovative efforts to gain critical patient assessments and feedback, and has been documenting the impact of psoriasis, and effective treatment, on such variables as work performance and earnings, and psychological function. Dr. Armstrong is also identifying current treatment patterns, investigating comorbidities, and examining the disease's economic burden. She has created an effective model for a patient-centered teledermatology program—*Collaborative Connected Health (CCH)*—for reaching the many rural psoriasis patients lacking access to dermatology care. Dr. Armstrong has become a recognized innovator among psoriasis experts and holds multiple leadership positions in professional societies.

Dr. Armstrong's deep concern for psoriasis—and atopic dermatitis—patients, and her determination to enable clinical care that normalizes patients' lives and is free of accessibility barriers, emerged as she cared for patients during her residency. When she began her junior faculty position, she applied for Dermatology Foundation research funding. The DF recognized her genuine dedication aligned with an outstanding ability to achieve her goals. She was awarded a 3-year CDA in 2009 for a telemedicine project addressing patients with atopic dermatitis, which was continued with an NIH grant. In 2010 Dr. Armstrong received a year's funding to study the association of coronary artery disease with psoriasis.

"My DF funding has been instrumental to my success," she underlines. "Recognition by the DF that my work is important was extremely validating. It really gave me great encouragement at a vulnerable and critical time in my career. It also helped to provide a competitive foundation to apply for federal funding. I am *immensely* grateful."

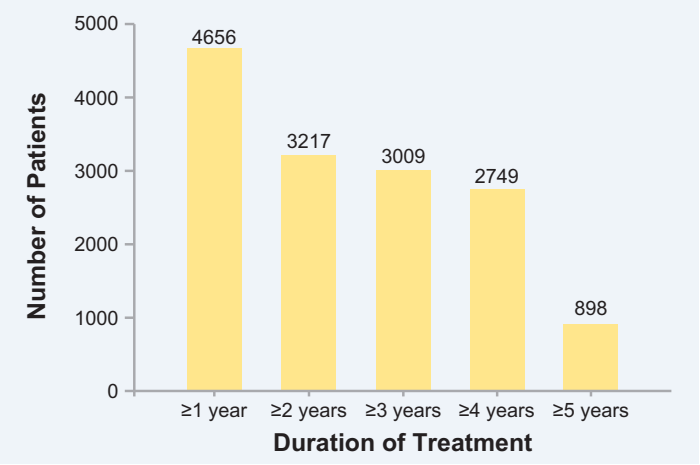
emergency department (ED) visits, total healthcare costs, and total drug costs. Among the substantial disparities they observed, the South had 30% fewer ambulatory visits PPPY and a 39% lower proportion of patients with ED visits compared to the rest of the country. "Patients in the South also had the greatest access to biologics," Armstrong points out, "which may help to explain this. When patients' psoriasis is well controlled with advanced therapies, they may not need to visit their dermatologists or the ED as frequently."

The biologics' superiority offers multiple benefits for treating patients with significant physical and psychological dysfunction. Early identification and treatment of such dysfunction may delay further disability, improve treatment adherence, and facilitate patient–provider decision making.

The World of Biologics

These therapies (see box on page 5) have progressively improved treatment outcomes in moderate-to-severe psoriasis over recent years, with more patients achieving clear skin. But extended real-world assessment is essential, because sustaining such responses with a biologic agent over time typically requires continuous maintenance therapy. This has been underscored by studies documenting the superior benefit for responders who continue regular use compared to those who are moved to treatment only as needed. As maintenance continues, the impact of treatment on comorbidities associated with psoriasis—such as cardiovascular disease and depression—as well as potential safety concerns associated with selective immunomodulation (including malignancy and infection) require special investigation. We cannot simply transpose the safety and efficacy outcomes of clinical trials years into the future.

And beyond that, looking at each drug in isolation provides only part of the picture. "When we're in clinical practice, the dermatologist and patient ultimately have to take all of the existing information into account in making their decision," Armstrong says. "And they are not selecting between Drug A vs Placebo or Drug B vs Placebo—but between Drug A vs B vs C, etc." Head-to-head drug comparisons are essential. Armstrong has been hard at work producing this, often within the setting of long-term comparisons.



Safety of ixekizumab treatment through 5 years. Number of patients by treatment duration, with a total number of 5,898 patients and total exposure of 17,003.4 patient-years. (Reprinted from A Armstrong et al. *Dermatol Ther.* 2020; 10:133–50)

Ixekizumab. This IL-17A inhibitor was approved in 2016. Armstrong integrated safety data from 13 clinical studies of adult patients with moderate-to-severe disease—providing a database of more than 17,000 patient-years of exposure, and 2,749 patients treated for ≥4 years—to assess its safety and tolerability for up to 5 years (see graph above). Rates for adverse effects (AEs)—including serious AEs, malignancies not included in that group, and MACE (major adverse cardiovascular events)—remained largely stable or declined. Rates

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Biologics Targeting Psoriasis

Biologic medicines—from recombinant insulin (approved in 1982) to human growth hormone (approved in 1984) to vaccines to TNF inhibitors to PD-L1 blockers—contain an active substance synthesized by or derived from a biological source. They interact with a precise target—most typically a protein—to produce highly specific molecular effects. The revolution generated as today's molecular technologies have evolved, combined with increasing successes in the molecular understanding of more and more of our challenging diseases, is making an increasing spectrum of biologic possibilities accessible and therapeutically relevant.

For years, treatment options for psoriasis patients were limited to topicals, oral cyclosporine and methotrexate, and tar baths for particularly severe and unresponsive disease. Once investigators began to identify the inflammatory immune pathways that initiate and maintain psoriasis and psoriatic arthritis (PA), biologics to inhibit them became the therapeutic goal. TNF-α inhibitors came first, with etanercept—FDA approved in 2004—the initial breakthrough. There are now 11 (with more on the horizon), now including inhibitors for IL-17, IL-23, and IL 12/23. All except the four with asterisks received approval for both plaque psoriasis and PA. (The nonbiologic oral PDE4 inhibitor apremilast was approved for psoriasis and psoriatic arthritis in 2014.)

TNF-α inhibitors. This category began with etanercept (2004), adding infliximab (2006), adalimumab (2008), and certolizumab (2018).

IL-12/23 inhibitors. Ustekinumab (2009).

IL-17 inhibitors. This includes ixekizumab (2016), brodalumab* (2017), and secukinumab (2018).

IL-23 inhibitors. Approval is for plaque psoriasis but not for PA: tildrakizumab* (2018), guselkumab* (2019), and risankizumab* (2019).

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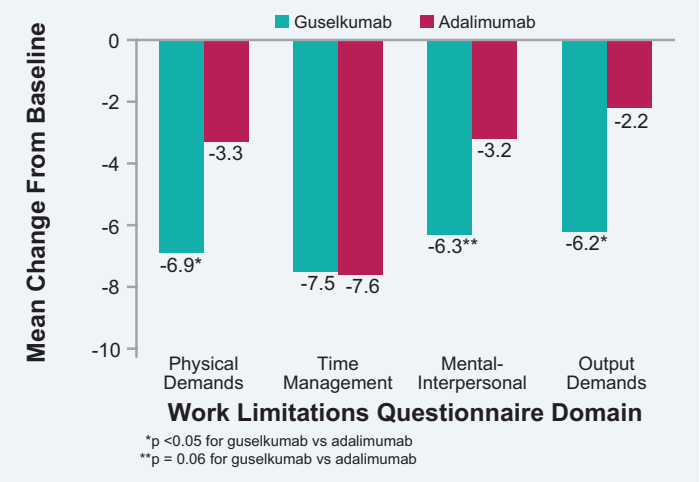

Guselkumab superior to adalimumab. At week 24, mean change from baseline domain scores in responses to the Work Limitations Questionnaire documents the significantly greater improvement among guselkumab-treated patients. (Reprinted from K Reich et al. *J Dermatolog Treat.* 2019;15:1–7)

for TEAEs (treatment-emergent AEs) leading to discontinuation decreased. This favorable 5-year safety picture is in line with reports for shorter exposures. Assessing the efficacy in attaining the patient-centered treatment targets established by the National Psoriasis Foundation—which integrated data from four phase III clinical trials—found that the majority of ixekizumab-treated patients had achieved these goals by 12 weeks, unlike the older biologics ***etanercept*** (51.8% of patients vs 14.9%) and ***ustekinumab*** (50.7% vs 24.1%).

Armstrong integrated results from three phase III clinical trials that used the WPAI-PSO (Work Productivity and Activity Impairment-Psoriasis) to examine the effect of ixekizumab treatment on work productivity, because time missed from work and reduced at-work productivity can have subsantial and extensive economic repercussions. Significant improvement at week 12 was sustained at week 60. The two studies including ***etanercept***-treated patients showed benefit equivalent to ixekizumab in one, and somewhat less in the other.

Guselkumab. This novel IL-23 inhibitor was approved in 2019 based on two pivotal phase III studies—VOYAGE 1 and VOYAGE 2. Because it blocks IL-23 without affecting IL-12, it does not compromise IL-12's activity in host resistance to intracellular pathogens, tumor surveillance, and possibly protection against skin inflammation. Guselkumab showed superior efficacy to the commonly used TNF-α inhibitor ***adalimumab*** in both trials, and established a favorable benefit:risk ratio through 1 year of treatment. Armstrong's updates at 2 and 3 years show that efficacy has been maintained, while rates of most AEs decreased during the second year. She will provide updates through 5 years.

The efficacy data in these trials are notable in incorporating patient-reported outcome measures, both the Dermatology Life Quality Index (DLQI) and the Psoriasis Symptoms and Signs Diary (PSSD). At week 24, more guselkumab than adalimumab recipients achieved a score = 0 (no impact) across all DLQI domains (see graph on front cover). DLQI 0/1 scores were associated with PSSD symptom or sign scores = 0 (no impact), and greater PASI and IGA improvement. And the proportion of guselkumab-treated patients reporting normal QOL has remained consistent.

Armstrong also assessed guselkumab's impact on work productivity—both absenteeism (inability to work) and presenteeism—by week 24. Results were stratified by baseline depression/anxiety status, which turned out not to influence results. A DLQI work/study score = 0—no effect of skin on work/study—was reported by 82.1% of patients on guselkumab vs 50.0% in the adalimumab group. In the same vein, mean improvements in the 4 measures of presenteeism were significantly greater in the guselkumab-treated group (see graph at left).

Armstrong was involved in the first head-to-head comparison of guselkumab with an IL-17A inhibitor (***secukinumab***). The primary endpoint in this 9-country study was the proportion of patients achieving ≥90% reduction in their PASI score by week 48, with a variety of secondary endpoints to assess other improvement patterns. Although the secondary endpoints and safety findings did not differentiate significantly between the two treatments, long-term efficacy was revealing: 84% of the guselkumab group had at least a PASI 90, compared to 70% in the secukinumab group. The take-home message is that guselkumab showed superior long-term efficacy compared to secukinumab.

Number Needed to Treat. "There are wide variations in patient responses to each of these established biologic therapies for moderate-to-severe disease," Armstrong points out. In this study, she determined the NNT—the number of patients who need to be treated—to achieve one additional patient reaching a 75% or 90% reduction in PASI score. The smaller the NNT, the more likely an individual patient will experience this benefit. Armstrong also estimated the total costs for each treatment to produce a responsive patient, both for the clinical trial period and annually. NNT and cost were determined relative to supportive care.

Results—similar for both PASI 75 and PASI 90—showed all biologic therapies to be statistically more efficacious than both the oral PDE4 inhibitor apremilast and supportive care. Adalimumab, infliximab, and secukinumab 300 mg had the lowest costs per additional PASI 75 responder. And the highest costs per additional PASI 75 responder were consistently tied to etanercept.

Cumulative Clinical Benefit. Armstrong recently pioneered the use of this innovative and dynamic concept, which examines the cumulative impact of a drug over time instead of the conventional snapshot from merely sampling improvement at prespecified, separate moments over time. *Cumulative clinical benefit* reflects the complete percentage of responders over a given time period, and is determined by measuring the area under the curve. Working with cumulative impairments on the disease side together with cumulative benefits on the treatment side incorporates a holistic, longitudinal perspective that captures both the rapidity and sustainability of treatment responses among responding patients. This perspective will facilitate consistent success in treating such high-impact diseases as psoriasis.

Armstrong assessed the cumulative benefit over 52 weeks in a clinical trial of recently approved secukinumab (300 mg, 150 mg) vs etanercept, the first biologic approved for psoriasis. Cumulative benefit was determined for PASI 75, PASI 90, PASI 100, and for DLQI. Comparing clinical benefit of the two secukinumab doses, 300 mg became 71% more effective for

2019: New Annenberg Circle Members

The DF Board of Trustees is truly pleased to welcome and recognize its newest AC members. Each has pledged $25,000 to meet the critical need for the research that will expand the platform to further patient care. They join more than 600 colleagues in making an invaluable investment, one with immeasurable returns for their patients.

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achieving PASI 100. Comparing secukinumab 300 mg and etanercept, the cumulative clinical benefit ratio increasingly favored secukinumab. For achieving PASI 75 over 52 weeks, the clinical benefit ratios—1.47 for secukinumab 300 mg vs etanercept and 1.25 for secukinumab 150 mg vs etanercept—tell us that patients would be experiencing 47% more benefit and 25% more benefit, respectively, after 1 year of treatment. The same cumulative benefit patterns emerged for DLQI improvement.

Undertreatment

Current treatment guidelines recommend topical therapy only for mild disease (as monotherapy or with phototherapy), and traditional oral systemic agents, biologic agents, or phototherapy for moderate to severe disease. Despite this, inadequate treatment, lack of treatment, and unsatisfactory disease control remain key concerns for healthcare professionals. Before attempting to address these treatment deficits, it is essential to know their extent. Armstrong and her team approached this by using health plan claims data over a 5-year period to determine overall treatment patterns and areas of undertreatment in insured U.S. patients with moderate-to-severe plaque psoriasis. These databases capture relevant information—including treatment history—from healthcare professionals caring for individual insured patients.

Armstrong identified an estimated 1.7 million insured U.S. patients with moderate-to-severe psoriasis, and discovered that 1 million—almost 60%—had not received any treatment at all for their disease in the preceding year. And among the close to 700,000 who had been treated, 42% had received only topical therapy, 32% received a traditional oral systemic, and only 22% were on a biologic. By the following year, 50% of that treated group had lapsed. Identifying the dynamics of treatment patterns spanning a 12-month period, Armstrong reported a high degree of flux that included starts, stops, restarts, switches, and complete stops. Even within the insured population, "moderate to severe psoriasis remains persistently untreated or undertreated," she asserts. The underlying reasons for this, and for the frequent treatment changes, need to be explored.

Collaborative Connected Health—Online Care to Reach the Unserved

Skin diseases account for 30% of all physician office visits. Many patients in the U.S. with chronic skin diseases—psoriasis included—lack regular access to dermatologists, and suffer poor clinical outcomes as a consequence. Armstrong is determined to change this. One of her passionate goals is "to make sure that patients—regardless of where they live—can get good quality care. I want to ensure that choosing to live in a rural area no longer means that meeting one's healthcare needs has to suffer. No one should have to pay that price." Armstrong is confident that we can leverage the advances in communication technology to realize this goal. And she has begun to make it happen.

Armstrong is not interested in pursuing the conventional consultant-based model of teledermatology, in which the patient has no direct contact with the dermatologist. In this scenario the patient's PCP is the go-between, transmitting photographs and clinical history, receiving the dermatologist's recommendations, then implementing them and managing the patient.

Her vision involves a novel model focusing on highly patient-centric collaborative care—the *collaborative connected health (CCH)* model for psoriasis management that she assessed during a 12-month pilot period. The patient is able to access the dermatologist directly, and the dermatologist makes recommentations, prescribes medications, and provides educational materials online directly to the patient. In the pilot, 296 adult patients with physician-diagnosed moderate-to-severe disiease were selected from California and Colorado, and randomly divided between in-person dermatology care and CCH. The adequacy of each was assessed at several points throughout the year.

96 New *Leaders Society* Members in 2019

The Board of Trustees is pleased to welcome the following new members to the *Leaders Society*. They have joined their colleagues in investing $1,500 annually to help ensure the advancement of research that further illuminates skin biology and significantly advances patient care in dermatology. Their confidence in the Foundation's continued ability to identify and fund the research enabling these goals is truly appreciated.

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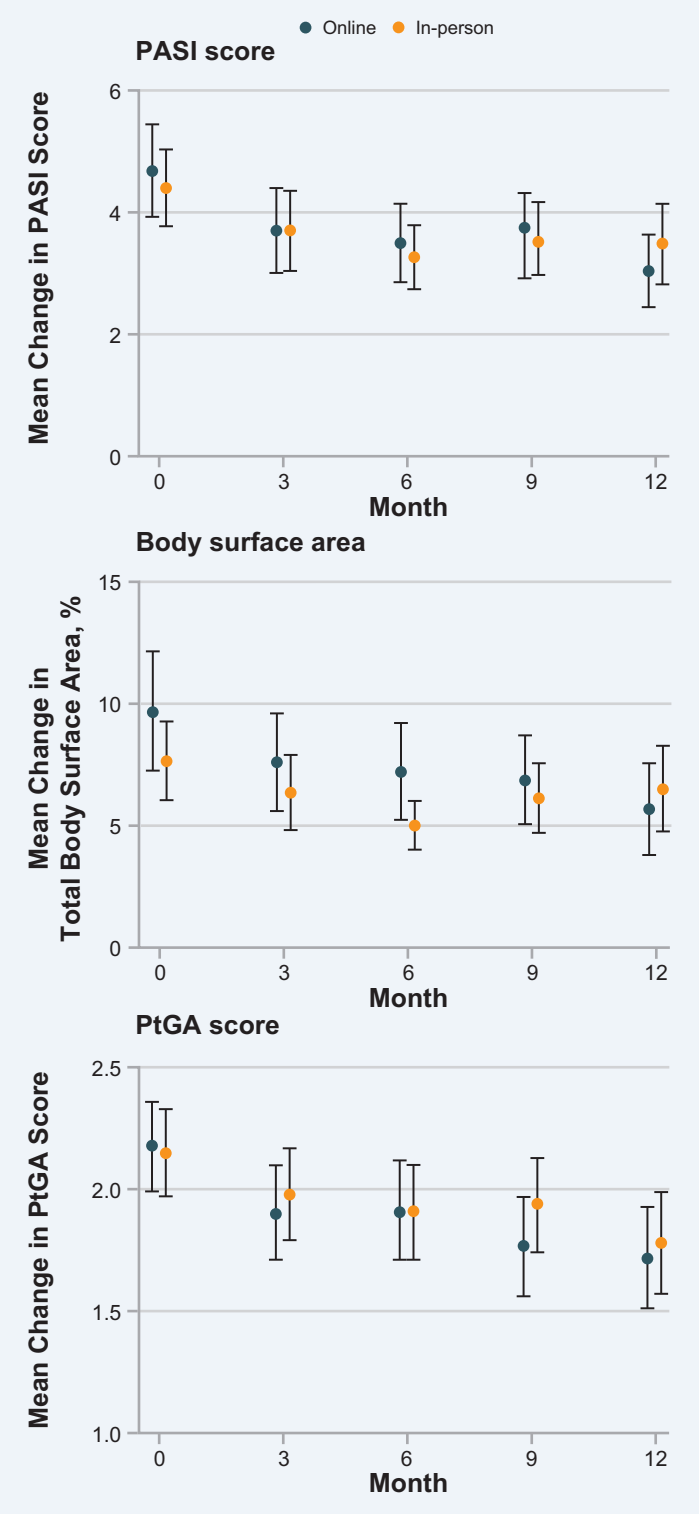
Italics = Young Leader (5 years or less out of residency)

CCH eliminated logistical barriers to accessing dermatology care. Per person, the mean distance traveled to and from appointments was 175.8 km for in-office visits and merely 2.2 km for CCH. The time taken by transportation and in-office waiting was 4 hours per person in the direct-visit group and 0.1 hour for CCH. Psoriasis patients and providers alike indicated high satisfaction with the CCH experience. They felt that it increased access to specialty care, and enabled safe and effective patient-centered management.

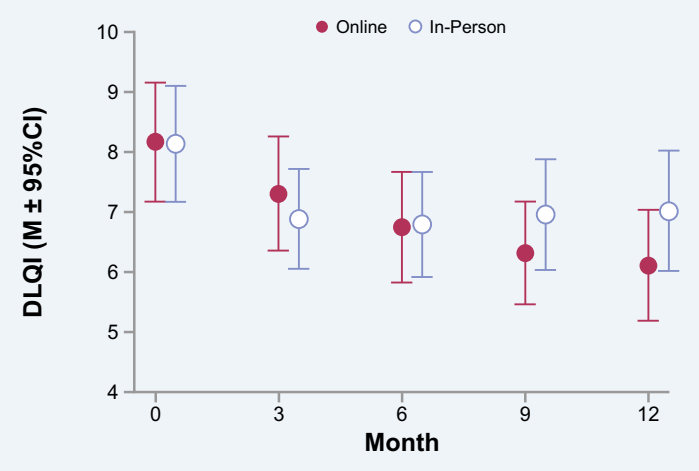
Efficacy was assessed within several domains, and prespecified equivalence margins were established to identify results reflecting comparable treatment impact from CCH and in-person dermatology care. This made it clear that the mean changes from baseline scores in the self-administered PASI, BSA, and PtGA were equivalent for the two groups. QOL improved equally as well, seen via Skindex-16 (how much patients are bothered by their skin condition) and DLQI (the impact of a skin disease on the patient's life). (See graphs on page 10.) The functional and psychological improvents were also equivalent. Armstrong and her team used the EQ-5D-5L (5-level EuroQol-5 Dimensions; standardized measure of health status) and the PHQ-9 (Patient Health Questionnaire-9; screens for depression, measures severity). The PHQ-9 is particularly important, because psoriasis patients experience significantly higher rates of depression than the general population.

Patients, PCPs, and dermatologists all found CCH to be highly useful for increasing specialty care access and delivering high-quality, coordinated care for patients with psoriasis, and this can be extended to other chronic skin diseases as well. Armstrong is delighted with the "robust and responsive specialist support for patients and PCPs online,"

calling it "a substantial improvement from some of the existing modalities of specialty healthcare delivery." This kind of innovative telehealth delivery model—emphasizing collaboration, quality, and efficiency—can be transformative for improving patient-centered outcomes among those with chronic diseases.



Online care model reduces disease severity. Clinical reduction in disease severity at the end of 1 year is equivalent to that achieved via in-person care, assessed by scores on PASI, body surface area, and Patient Global Assessment. (Reprinted from AW Armstrong et al. *JAMA Network Open*. 2018;1:e183062. doi: 10.1001/jamanetworkopen.2018.3062)



Online care model improves quality of life. Improvement in DLQI scores at the end of 1 year is equivalent to that achieved via in-person care. (Reprinted with permission from AW Armstrong et al. *J Invest Dermatol*. 2019;139:1037–44)

And In Addition….

"Psoriasis carries significant patient burdens. And this, along with patients' experience with the treatments they receive for their disease, can be best assessed by the patients themselves," Armstrong says. This can include assessment of health-related QOL, signs and symptoms of psoriasis, depression and anxiety, and the ability to work. She is involved in developing patient-centered tools for far more rigorous measurements of a given treatment's impact on these burdens. Part of this process involves a careful refinement, not just of the questions asked, but how they are phrased. "You want to make sure they are in patient-appropriate language. So we really probe our test group of patients to understand why they made specific choices on the draft questionnaire to see if their responses show that they understood each question, or if any of them need to be rephrased." Armstrong underscores the need for future clinical trials to assess the full spectrum of disease and treatment impact.

In another vein of inquiry, Armstrong wanted to know why fewer than 3% of psoriasis patients account for 13% of psoriasis-related healthcare expenditures. She has been teasing out the drivers of healthcare costs for these costliest patients, and the culprit turned out to be the care required by comorbidities, not by psoriasis itself. Armstrong has also been probing mental health issues among psoriasis patients, because she is convinced that investigators have underappreciated links to psychiatric comorbidities—especially anxiety, depression, and suicidality—and thus they are not adequately screened for or treated. And there is still more: Armstrong and her group are also characterizing the more challenging psoriasis-specific aspects of the associated comorbidities.

Final Comments

"I'm very passionate about what I do," Armstrong asserts, "and it all happened because of my psoriasis patients. They have taught me how deeply gratifying it is to take care of patients with chronic diseases over time, seeing their lives improve—and feeling that you are part of this, that you have made a true difference in their lives."

(Continued on page 13)

For adults with plaque psoriasis

bettertogether

The first and only steroid/retinoid therapy, allowing **halobetasol** and **tazarotene** to work together in an advanced, once-daily lotion that can be dosed to clearance[1-3]

DUOBRII™
(halobetasol propionate and tazarotene)
Lotion 0.01% / 0.045%

mechanisms of change

Halobetasol (0.01%)

Provides powerful antiinflammatory effects and reduces skin irritation, which is often associated with retinoids[1,4,5]

Tazarotene (0.045%)

Regulates cell growth and specialization to reduce hyperproliferation, increases collagen, and extends remission post treatment[4,6,7]

The only FDA-approved treatment with a potent-to-superpotent steroid that can be used until control is achieved

The efficacy and safety of DUOBRII Lotion was investigated in two 8-week clinical trials and an additional 1 year safety study.[1,3]
Discontinue treatment with DUOBRII Lotion when control is achieved or if atrophy, striae, telangiectasias, or folliculitis occurs.[1]

American Academy of Dermatology (AAD) Guidelines give the combination of a corticosteroid and a retinoid an A rating with Evidence Level I for the treatment of psoriasis[4]

Indication

DUOBRII™ (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, is indicated for the topical treatment of plaque psoriasis in adults.

Important Safety Information

Contraindication

DUOBRII Lotion is contraindicated in pregnancy.

Warnings and Precautions

- Women of child-bearing potential should be warned of the potential risk of fetal harm from DUOBRII and use adequate birth-control. A negative result for pregnancy should be obtained within 2 weeks prior to treatment. If the patient becomes pregnant during treatment, discontinue DUOBRII Lotion and advise patient of the potential hazard to the fetus.
- DUOBRII Lotion has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis during or after treatment and may require that patients be evaluated periodically during treatment.
- Predisposing factors for HPA axis suppression include: use of more potent corticosteroids, use on large areas, use under occlusive dressings, use on altered skin barrier, concomitant use of other steroids, liver failure and young age.
- Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria.
- Local adverse reactions may include atrophy, striae, telangiectasias, folliculitis and contact dermatitis. If these effects occur, discontinue until the integrity of the skin has been restored. Do not resume treatment if contact dermatitis is identified. DUOBRII Lotion should not be used on eczematous skin, as it may cause severe irritation.
- Avoid exposure to sunlight, sunlamps and weather extremes. Patients with sunburn should be advised not to use DUOBRII Lotion until fully recovered. DUOBRII Lotion should be administered with caution if the patient is also taking drugs known to be photosensitizers because of the increased potential for photosensitivity.
- Topical corticosteroids may increase the risk of cataracts and glaucoma; advise patients to report any visual symptoms and refer to an ophthalmologist if needed.

Adverse Events

- The most common adverse events in clinical trials were contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%).

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of full Prescribing Information on the following page.

References **1.** DUOBRII Lotion [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC. **2.** Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Accessed April 29, 2019. **3.** Data on file. **4.** Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol*. 2009;60(4):643-659. **5.** Orfanos CE, Schmidt HW, Mahrle G, et al. Retinoic acid in psoriasis: its value for topical therapy with and without corticosteroids: clinical, histological and electron microscopical studies on forty-four hospitalized patients with extensive psoriasis. *Br J Dermatol*. 1973;88(2):167-182. **6.** Lesnik RH, Mezick JA, Capetola R, Kligman LH. Topical all-trans-retinoic acid prevents corticosteroid-induced skin atrophy without abrogating the anti-inflammatory effect. *J Am Acad Dermatol*. 1989;21(2 Pt 1):186-190. **7.** Weinstein GD, Krueger GG, Lowe NJ, et al. Tazarotene gel, a new retinoid, for topical therapy of psoriasis: vehicle-controlled study of safety, efficacy, and duration of therapeutic effect. *J Am Acad Dermatol*. 1997;37(1):85-92.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to prescribe DUOBRII safely and effectively. See full Prescribing Information for DUOBRII.

DUOBRII™ (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045% for topical use

INDICATIONS AND USAGE

DUOBRII (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045% is indicated for the topical treatment of plaque psoriasis in adults.

CONTRAINDICATIONS

Pregnancy

DUOBRII Lotion is contraindicated in pregnancy *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Embryofetal Risk

Based on data from animal reproduction studies, retinoid pharmacology, and the potential for systemic absorption, DUOBRII Lotion may cause fetal harm when administered to a pregnant female and is contraindicated during pregnancy. Tazarotene is teratogenic, and it is not known what level of exposure is required for teratogenicity in humans *[see Contraindications and Clinical Pharmacology]*. Tazarotene elicits teratogenic and developmental effects associated with retinoids after topical or systemic administration in rats and rabbits *[see Use in Specific Populations]*.

Advise pregnant females of the potential risk to a fetus. Obtain a pregnancy test within 2 weeks prior to DUOBRII Lotion therapy. Initiate DUOBRII Lotion therapy during a menstrual period. Advise females of reproductive potential to use effective contraception during treatment with DUOBRII Lotion therapy *[see Use in Specific Populations]*.

Hypothalamic–Pituitary–Adrenal (HPA) Axis Suppression and Other Unwanted Systemic Glucocorticoid Effects

DUOBRII Lotion contains halobetasol propionate, a corticosteroid, and has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic effects of topical corticosteroids may include reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment of the topical corticosteroid.

The potential for hypothalamic-pituitary-adrenal (HPA) axis suppression with DUOBRII Lotion was evaluated in a study of 20 adult subjects with moderate to severe plaque psoriasis involving ≥20% of their body surface area. The subjects were treated once daily for 8 weeks and assessed for HPA axis suppression at Weeks 4 and 8. HPA axis suppression occurred in 3 out of 20 (15%) subjects at Week 4 and none (0%) of these 20 subjects had HPA axis suppression at Week 8 *[see Clinical Pharmacology in full Prescribing Information]*.

Because of the potential for systemic absorption, use of topical corticosteroids, including DUOBRII Lotion, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use over large surface areas, occlusive use, use on an altered skin barrier, concomitant use of multiple corticosteroid-containing products, liver failure, and young age. An adrenocorticotropic hormone (ACTH) stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, attempt to gradually withdraw the drug or reduce the frequency of application. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids. Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids because of their larger surface-to-body mass ratio *[see Use in Specific Populations]*.

Local Adverse Reactions

Local adverse reactions may include atrophy, striae, telangiectasias, folliculitis and contact dermatitis. Some local adverse reactions may be irreversible. If these adverse reactions occur, discontinue the medication at least until the integrity of the skin is restored; do not resume treatment if allergic contact dermatitis is identified.

Avoid use of DUOBRII Lotion on eczematous skin, as it may cause severe irritation.

Photosensitivity and Risk for Sunburn

Because of heightened burning susceptibility, exposure to sunlight (including sunlamps) should be avoided unless deemed medically necessary, and in such cases, exposure should be minimized during the use of DUOBRII Lotion. Patients must be instructed to use sunscreens and protective clothing when using DUOBRII Lotion. Patients with sunburn should be advised not to use DUOBRII Lotion until fully recovered. Patients who may have considerable sun exposure due to their occupation and those patients with inherent sensitivity to sunlight should exercise particular caution when using DUOBRII Lotion.

DUOBRII Lotion should be administered with caution if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the increased possibility of augmented photosensitivity.

Ophthalmic Adverse Reactions

Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported postmarketing with the use of topical corticosteroid products. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

Concomitant Skin Infections

Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of DUOBRII Lotion until the infection has been adequately treated.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In randomized, double-blind, multicenter, vehicle-controlled clinical trials, 410 adults with plaque psoriasis were treated with DUOBRII Lotion or vehicle lotion and had post-baseline safety data. Subjects applied DUOBRII Lotion or vehicle lotion once daily for up to eight weeks. The adverse reactions occurring in ≥1% of the subjects treated with DUOBRII through Week 8 were contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%).

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on data from animal reproduction studies, retinoid pharmacology, and the potential for systemic absorption, DUOBRII Lotion may cause fetal harm when administered to a pregnant female and is contraindicated during pregnancy. Safety in pregnant females has not been established. The potential risk to the fetus outweighs the potential benefit to the mother from DUOBRII Lotion during pregnancy; therefore, DUOBRII Lotion should be discontinued as soon as pregnancy is recognized *[see Contraindications, Warnings and Precautions, Clinical Pharmacology]*.

Observational studies suggest an increased risk of low birthweight in infants with the maternal use of potent or very potent topical corticosteroids *(see Data)*.

In animal reproduction studies with pregnant rats, reduced fetal body weights and reduced skeletal ossification were observed after topical administration of a tazarotene gel formulation during the period of organogenesis at a dose 11 times the maximum recommended human dose (MRHD) (based on AUC comparison). In animal reproduction studies with pregnant rabbits, single incidences of known retinoid malformations, including spina bifida, hydrocephaly, and heart anomalies were observed after topical administration of a tazarotene gel formulation at 116 times the MRHD (based on AUC comparison) *(see Data)*.

In animal reproduction studies with pregnant rats and rabbits, malformations, fetal toxicity, developmental delays, and/or behavioral delays were observed after oral administration of tazarotene during the period of organogenesis at doses 9 and 228 times, respectively, the MRHD (based on AUC comparison). In pregnant rats, decreased litter size, decreased numbers of live fetuses, decreased fetal body weights, and increased malformations were observed after oral administration of tazarotene prior to mating through early gestation at doses 9 times the MRHD (based on AUC comparison) *(see Data)*.

In animal reproduction studies, increased malformations, including cleft palate and omphalocele, were observed after oral administration of halobetasol propionate during the period of organogenesis to pregnant rats and rabbits *(see Data)*. The available data do not support relevant comparisons of systemic halobetasol propionate exposures achieved in the animal studies to exposures observed in humans after topical use of DUOBRII Lotion.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk in the U.S. general population of major birth defects is 2 to 4%, and of miscarriage is 15 to 20%, of clinically recognized pregnancies.

Data

Human Data

Available observational studies in pregnant women did not identify a drug-associated risk of major birth defects, preterm delivery, or fetal mortality with the use of topical corticosteroids of any potency. However, when the dispensed amount of potent or very potent topical corticosteroids exceeded 300 g during the entire pregnancy, maternal use was associated with an increased risk of low birth weight in infants.

Animal Data

Halobetasol propionate has been shown to cause malformations in rats and rabbits when given orally during organogenesis at doses of 0.04 to 0.1 mg/kg/day in rats and 0.01 mg/kg/day in rabbits. Halobetasol propionate was embryotoxic in rabbits but not in rats. Cleft palate was observed in both rats and rabbits. Omphalocele was seen in rats but not in rabbits.

In an embryofetal development study in rats, a tazarotene gel formulation, 0.5% (0.25 mg/kg/day tazarotene) was topically administered to pregnant rats during gestation days 6 through 17. Reduced fetal body weights and reduced skeletal ossification occurred at this dose (11 times the MRHD based on AUC comparison). In an embryofetal development study in rabbits, a tazarotene gel formulation, 0.5%, 0.25 mg/kg/day tazarotene) was topically administered to pregnant rabbits during gestation days 6 through 18. Single incidences of known retinoid malformations, including spina bifida, hydrocephaly, and heart anomalies were noted at this dose (116 times the MRHD based on AUC comparison).

When tazarotene was given orally to animals, developmental delays were seen in rats; malformations and post-implantation loss were observed in rats and rabbits at doses producing 9 and 228 times, respectively, the MRHD (based on AUC comparisons).

In female rats orally administered 2 mg/kg/day of tazarotene from 15 days before mating through gestation day 7, classic developmental effects of retinoids including decreased number of implantation sites, decreased litter size, decreased numbers of live fetuses, and decreased fetal body weights were observed at this dose (16 times the MRHD based on AUC comparison). A low incidence of retinoid-related malformations was observed at that dose.

In a pre- and postnatal development toxicity study, topical administration of a tazarotene gel formulation (0.125 mg/kg/day) to pregnant female rats from gestation day 16 through lactation day 20 reduced pup survival but did not affect the reproductive capacity of the offspring. Based on data from another study, the systemic drug exposure in the rat at this dose would be equivalent to 5 times the MRHD (based on AUC comparison).

Lactation

Risk Summary

There are no data on the presence of tazarotene, halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after treatment with DUOBRII Lotion.

After single topical doses of a ^{14}C-tazarotene gel formulation to the skin of lactating rats, radioactivity was detected in rat milk.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUOBRII Lotion and any potential adverse effects on the breastfed child from DUOBRII Lotion.

Clinical Considerations

Advise breastfeeding women not to apply DUOBRII Lotion directly to the nipple and areola to avoid direct infant exposure.

Females and Males of Reproductive Potential

Pregnancy Testing

DUOBRII Lotion is contraindicated in women who are pregnant. Females of reproductive potential should be warned of the potential risk and use adequate birth-control measures during treatment with DUOBRII Lotion. The possibility that a female of reproductive potential is pregnant at the time of institution of therapy should be considered. A negative result for pregnancy should be obtained within 2 weeks prior to DUOBRII Lotion therapy, which should begin during menstruation.

Contraception

Based on animal studies, DUOBRII Lotion may cause fetal harm when administered to a pregnant female *[see Use in Specific Populations]*. Advise females of reproductive potential to use effective contraception during treatment with DUOBRII Lotion.

Pediatric Use

Safety and effectiveness of DUOBRII Lotion in pediatric patients under the age of 18 years have not been evaluated.

Because of higher skin surface area to body mass ratios, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children *[see Warnings and Precautions]*.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema *[see Warnings and Precautions]*.

Geriatric Use

Of the 270 subjects exposed to DUOBRII Lotion in clinical trials, 39 subjects were 65 years or older. Clinical trials of DUOBRII Lotion did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate.

A long-term study of tazarotene following oral administration of 0.025, 0.050, and 0.125 mg/kg/day to rats showed no indications of increased carcinogenic risks. Based on pharmacokinetic data from a shorter term study in rats, the highest dose of 0.125 mg/kg/day was anticipated to give systemic exposure in the rat equivalent to 1.4 times the MRHD (based on AUC comparison).

A long-term study with topical application of up to 0.1% of tazarotene in a gel formulation in mice terminated at 88 weeks showed that dose levels of 0.05, 0.125, 0.25, and 1 mg/kg/day (reduced to 0.5 mg/kg/day for males after 41 weeks due to severe dermal irritation) revealed no apparent carcinogenic effects when compared to vehicle control animals. Tazarotenic acid systemic exposure at the highest dose was 35 times the MRHD (based on AUC comparison).

Halobetasol propionate was not genotoxic in the Ames assay, in the sister chromatid exchange test in Chinese hamster somatic cells, in chromosome aberration studies of germinal and somatic cells of rodents, and in a mammalian spot test. Positive mutagenicity effects were observed in a mouse lymphoma gene mutation assay in vitro and in a Chinese hamster micronucleus test.

Tazarotene was non-mutagenic in the Ames assay and did not produce structural chromosomal aberrations in human lymphocytes. Tazarotene was non-mutagenic in the CHO/HGPRT mammalian cell forward gene mutation assay and was non-clastogenic in an in vivo mouse micronucleus test.

Studies in rats following oral administration of halobetasol propionate at dose levels up to 0.05 mg/kg/day, approximately 0.53 times the MRHD based on BSA comparisons, indicated no impairment of fertility or general reproductive performance.

No impairment of fertility occurred in rats when male animals were treated for 70 days prior to mating and female animals were treated for 14 days prior to mating and continuing through gestation and lactation with topical doses of a tazarotene gel formulation up to 0.125 mg/kg/day. Based on data from another study, the systemic drug exposure in the rat at the highest dose was 5 times the MRHD (based on AUC comparison).

No impairment of mating performance or fertility was observed in male rats treated for 70 days prior to mating with oral doses of up to 1 mg/kg/day tazarotene, which produced a systemic exposure 17 times the MRHD (based on AUC comparison).

No impairment of mating performance or fertility was observed in female rats treated for 15 days prior to mating and continuing through gestation day 7 with oral doses of tazarotene up to 2 mg/kg/day. However, there was a significant decrease in the number of estrous stages and an increase in developmental effects at that dose, which produced a systemic exposure 30 times the MRHD (based on AUC comparison).

Manufactured for:
Bausch Health Americas, Inc.
Bridgewater, NJ 08807 USA

By:
Bausch Health Companies Inc.
Laval, Quebec H7L 4A8, Canada

U.S. Patent Numbers: 6,517,847; 8,809,307 and 10,251,895

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2020 Medical & Scientific Committee

Ensuring Progress in Dermatology Care

The Foundation's Medical & Scientific Committee is the key group of volunteer experts charged with continuing the DF's outstanding record of identifying innovative research and promising investigators across the specialty who will drive advances in patient care. The carefully defined evaluation process was derived from the NIH grant review procedure and refined over the DF's many years of experience to recognize those research proposals holding the greatest potential.

The M & S Committee and its Panel have begun evaluating applications for 2020 funding in 15 award categories. The Committee members perform reviews involving the award categories supporting basic science research. The Panel members carry out the reviews in all award categories involving clinically oriented research projects. The Dermatology Foundation is deeply grateful to the Committee and Panel chairs who are leading this year's deliberations: Jonathan H. Zippin, MD, PhD and Anna Bruckner, MD. We are pleased to present the 2020 Medical & Scientific Committee, and extend our utmost appreciation to every member for the substantial time and effort they are devoting to this year's Research Awards Program.

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Suggested Readings

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*In USC's department of dermatology Dr. Armstrong is Vice Chair, Director of Clinical Trials and Outcomes Research, and Director of the Psoriasis Program. She serves as Associate Dean of Clinical Research at the Keck School of Medicine, and Director of Clinical Research for the SC CTSI (Southern California Clinical and Translational Research Institute).

2020 DF Annual Meeting Events

Mark Your Calendar

As you make your plans to travel to Denver toward the end of March, we hope you include the Dermatology Foundation events in your schedule. Join your many colleagues from across the country at the Annual Meeting of Membership to hear the latest news about the DF's work to enable advancements in patient care, and to recognize this year's honorary awardees as well as the recipients of the DF's 2020 research awards.

Friday, March 20 – Sunday, March 22
DF Exhibit Booth #2907
Colorado Convention Center

★ ★ ★ ★

Saturday, March 21
DF Annual Meeting of Membership
Capitol Ballroom Salon 5/6/7
Hyatt Regency Denver
5:30 – 6:30 pm
(Includes honorary awards presentations)

★ ★ ★ ★

Sunday, March 22
Annual Leadership Gala
7:30 – 9:00 pm
History Colorado Center

Co-sponsored by:
Galderma Laboratories, LP
Lilly USA, LLC
AbbVie Amgen Ortho Dermatologics
(By invitation only—tickets required)

DF Honors Excellence in Dermatology

The Foundation is pleased to honor four dermatologists—true role models—for their career-long contributions to the specialty. Each 2019 honorary awardee will be recognized at the DF's Annual Meeting in Denver. Colleagues, friends, and family are invited to attend.

Gerald G. Krueger, MD
Distinguished Service Award
The highest honor the DF bestows upon a colleague in recognition of exemplary leadership and service to the specialty

Victoria P. Werth, MD
Lifetime Career Educator
An academic dermatologist with a career-long history of dedicated service as a mentor, role model, and inspirational teacher

William S. Sawchuk, MD
Practitioner of the Year
Exemplary service as a private practitioner combined with significant contributions to the specialty through leadership and teaching

Valerie D. Callender, MD
Clark W. Finnerud Award
The exceptional clinician who is simultaneously a dedicated and highly effective part-time teacher

2019 Corporate Honor Society

Partners in Shaping Dermatology's Future

The Dermatology Foundation is grateful to the following corporations for their generous contributions last year. Their support furthers the DF's ability to fund innovative research that shapes the future of dermatology.

Platinum Benefactors

($200,000 or more)

GALDERMA

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($100,000 or more)

AbbVie **Ortho Dermatologics** **Pfizer**

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Novartis

Dermatology Focus
c/o Dermatology Foundation
1560 Sherman Avenue, Suite 500
Evanston, Illinois 60201-4806

In Memory of Glenn A. Oclassen

The DF wishes to share its deep condolences with the family and friends of Glenn A. Oclassen of San Rafael, CA, who passed away on November 13, 2019. Mr. Oclassen joined the DF in 2001 as an Annenberg Circle and then AC *Sustaining* member. He also served on the Board of Trustees and Executive Committee from 2002 to 2007. As a prominent figure in industry he brought a unique perspective to the Board, and a great appreciation for the important work of the Foundation that was readily apparent in his contributions during his tenure.

Oclassen's multifaceted support of the DF maintained the family tradition begun by his father, Charles A. Oclassen, a pioneer in dermatology's pharmaceutical development. Mr. Oclassen, who shared his father's passion for helping patients, continued his legacy as a leader in the industry. He was the general manager of Allergan in the 1970s, then president of Neutrogena's Dermatologics Division, and founded Oclassen Pharmaceuticals in 1985. After selling the company to Watson Laboratories in 1997, he continued his career as CEO and president at Paratek Pharmaceuticals and CEO and president of Transcept Pharmaceuticals. After retiring in 2014, Mr. Oclassen joined Verrica's Board of Directors.

The Foundation is profoundly grateful for Mr. Oclassen's exceptional support and guidance. Bruce U. Wintroub, MD, chair of the DF Board of Trustees, shared his sincere appreciation and high regard for Mr. Oclassen's long-term support of the Foundation's mission to further patient care—both as a generous member and a valued board member. Dr. Wintroub recalls "his substantial role in initiating key programs at the DF—including our annual Clinical Symposia and the research endowment fund. We all feel fortunate to have worked with Glenn, and will miss his leadership, generosity, and friendship."

Mr. Oclassen is the initial Founding Member of the DF's Visionary Society. The Foundation is honored to be the recipient of a generous gift from his estate. His visionary bequest has added strength to the Research Endowment Fund's capacity to support essential future research.

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