2022 in Review

The past year brought many new approvals and advances to dermatology for improved patient care.

APPROVALS AND LAUNCHES OF 2022
Acne and Rosacea

In November, the FDA cleared Accure Acne Inc’s Accure Laser System to treat mild to severe inflammatory acne vulgaris. The Accure Laser System builds upon the unique selectivity of the 1726nm laser wavelength, adding proprietary technology to precisely control thermal gradient depth. This technology breakthrough is accomplished through a unique pulsing algorithm, integrated temperature monitoring, and precise automated control of the laser.

Accure’s clinical and technical development teams represent an enduring collaboration of engineering acumen and clinical expertise, led by R. Rox Anderson, MD, Co-Founder and Chief Scientific and Medical Officer of Accure. The lead clinician of the Accure Laser System’s clinical development program is Emil A. Tanghetti, MD of The Center for Dermatology and Laser Surgery in Sacramento, CA. “We see compelling histological evidence of sebaceous gland damage at depths unique to this device’s mechanism of action. The technology is tremendously sophisticated, yet elegantly simple to use. I see this as a game-changer,” says Dr. Tanghetti.

Cutera, Inc.’s AviClear, the first energy device FDA cleared for the treatment of mild, moderate, and severe acne, with additional approval in Canada for acne scars, is now broadly available to physicians and practitioners treating patients throughout North America. In November, Cutera also announced a new, monthly financing plan to US consumers starting at $99 a month.

AviClear has seen widespread interest from physicians and patients following its FDA clearance in March 2022. “I was an early AviClear adopter because I know this treatment will change the way my acne patients face the world,” says Sonia Batra, MD, founder of Batra Dermatology in Santa Monica, Calif., in a news release. “I am thrilled my colleagues nationwide will now have access to this device, and I am even happier for their patients who have not wanted or could not proceed with prescription options. What makes the treatment even more appealing is that it can be used on all skin types and acne severities without adverse effects. I have no doubt it will be the treatment of choice for many acne sufferers.”

In additional acne news, Galderma launched Twyneo (tretinoin and benzoyl peroxide) Cream, 0.1%/3% in the US in March. Twyneo Cream, which was FDA approved in 2021, features patented microencapsulation technology that allows the delivery of two ingredients that have not been previously combined and enables their controlled release. It is the first and only 0.1% tretinoin and 3% benzoyl peroxide (BPO) 2-in-1 combination proven to rapidly treat moderate to severe facial acne.

In rosacea news, the FDA approved Sol-Gel Technologies’ Epsolay, a cream formulation of benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults.

The benzoyl peroxide in Epsolay is encapsulated within silica-based patented microcapsules. The silica-based shell is designed to slowly release benzoyl peroxide over time to provide a favorable efficacy and safety profile. The approval is supported by data from two positive, identical Phase 3 randomized, double-blind, multicenter, 12-week, clinical trials that evaluated the safety and efficacy of Epsolay compared to vehicle in people with inflammatory lesions of rosacea (N = 733). The coprimary endpoints in both trials were the proportion of subjects with treatment success and the absolute change from baseline in lesion counts at Week 12. Epsolay was more effective than vehicle cream on the co-primary efficacy endpoints starting from 4 weeks of treatment in both trials. With Epsolay treatment, inflammatory lesions of rosacea were reduced by nearly 70% by the end of both 12-week trials vs. 38-46% with vehicle. Nearly 50% of subjects were ‘clear’ (IGA=0) or ‘almost clear’ (IGA=1) at 12 weeks vs. 38-46% with placebo. Post-hoc analysis of lesion count and IGA success at Week 2 confirmed a significantly greater treatment effect for Epsolay relative to vehicle as early as Week 2. In the open-label extension, 73% of subjects were ‘clear’ (IGA=0) or ‘almost clear’ (IGA=1) at 52 weeks (N = 547).

Sol-Gel has granted exclusive rights to commercialize Epsolay in the US to Galderma Holding SA.

Sebaceous Hyperplasia

In late September, the FDA granted Pulse Bioscience’s CellFX System 510(k) marketing clearance for the treatment of sebaceous hyperplasia in patients with Fitzpatrick skin types I-II. This specific indication clearance enhances the CellFX System’s general indication FDA clearance and enables the company to support clinics in marketing and promoting CellFX treatments specifically for patients with
**Aesthetic Dermatology Update**

It was a good year for aesthetic dermatology, with new approvals, expanded indications, and launches. Here’s a look at some of the highlights.

The FDA recently approved Aesthetics Biomedical Inc.’s Vivace Ultra for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. An reimagination and technical upgrade of the legacy Vivace Microneedle RF device, the Vivace Ultra combines two unique modalities into one compact device—exclusive uniform radiofrequency microneedling and industry-first, ultrasound imaging and mapping. Vivace Ultra, the next generation and of personalized aesthetics, offers the largest variety of frequency options of any RF microneedling device, along with insulated and non-insulated needle sets for smaller precise areas as well as larger areas. In addition, this technology offers four unique delay speeds for optimal time pulses as well as the ability to toggle radiofrequency on or off. An exclusive new feature available solely with Vivace Ultra is a patent pending uniform delivery system designed to evenly distribute heat energy into the dermis, up to 4.0mm (0.1mm step) deep. This feature provides a large leap forward in treatment accuracy.

Using linear array ultrasound technology, Vivace Ultra can visually map the skin across its large 21.5” display screen, allowing an aesthetic provider to develop a personalized treatment in each layer of the skin, delivering robust efficacious clinical results. First-to-market, ultrasound-based imaging and visualization of the epidermis and dermis provide personalized depth measurements to determine the optimal needle depth, eliminating a large portion of guesswork ensuring improved outcomes.

Medical aesthetic providers will have the ability to store treatment data on a variety of areas and receive recommendations for optimal treatment. Patient experience and colorblind versatility is core to Aesthetics Biomedical’s legacy Vivace Experience branding and treatment, so Vivace Ultra is virtually pain-free for the patient, and effective for light to dark skin types. In addition to visualization, the ultrasound software offers HIPAA compliant cloud connectivity harnessing the ability to collect data about the patient’s various treatment areas beyond the surface for an optimized treatment plan.

In September, Daxify (DaxibotulinumtoxinA-lanm) from Revance won FDA approval for the temporary improvement of moderate to severe frown lines (glabellar lines) in adults. Daxify is the first and only neuromodulator stabilized with Peptide Exchange Technology (PXT) and is free of both human serum albumin and animal-based components.

The US approval of Daxify was based on data from the SAKURA Phase 3 clinical trial program (SAKURA 1,2,3), which included more than 2,700 patients and approximately 4,200 treatments. In the pivotal trials 74% of subjects achieved a ≥2-grade improvement in glabellar lines at week 4 per both investigator and patient assessment; 88% achieved ≥2-grade improvement at week 4 per investigator assessment; and 98% of subjects achieved none or mild wrinkle severity at week 4 per investigator assessment. Results showed a 6-month median duration, and some patients maintained treatment results at 9 months. Results were seen as early as 1 day after treatment, typically seen within 2 days.

Daxify is generally safe and well tolerated with no serious treatment-related adverse events reported in the clinical trials and has a safety profile consistent with other currently available neuromodulators in the aesthetics market. The most common treatment-related adverse events with Daxify observed in the pivotal trials were headache (6%) followed by eyelid ptosis (2%) and facial paresis, including facial asymmetry (1%).

Also in September, Revelle Aesthetics, Inc. scored an extended FDA clearance for Avéli for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females, demonstrating benefits through one year.

Avéli allows a provider to identify which of the fibrous septa bands are causing a cellulite dimple, and then confirm in real-time they are releasing those targeted septa to deliver visibly smoother skin. Results are visible quickly after a single in-office procedure with little-to-no downtime.

Revelle’s approach to successful integration into practices consists of clinical proctoring along with dedicated marketing and educational support.

**BTL launched Emface** this fall. Emface simultaneously emits both synchronized radio frequency and HIFES-brand energies. The homogenous radiofrequency heats collagen and elastin fibers while the HIFES stimulation emits thousands of pulses per session to contract delicate facial muscles.

The recommended treatment course for the EMFACE therapy calls for four 20-minute sessions, with each session completed 2-14 days apart.

The findings from nine clinical studies concluded that participants who completed the recommended treatment course experienced, on average, a 37% reduction in wrinkles, 30% increase in facial muscle tone, and 23% lifting effect—with optimal results seen 6-12 weeks after final treatment. The 2-in-1 procedure is needle- and injectable-free and requires no pre- or post-preparation or downtime.
BTL also launched the EmSculpt NEO Edge Applicator to treat the entire lateral abdomen. Designed to allow for a better contour of curvy areas of the body, the Edge applicator utilizes radiofrequency and HIFEM technology to simultaneously address fat deposits and muscle groups in the lateral abdomen region. The new device extension tones the oblique muscles when treating the lateral abdomen, and many patients experience a significant improvement in their posture, core, and back discomfort.

Expected to be available in early 2023, the FDA approved Allergan Aesthetics’ Juvéderm Volux XC for the improvement of jawline definition in adults over the age of 21 with moderate to severe loss of jawline definition. The approval of Juvéderm Volux XC marks the sixth product offering in the lineup alongside Juvéderm Voluma XC, Juvéderm Vollure XC, Juvéderm Ultra Plus XC, Juvéderm Ultra XC, and Juvéderm Volbella XC. Juvéderm Volbella XC received FDA approval for improvement of infraorbital hollows in adults over the age of 21 in early 2022.

In the pivotal clinical study, Juvéderm Volux XC was found to effectively improve jawline definition (69.9%, 102/146) at 6 months. Participants reported satisfaction using the Satisfaction with Lower Face and Jawline module of the FACE-Q questionnaire, most treatment group participants (82.3%, 116/141) reported satisfaction with the appearance of their lower face and jawline through 12 months following treatment with Juvéderm Volux XC. Additionally, 81.5% (119/146) of participants at 6 months were satisfied with how sculpted (well-defined) their jawline looked compared to 12.2% (19/156) at baseline. At 6 months, 70.5% (103/146) of participants were satisfied with how smooth their lower face looked (i.e., no jowls or folds of fatty skin) compared to 7.7% (12/156) at baseline and 73.1% (106/145) of participants at six months were satisfied with how nice their lower face looked compared to 9.0% (14/156) at baseline.

Allergan Medical Institute is providing an in-depth product training program for Juvéderm Volux XC, including facial anatomy, considerations for safe injection in this area, appropriate patient selection, and aseptic technique.

In February, Merz Aesthetics launched Radiesse (+) Lidocaine for jawline contouring in adults over the age of 21. The first product in the portfolio, Radiesse, is an injectable biostimulator indicated for correction of moderate to severe lower face wrinkles and folds and for the improvement of volume loss in the dorsum of the hands. Radiesse (+) is also approved for moderate to severe lower face wrinkles and folds, and the new indication brings the unique properties of calcium hydroxyapatite (CaHA) to jawline treatment.

The Radiesse (+) jawline indication is based on a pivotal, prospective, randomized, controlled, evaluator-blinded study evaluating the safety and effectiveness of Radiesse (+) in 180 subjects aged 26-65 years of age, who presented with moderate to severe jawline volume loss and desired improvement of jawline volume and contour. The study duration was 60 weeks. The primary endpoint was defined as a subject who obtained ≥1-point improvement on the Merz Jawline Assessment Scale (MJAS) on both jawlines compared to baseline.

Radiesse (+) provided a clinically and statistically significant improvement in the contour of the jawline and overall satisfaction, with 75.6% of treated subjects achieving at least a 1-point improvement on the MJAS on both jawlines at Week 12. No treatment-related serious adverse events (AEs) occurred. The most common treatment-related AEs were injection site reactions and were mild, transient and resolved without sequelae.

Merz Aesthetics North America provides an indication-specific training program (facial anatomy and vasculature, consideration for safe injection techniques, and identification and management of potential adverse events, including intravascular complications) regarding jawline contour injections. Radiesse (+) treatments of jawline contour should only be administered by providers who have appropriate training and experience.

In January, the FDA accepted updates to Suneva Medical’s Plasma IQ label, including the removal of the product’s eye contraindication. The removal of this contraindication was due in part to a compilation of literature provided to the FDA showing the safety and efficacy of the ablative device on skin tissue, particularly around the eye area. This label update allows Suneva to address treatment around the eye with patients in the US. Plasma IQ is a handheld FDA-cleared plasma energy device indicated for the removal and destruction of skin lesions and coagulation of tissue. It delivers focused, controlled energy to effectively create microinjuries on the skin, renewing and restoring it.

Allergan Aesthetics, an AbbVie company, launched CoolSculptingElite, its next generation fat reduction system with applicators designed to complement the body’s natural curves. CoolSculpting Elite is FDA cleared to treat visible fat bulges in nine areas of the body including the thigh, abdomen, and flank, along with bra fat, back fat, underneath the buttocks, upper arm, and the submental and submandibular areas.

Candela launched its Frax Pro system at the beginning of 2022. This platform features Frax 1550 and the novel Frax 1940 applicators. The Frax 1940 handpiece delivers a 1940 nm wavelength laser beam for a shallow, epidermal approach, with focal reach extending to approximately 200 μm in depth. The 1550 nm wavelength of the Frax 1550 handpiece penetrates deeper, with histological analysis showing up to 800 μm penetration. Clinical studies demonstrate high rates of textural improvement and patient satisfaction with the Frax 1550 and Frax 1940 handpieces.
sebaceous hyperplasia. The clearance was based on clinical data from the Company’s IDE approved study for the treatment of sebaceous hyperplasia.

Pulse Bioscience also recently received FDA 510(k) clearance of two additional treatment tips with larger spot sizes, specifically 7.5mm and 10mm tip sizes, for treating larger benign lesions.

Psoriasis
In September, the FDA approved Bristol Myers Squibb Sotyktu (deucravacitinib), a first-in-class, oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Sotyktu is not recommended for use in combination with other potent immunosuppressants.

The approval was based on results from the pivotal Phase 3 POETYK PSO-1 and POETYK PSO-2 clinical trials, which demonstrated superior efficacy of once-daily Sotyktu compared to placebo and twice-daily Otezla (apremilast).

PRACTICAL DERMATOLOGY
Choosing the right skincare product is patient education and consumers. They’re also big on education. A substantial part of their needs, and also understand that accessibility is really important," she says. "They’re big on sensitive care products for their skin and then moving from there."

Dr. Howard says she appreciates the opportunity to recommend a brand like Cetaphil that has a history of use. "They have had many times to get the formula right. They have had many times to understand the market, understand what the consumer needs, and also understand that accessibility is really important," she says. "They’re big on sensitive care products for their consumers. They’re also big on education. A substantial part of choosing the right skincare product is patient education and them understanding why they are using a product." She says the brand, "communicates in a bidirectional way with the dermatologist and also with consumers and patients."

Especially for skin conditions like acne, the intended action of certain prescription medications is associated with skin irritation. Dr. Howard says that's where reliable skincare recommendations come in. "These are products that I can recommend along with whatever I'm doing in the office, and I know that when the patient goes home and uses this product, I'm unlikely to receive a phone call about irritation, about something that I didn't intend for it to do at all," she says.

As the skincare space continues to evolve, Dr. Howard hopes for increased emphasis on lifelong skin health. "I don't know where this happened, but I do feel that we forget that the skin is an organ—just like your heart, your liver. Skincare really starts out early. I think it's really important for us to think of skincare as just like caring for any other organ. If you exercise, you feel better, you look better, it's good for your heart and your muscles. If you do puzzles every day, it's really good for your brain development," Dr. Howard observes. "There is a little bit of a void in the skincare space; we need to understand that moisturizing your skin and cleansing your skin is just as important as going to the gym and exercising. Putting sunscreen on is just as important as taking an Omega-3, because we have to take care of the skin as an organ."
**HIGHLIGHTS FROM 2022**

**CARE Curriculum Launched by DREAM Initiative from Allergan Aesthetics, SkinBetter Science**

The DREAM Initiative, developed by Allergan Aesthetics and skinbetter science, has supported the development of a racial equity curriculum for dermatology residency programs. The Curriculum for Advancing Racial Equity (CARE), developed by Solomé Rose Consulting, LLC, is designed to equip physicians with the tools and knowledge to address the impact of racism in medicine.

The DREAM Initiative (Driving Racial Equity in Aesthetic Medicine) seeks to address the multiple effects of systemic racism in aesthetic medicine through educational efforts and awareness-raising initiatives.

**Report: AI Skin Technology on The Rise**

Perfect Corp.’s latest Global Beauty Trend Report, “The Rise of AI Skin Technology” documents the rise in consumer interest in skin care and the growing role that artificial intelligence (AI) technology and digital skin analysis is playing in this uptick.

In 2022, there were more than 19 million interactions with the skin score quiz in Perfect Corp.’s YouCam Makeup app, which helps users better understand their skin and the products needed to treat their unique skin concerns.

The report also explores the findings of Dr. Steven Feldman’s recent study, which compared Perfect Corp.’s AI Skin technology to both physician skin assessments and the imaging systems commonly used in clinical settings. The study confirmed that Perfect Corp.’s AI Skin technology is a precise tool for performing skin assessments in clinical settings, paving the way for the technology to transform how dermatologists and medical spa providers deliver skin assessments in clinical settings.

**Arcutis Biotherapeutics’ Zoryve (roflumilast) cream 0.3% won the FDA nod this past summer for the treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age or older.**

The first topical phosphodiesterase-4 (PDE4) inhibitor approved for the treatment of plaque psoriasis, Zoryve provides rapid clearance of psoriasis plaques and reduces itch in all affected areas of the body. Zoryve is a once-daily, steroid-free cream in a safe and well tolerated formulation designed to be patient-friendly.

Zoryve features HydroARQ Technology, a proprietary drug delivery formulation that creates a non-greasy moisturizing cream that spreads easily and absorbs quickly.

In additional good news for patients with psoriasis, the FDA also approved Vtama (tapinarof) cream, 1%, an aryl hydrocarbon receptor agonist from Dermavant for the topical treatment of plaque psoriasis in adults this year. Vtama cream is the first FDA-approved steroid-free topical medication in its class.

Across PSOARING 1 and PSOARING 2, Vtama cream demonstrated highly statistically significant improvement in Physician Global Assessment (PGA) score of “clear” (PGA=0) or “almost clear” (PGA=1) with a minimum 2-grade improvement compared with vehicle from baseline at week 12. Vtama cream also demonstrated a highly statistically significant improvement in all secondary endpoints versus vehicle, including ≥75% Improvement in Psoriasis Area and Severity Index (PASI) score (PASI-75) from baseline at week 12. The adverse event (AE) profile of Vtama cream reported in PSOARING 1 and PSOARING 2 demonstrated that the majority of AEs were localized to application site and were mild to moderate in nature.

Injection site pain is a common adverse event for biologics and may create a negative patient experience. Ixekizumab, an IL-17 antagonist biologic, offers high skin clearance, durable efficacy, and rapid onset of action, however, injection site reactions have been reported to occur in up to 20 percent of patients. A recently FDA-approved citrate-free formulation of Lilly’s Taltz (ixekizumab) is now available. It replaces the original com-
USPS Task Force Says More Research Needed to Recommend Screening Adolescents and Adults without Skin Cancer Symptoms

More research is needed to recommend for or against screening adolescents and adults without skin cancer symptoms, according to the U.S. Preventive Services Task Force.

The Task Force determined that there is not enough evidence to recommend for or against screening people without symptoms. This is an I statement, meaning that the balance of benefits and harms cannot be determined. For this recommendation, screening is defined as a visual skin exam by a primary care professional. The recommendation does not apply to people with a family history of skin cancer or those with signs or symptoms, such as irregular moles. “In updating our recommendation, the Task Force looked to see if there was any new evidence about the effectiveness of primary care professionals screening for skin cancer,” says Task Force member Katrina Donahue, MD, MPH, in a news release. “Unfortunately, there is not enough evidence to know whether or not screening adolescents and adults without symptoms reduces complications or death, so we are calling for more research.”

People at increased risk for developing skin cancer include people who have had many sunburns, males, and older people. Use of indoor tanning beds is also an important risk factor, particularly for adolescents and young adults. For melanoma specifically, people at increased risk include those with fair skin, light colored eyes, red or blond hair, and people who have a large number of moles, or a family or personal history of skin cancer.

It is important to note that this recommendation does not apply to people with a personal or family history of skin cancer or with symptoms, such as irregular moles. “We recognize that skin cancer is a common cancer, however we need more research on the effectiveness of visual skin exams by a primary care professional to screen people without symptoms,” says Task Force member Martha Kubik, PhD, RN “In the absence of evidence, we encourage healthcare professionals to use their judgment when deciding whether to screen individual patients.”

While evidence is limited in all people, the Task Force is using this recommendation to draw attention to the need for future research to be reflective of the United States, both in terms of including study populations with a diversity of skin tones and settings where access to healthcare varies. People who have noticed changes to their skin or have concerns about skin cancer should talk to their healthcare professional so that they can get the care they need. It is important that people take actions to protect their skin.

The Task Force has a separate, related recommendation on counseling to prevent skin cancer that provides additional guidance to primary care professionals and patients.

This is not the first time the U.S. Preventative Services Task Force has deemed low-risk skin exams unnecessary, said New York City dermatologist Orit Markowitz, MD. “They have been doing this for various other specialties as well, such as downgrading annual pap smears to limiting the necessity for mammograms,” she said. “This especially impacts people who are low-risk—you’re only low-risk until you’re suddenly high-risk. Oftentimes the USPSTF’s recommendations are not based on individuals, but rather on the greater cost of overall health care.”

Plus, the evidence that the USPSTF is evaluating doesn’t always include new technologies, such as DermTech’s non-invasive Smart Sticker, which helps prevent unnecessary biopsies, dermoscopy, confocal microscopy and more, she said. “Additionally, the USPSTF may not be considering how effective dermatologists are at short-term mole monitoring, or how much less money we’re spending and more lives we’re saving when utilizing new technologies.”

From a cost perspective, technology like the Smart Sticker, dermoscopy and other non-invasive tools allow for fewer expensive biopsies, she added. “From a patient advocacy perspective, these tools enable us to catch things much earlier: Not only are we saving the government money, but we’re also saving lives,” she said. “Unfortunately, the USPSTF’s recommendations don’t always take these factors into account—and, more importantly, this will not change if dermatologists don’t start implementing these non-invasive tools and technologies into our practices.”

The draft recommendation was available for public comment through Nov. 21. “I would advise dermatologists to look at some of the literature that considers the use of non-invasive tools for skin exams,” she said. “I would also remind everybody that the USPSTF is not considering this literature when they’re making their recommendations; rather, it’s focusing on more archaic tools. It’s unfortunate that they are not more up to date with what is actually available to diagnose and manage patients.”

Melanoma is the number one cause of cancer death for patients in their mid-twenties, and we also know that skin cancer is the most common form of cancer, Dr. Markowitz said. “Annually, there are more cases than breast, colon, lung and prostate cancer combined [and] with this in mind, it’s important to realize the cruciality of skin exams. They are so straightforward compared to exams for other cancers—you simply need your eyes and a few other very affordable tools.”

Disclosures: Dr. Markowitz serves as a consultant for DermTech on a case-by-case basis.
HIGHLIGHTS FROM 2022

Atopic Dermatitis

In June, the FDA approved Regeneron Pharmaceuticals, Inc. and Sanofi’s Dupixent (dupilumab) for children aged 6 months to 5 years with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

This year, the FDA also gave the nod to AbbVie’s Rinvoq (upadacitinib) for the treatment of moderate to severe atopic dermatitis in adults and children 12 years of age and older whose disease did not respond to previous treatment and is not well controlled or recommended with other pills or injections, including biologic medicines.

Rinvoq 15mg once daily can be initiated in adults and children 12 years of age and older weighing at least 40kg. In these children and adults less than 65 years of age who do not achieve an adequate response, the dose may be increased to 30mg once daily.

The FDA approval is supported by efficacy and safety data from one of the largest registrational Phase 3 programs for atopic dermatitis with more than 2,500 patients evaluated across three studies. Approximately 52% of the patients had prior exposure to systemic atopic dermatitis treatment. These studies evaluated the efficacy and safety of Rinvoq monotherapy (Measure Up 1 and 2) and with topical corticosteroids (AD Up), compared to placebo, in adults and children 12 years of age and older with moderate to severe atopic dermatitis.

Across the three atopic dermatitis pivotal studies, Rinvoq (15mg and 30mg, once daily) monotherapy and with topical corticosteroids met all primary and secondary endpoints at week 16, with some patients achieving higher levels of skin clearance (EASI 90 and 100). In all three studies, a significant improvement in itch (Worst Pruritus NRS ≥4) was observed as early as week one, compared to placebo.

At the beginning of the year, Pfizer’s Cibinqo (abrocitinib), an oral, once-daily, Janus kinase 1 (JAK1) inhibitor, was also FDA approved for the treatment of adults with refractory, moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Cibinqo is approved at a dose of 100mg that can be stepped up to 200mg, for patients who are not responding. Additionally, a 50mg dose was approved to treat moderate to severe AD specifically in patients with moderate renal impairment (kidney failure), certain patients receiving treatment with inhibitors of cytochrome P450 (CYP) 2C19, or patients who are known or suspected to be poor metabolizers of CYP2C19. For patients with moderate renal impairment who are not responding to 50mg once daily, 100mg once daily may also be prescribed.

FDA approval is based on results of five clinical trials from a large-scale clinical trial program of more than 1,600 patients. The safety and efficacy of Cibinqo was evaluated in three randomized, placebo-controlled, Phase 3 trials. Safety was evaluated through a randomized, placebo-controlled, dose-ranging trial and an ongoing long-term open-label extension trial.

Across the trials, Cibinqo demonstrated a consistent safety profile and profound improvements in skin clearance, extent of disease, and severity, as well as rapid improvement in itch after two weeks, for some people living with AD versus placebo. In addition, a higher proportion of subjects treated with Cibinqo in two monotherapy trials achieved improvement in itching at week 12 compared to placebo.

Vitiligo

Opzelura (ruxolitinib) cream 1.5% from Incyte is now approved for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Opzelura is the first and only FDA-approved treatment for repigmentation in patients with vitiligo and the only topical formulation of a Janus kinase (JAK) inhibitor approved in the US.

In patients with non-segmental vitiligo, Opzelura is approved for continuous topical use twice daily to affected areas of up to 10% body surface area. Satisfactory patient response may require treatment with Opzelura for more than 24 weeks.

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Alopecia Areata

2022 saw the first approval of a systemic treatment for alopecia areata. Olumiant (baricitinib) from Eli Lilly and Company is now approved to treat adult patients with severe alopecia areata. Olumiant is a Janus kinase (JAK) inhibitor. The efficacy and safety of olumiant in alopecia areata was studied in two randomized, double-blind, placebo-controlled trials (Trial AA-1 and Trial AA-2) with patients who had at least 50% scalp hair loss as measured by the Severity of Alopecia Tool for more than six months. Patients in these trials received either a placebo, 2mg of Olumiant, or 4mg of Olumiant every day. The primary measurement of efficacy for both trials was the proportion of patients who achieved at least 80% scalp hair coverage at week 36.

In Trial AA-1, 22% of the 184 patients who received 2mg of Olumiant and 35% of the 281 patients who received 4mg of Olumiant achieved adequate scalp hair coverage, compared to 5% of the 189 patients who received a placebo. In Trial AA-2, 17% of the 156 patients who received 2mg of Olumiant and 32% of the 234 patients who received 4mg of Olumiant achieved adequate scalp hair coverage, compared to 3% of the 156 patients who received a placebo.

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