New Drugs in Psoriasis

The last two years have seen a number of new drugs approved to treat psoriasis—from targeted biologics to new topicals.

The armamentarium of psoriasis therapies has grown significantly over the last few years, and more treatments in the pipeline look promising.

“Everything about treating psoriasis has changed and everything has changed in the last two years compared with the previous five years. So this is an area where things are happening, and they’re happening fast,” said Craig Leonardi, MD, in a DermTube.com interview earlier this year. Dr. Leonardi said there have been developments with the small molecules as well as significant developments with biologic drugs, including IL-23 antagonists, IL-17 antagonists, and an IL-17 receptor antagonist, adding that there are “a lot of new drug developments for dermatologists who have an intense need for more of everything.”

MODERATE-TO-SEVERE PSORIASIS

For moderate-to-severe psoriasis, new therapeutics target new molecules that are thought to be central to the pathophysiology of psoriasis, particularly drugs that block IL-17 that achieve levels of efficacy not seen previously in clinical trial for various psoriasis treatments, noted Bruce Strober, MD, in an interview with DermTube.com earlier this year. IL-17 inhibitors ixekizumab (Taltz) and secukinumab (Cosentyx) are both FDA approved for the treatment of moderate-to-severe plaque psoriasis in adults. “Both achieve levels of efficacy really not seen in previous clinical trials for various drugs in the treatment of moderate to severe psoriasis,” Dr. Strober said.

Cosentyx from Novartis was approved in early 2015 based on the efficacy and safety outcomes from 10 Phase 2 and 3 studies, including more than 3,990 patients with moderate-to-severe plaque psoriasis, which demonstrated that Cosentyx resulted in clear or almost clear skin in the majority of patients and had an acceptable safety profile.

More recently, Novartis reported data from the head-to-head CLEAR study, showing that Cosentyx was superior in achieving a key secondary efficacy endpoint of near clear skin on the Psoriasis Area Severity Index (PASI 90) in significantly more moderate-to-severe psoriasis patients compared to ustekinumab at Week 52. Cosentyx, a fully human interleukin-17A (IL-17A) antagonist, with almost 15,000 US patients prescribed to date was also recently FDA-approved for the treatment of psoriatic arthritis and ankylosing spondylitis.

Eli Lilly and Company’s IL-17A blocker Taltz was FDA approved in March 2016. Given via 80mg/mL injection, Taltz’s active ingredient is an antibody (ixekizumab) that binds to a protein (IL-17A) that causes inflammation. It is intended for patients who are candidates for systemic therapy, phototherapy, or a combination of both.

Taltz’s safety and efficacy were established in three randomized, placebo-controlled clinical trials with a total of 3,866 participants with plaque psoriasis who were candidates for systemic or phototherapy therapy. The results showed that Taltz achieved greater clinical response than placebo, with skin that was clear or almost clear, as assessed by scoring of the extent, nature and severity of psoriatic changes of the skin. The efficacy and safety of Taltz through 60 weeks was demonstrated among patients with moderate-to-severe plaque psoriasis in more recently published data that appeared in the New England Journal of Medicine.

Also new to the options for treating moderate-to-severe psoriasis, the FDA approved Celgene’s apremilast (Otezla), an oral, selective inhibitor of phosphodiesterase 4 (PDE4) in late 2014. Otezla is the first and only PDE4 inhibitor approved for the treatment of plaque psoriasis. The approval was based primarily on safety and efficacy results from the ESTEEM trials, in which Otezla treatment resulted in significant and clinically meaningful improvements in plaque psoriasis as measured by PASI scores at week 16. More recently, results from Celgene’s ongoing Phase 3 LIBERATE trial evaluating Otezla found that half of psoriasis patients treated with oral Otezla achieved PASI 75 at week 52. The LIBERATE study evaluated the clinical efficacy and safety of either oral Otezla 30mg twice daily or weekly subcutaneous (SC) etanercept 50mg compared with placebo at week 16 in 250 patients who had no prior exposure to a biological therapy. It also examined the relative safety of a switch from etanercept to Otezla after week 16 during an open label extension phase.

In the group of patients who started on etanercept and switched to Otezla at week 16, 55 percent achieved PASI 75 at Week 52.

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Otezla was also found to significantly reduce itch by week 16 and was associated with improvements in quality of life.

MILD-TO-MODERATE PSORIASIS

Beyond biologics, new efficacious and safe topical treatments have also been approved for treating mild-to-moderate psoriasis.

The FDA recently approved Promius Pharma’s Sernivo (betamethasone dipropionate) Spray 0.05%, a prescription topical steroid, for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older.

Promius, a subsidiary of Dr. Reddy’s, conducted two successful multi-center, randomized, double-blind, vehicle-controlled clinical trials in subjects aged 18 years and older with moderate plaque psoriasis to evaluate the safety and efficacy of Sernivo Spray. In both trials, randomized subjects applied Sernivo Spray or vehicle spray to the affected areas twice daily for 28 days. Treatment success was achieved in significantly more patients using Sernivo than vehicle at both Day 15 and Day 29 across both studies.

The FDA also recently approved LEO Pharma Inc’s Enstilar Foam (calcipotriene and betamethasone dipropionate) for the topical treatment of plaque psoriasis in adults 18 years of age and older.

Enstilar is a once-daily, alcohol-free foam formulation in a pressurized spray can that allows application across large body areas of plaque psoriasis. In the pivotal Phase 3 clinical trial, more than half of patients treated with Enstilar were “Clear” or “Almost Clear” by week four as assessed by the Investigator Global Assessment (IGA) score of disease severity. Additionally, more than half of patients treated with Enstilar achieved PASI 75.

“For the vast majority of plaque psoriasis patients using topical therapies as a first-line treatment option, having a therapy that can safely and effectively treat their symptoms is key,” said Dr. Leonardi in a statement.

A PROMISING TIME FOR PSORIASIS TREATMENTS

“One thing I would say, if you’re a psoriasis sufferer, if you’ve had real doubts about what your life would be like moving forward, there’s never been a better time for you and your disease,” Dr. Leonardi told DermTube.com. “The pharmaceutical industry is paying an extraordinary amount of attention to this disease. There’s a whole derm ecosystem that is involved in clinical research, new methods of evaluating efficacies—it’s all good, it’s all good for our patients, and it couldn’t happen to a nicer crew or a more deserving crew.”

To watch the full videos with Dr. Leonardi and Dr. Strober, go to www.DermTube.com and visit the Psoriasis Resource Center.