

Psoriasis Is a Chronic Disease: Long Term Efficacy and Safety of New Biologics Is Important



Leon H. Kircik MD

As clinicians, we tend to eagerly await new drug approvals, especially when the drug represents a new class of treatment and is likely to fulfill an unmet need. We analyze the efficacy data, wondering how the new agent may eventually benefit our patients; if study results are promising, our excitement mounts.

Increased understanding of psoriasis has led to a shift in treatments from non-specific immunosuppressants to targeted biologics. Studies in psoriasis have demonstrated minimal risk and substantial benefit. As a result, dermatologists and patients are more frequently choosing biologics as first-line treatments for moderate-to-severe disease as our biologics options have recently increased.

Cosentyx (secukinumab) is the first in a class of interleukin (IL)-17 inhibitors approved for the treatment of psoriasis and psoriatic arthritis.¹ The drug gained FDA approval for the treatment of moderate-to-severe plaque psoriasis after showing statistically significant efficacy in clinical trials compared to placebo. In addition, the safety profile was very favorable. However, not all clinical trials tell the full story, as initial efficacy and safety data from studies is for a very short period of time (typically three to four months). It is obvious that “psoriasis is a lifelong chronic disease.” Therefore, we are in desperate need of long-term efficacy and safety data.

Recently, data from clinical trials up to four years of efficacy and safety have become available for Cosentyx. We now know that psoriasis patients are able to maintain their initial rates of clearance after four years of treatment.² In addition, no new safety concerns have been identified. Recently published research has also demonstrated efficacy of this drug in difficult to treat areas of psoriasis such as palmoplantar, nail, and scalp psoriasis from unique and separate studies^{3,4} – not as sub-analyses of these special areas from pivotal study data.

What’s more, Cosentyx is now additionally approved for the treatment of psoriatic arthritis (PsA). Data suggest that nearly one-third of patients with psoriasis will develop psoriatic arthritis. Unfortunately, some patients with PsA may not even receive a proper diagnosis. As dermatologists, we had for years focused on the skin signs of psoriasis, sometimes overlooking the joint symptoms. As our approach to psoriasis management has evolved, we have become more sensitive to the issue of PsA and the need for effective treatment. In clinical trials, after two years of treatment, the majority of PsA patients treated with Cosentyx maintained their ACR 20 response.⁵

Having these dual indications, moderate-to-severe plaque psoriasis and psoriatic arthritis, is important. Additionally, the dosing schedule is favorable for many patients, with initial doses given at weeks 0, 1, 2, 3, and 4, with maintenance doses provided at four-week intervals.¹ With its documented long-term efficacy and safety, Cosentyx continues to establish itself as an important treatment consideration for patients with moderate to severe plaque psoriasis and psoriatic arthritis.

In the next several pages, my colleagues and I will focus on the long-term efficacy and safety data of Cosentyx for moderate-to-severe plaque-type psoriasis as well as pivotal clinical trials that led the approval for psoriatic arthritis.

Leon H. Kircik MD

*Icahn School of Medicine at Mount Sinai, NY
Indiana School of Medicine, Indianapolis, IN
Physicians Skin Care, PLLC, Louisville, KY
Skin Sciences, PLLC, Louisville, KY*

Disclosures

Dr. Kircik receives compensation for his editorial support from JDD and serves either as consultant, speaker, or an investigator for Novartis, Eli Lilly, Amgen, Abbvie, Boehringer Ingelheim, Janssen, Celgene, Valeant, Pfizer, Cellceutix, Promius, and Xenoport.

REFERENCES

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2016.
2. Bissonnette R, Luger T, Diamant T, Toth D, Letzelter K, Xia S, Mazur R, Milutinovic M, Leonardi C. Secukinumab Demonstrates Sustained High Efficacy and a Favorable Safety Profile in Moderate to Severe Psoriasis Patients Through 4 Years of Treatment. Oral presentation at: 25th European Academy of Dermatology and Venereology Congress, 28th September – 2nd October 2016, Vienna, Austria.
3. Gottlieb A, Sullivan J, van Doorn M, Kubanov A, You RQ, Parneix A, et al. Secukinumab shows significant efficacy in palmoplantar psoriasis: Results from GESTURE, a randomized controlled trial. *J Am Acad Dermatol*. 2017;76(1):70-80.
4. Reich K SJ, Arenberger P, Mrowietz U, Jazayeri S, Augustin M, Parneix A, Regnault P, You R, Milutinovic M. Secukinumab Shows Significant Efficacy in Nail Psoriasis: Week 32 Results from the TRANSFIGURE Study. Poster presented at: 25th European Academy of Dermatology and Venereology Congress, 28th September – 2nd October 2016, Vienna, Austria.
5. Kavanaugh A, Mease PJ, Reimold AM, Tahir H, Rech J, Hall S, et al. Secukinumab for long-term treatment of psoriatic arthritis: 2-year follow-up from a phase 3, randomized, double-blind, placebo-controlled study. *Arthritis Care Res*. 2016.