Year in Review

A look at the year's clinically relevant discoveries and significant advances in the field of dermatology.

Biologics in Practice: Off-Label Uses in Dermatology

The Psychological Impact of Scars in Children, Part III

Psoriasis Review

Year-End Article & Author Index
PHOTOMEDEX LAUNCHES NEW PATIENT EDUCATION CAMPAIGN

PhotoMedex announced that it has launched a direct-to-consumer and physician education campaign for patients with psoriasis and vitiligo. The Live Clear. Live Free. campaign is designed to accelerate awareness of the Xtrac excimer laser treatment, improve patient care, expedite information sharing and reduce healthcare costs, according to the company.

A national direct-to-consumer radio and television blitz is currently airing, supported with a direct mail campaign. A 24/7 call center staffed with clinical specialists provides insurance guidance, answers questions on Xtrac therapy and expedites appointments with physicians. The Xtrac website, www.LiveXTRACClear.com, has been redesigned to serve as a patient and physician resource, and new patient education materials have been delivered to all 300 authorized Xtrac practices nationwide.

PhotoMedex says it has long advocated the need for improved medical care and best practices, beginning in 2002 when the company teamed with the American Academy of Dermatology and the American Medical Associations CPT (Current Protocol Terminology) Editorial Board. The partnership secured approval for an Xtrac laser therapy CPT code for inflammatory skin disease (psoriasis).

The Live Clear. Live Free. campaign also drives awareness of the standard of care for psoriasis and vitiligo. The Xtrac laser delivers a highly targeted therapeutic level of UVB light to areas of the skin affected by psoriasis or vitiligo, without harming the surrounding tissue. In psoriasis, the UVB therapy slows and reverses the growth of cells, while UVB light stimulates re-pigmentation of areas that have lost color for those with vitiligo. Patients can start to see results in weeks, and treatments are covered by most major insurance companies. To learn more about the new program, visit www.LiveXTRACClear.com.

NEW DRUG FROM CELGENE SHOWS PROMISE FOR PSORIATIC ARTHRITIS

Celgene International Sàrl, a subsidiary of Celgene Corporation, presented the results from PALACE-1, a Phase III study in psoriatic arthritis, at the American College of Rheumatology Annual Meeting.

The company previously announced statistical significance for the primary endpoint of ACR20 for patients receiving apremilast in the PALACE-1 study, the first of three pivotal Phase III, randomized, placebo-controlled studies evaluating the novel, oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) in patients with psoriatic arthritis who had received oral disease-modifying antirheumatic drugs (DMARD) and/or biologic therapy and/or had failed on an anti-tumor necrosis factor (TNF) agent. Apremilast treatment in this study was used alone or in combination with oral DMARDs.

PALACE-1 is the first Phase III study demonstrating statistical significance in a psoriatic arthritis patient population that included both prior biologic exposure (23.6%) and biologic failures (9.3%).

In the study, apremilast demonstrated statistically significant and higher ACR20 responses at week 16 in patients receiving either apremilast 20 mg or 30 mg BID monotherapy (31.5% and 50.8%, respectively vs. 10.5% for placebo; P<0.05 and P≤0.0001), with no meaningful advantage to adding oral DMARDs to apremilast. A higher ACR20 response at week 16 was also demonstrated in biologic-naïve patients receiving apremilast 30 mg BID monotherapy compared with placebo (59% vs. 12%; P<0.005).

Across the study population, statistically significant changes in reducing signs and symptoms of PsA, as measured by the primary endpoint of ACR20 at week 16, were achieved for patients receiving apremilast 30 mg BID vs. placebo (41.01% vs. 19.4%; P≤0.0001). This was further supported by a robust and consistent response (P≤0.001) across all arthritis-related secondary endpoints, including ACR50, ACR70, DAS-28, good or moderate EULAR response achievement and CDAI at week 24. Statistically significant results were also demonstrated in measures of physical function (HAQ-DI, SF-36 physical function domain score) at week 16 (P=0.0015 and P=0.0049 respectively). Results were maintained at week 24.

The overall safety profile was consistent with previous experiences in the Phase II program. No opportunistic infections (including TB) or lymphoma were observed through week 24 and there was no increase in risk of cardiovascular events. Apremilast was generally well tolerated. The majority of AEs (>95%) were mild or moderate, with serious AEs and discontinuations due to AEs similar across all treatment arms.

An NDA submission to the FDA, based on the combined PALACE program for PsA, is expected in the first half of 2013. The sNDA submission for psoriasis is expected to follow in the second half of 2013. A combined MAA submission in Europe is also planned for the second half of 2013.

Top-line positive results from two pivotal randomized, placebo-controlled Phase III studies of apremilast in PsA (PALACE 2 and PALACE 3) were released in September 2012. Results from PSA-001 were recently published online in the journal Arthritis & Rheumatism.

In addition, two large, pivotal global studies of apremilast in more than 1,200 patients with moderate-to-severe psoriasis (ESTEEM 1 and 2) are ongoing with beginning data expected by the end of this year. Results from PSOR-005, a Phase IIb dose-range study, were recently published in The Lancet.

ONLINE EXTRA
For more news, research and treatment trends in psoriasis, please visit www.thedermatologist.com/psoriasis.