17817

Prospective observational study to evaluate the benefits for the patient associated with the treatment of plaque psoriasis with apremilast after other systemic treatments in conditions of clinical practice in Spain (APPROPRIATE study)

Pablo de la Cueva Dobao, Hospital Infanta Leonor; Susana Armesto Alonso, Mar Llamas-Velasco, MD, PhD, Hospital Universitario de la Princesa; Raquel Rivera, MD, Hospital Universitario 12 de Octubre; José-Manuel Carrascosa, Hospital Universitari Germans Trías i Pujol, Universitario Autònoma de Barcelona; Encarna Montesinos, MD, Hospital Clínico Valencia; Mercedes Gonzalez, MD, Hospital Universitario Puerta de Hierro Majadahonda; Mariano Ara-Martin, MD, PhD, Hospital Clinico Universitario Lozano Blesa; Carmen García Calvo, MD, PhD, Medical Department, Celgene Spain; Luis Puig, Hospital de la Santa Creu i Sant Pau

The aim of this 12-month, observational, prospective, multicenter study was to assess the benefits of apremilast for the treatment of moderate-severe plaque psoriasis in routine practice in Spain. Interim analysis including 75 patients (mean age 52.7 years [SD15.6]) who started apremilast treatment 3 months before inclusion. 75 were followed for 3 months, and 41 for 6; 9 (12%) discontinued during the 6-month period, 6 of them due to adverse events (AEs). All patients had previously received at least one conventional systemic treatment and had not received biologicals. Mean (SD) Psoriasis Area Severity Index (PASI) was 8.3 (5.6), 3.5 (3.1), and 3.2 (4.6) at baseline, 3, and 6 months, respectively (*P * 1 and 54.2% (39/72) PBI ≥3. Pruritus intensity (VAS (SD)) decreased from 52.0 (32.6) at baseline to 28.0 (29.6, *$P < .0001$) and 35.4 (33.3, *$P = .0048$) and Dermatology Life Quality Index (DLQI [SD]) decreased from 10.6 (6.6) to 4.5 (6.2, *$P < .0001$) and 3.7 (5.4, *$P < .0001$). 45.2% (33/73) and 47.4% (18/38) of patients achieved DLQI 0/1 at months 3 and 6 respectively (***$P < .0001$). 25 patients (33.3%) reported AEs (1/31 [3%] was serious). The most frequent AEs were gastrointestinal alterations (14.7%). These preliminary data suggest apremilast is an effective treatment with an acceptable safety profile, providing substantial benefits for patients with moderate to severe psoriasis. *Paired *t* test; **McNemar test; ***Symmetry test.

Commercial disclosure: 100% sponsored by Celgene Corporation.

17818

Decrease in therapeutic effect among botulinum neurotoxin type A agents: Updated analysis of the FDA Adverse Event Reporting System database

Rashid Kazerooni, PharmD, MS, BCPS, Merz North America

Background: Sufficient long term data comparing botulinum neurotoxin type A (BoNT-A) agents for antibody formation, resistance, and loss of effect is lacking. IncobotulinumtoxinA is the only BoNT-A agent that has removed unnecessary proteins, leaving just the 150-kDa active component.

Methods: The US Food and Drug Administration (FDA) Adverse Event Reporting System database was used. The analysis was conducted on data from March 2014 to June 2019. BoNT-A cases were included when it was considered the "primary suspect" drug. The primary outcome was relative rate of decreased therapeutic effect over time by drug, defined as presence of "therapeutic response decreased" and/or "drug effect decreased" being reported as an adverse event. This relative rate methodology has been well described previously in the pharmacovigilance literature.

Results: A total of 23,789 unique BoNT-A cases were included across a wide array of cosmetic and therapeutic indications. Relative incidence of decreased therapeutic effect for patients on >1 year of treatment <1 year was significantly higher for onabotulinumtoxinA [14.4% (609/4219) vs 7.6% (753/9909); [$P < .001$] and abobotulinumtoxinA [9.9% (59/597) vs 3.3% (38/1144); $P < .001$]. This phenomenon was not observed with incobotulinumtoxinA [0.0% (0/34) vs 3.7% (18/485); $P = .62$].

Conclusions: Causal relationships cannot be established from pharmacovigilance analyses. However, a clear safety signal was detected in this analysis of one of the largest BoNT-A safety data sets ever researched. Long term differences in decreased BoNT-A therapeutic effect by agent warrants further study, including whether even lower dose indications are not immune from this phenomenon over time.

Commercial disclosure: None identified.

17847

A critical appraisal of the history of Mohs micrographic surgery and its evolution in the management of primary mucinous adenocarcinoma

Patrick M. Zito, DO, PharmD, Larkin Community Hospital, Palm Springs Campus; Hamza D. Bhatti, DO, Eduardo Weiss, MD

Primary mucinous carcinoma (PMC) of the skin is a rare head and neck malignancy. It is resistant to chemotherapy and radiation; therefore, standard treatment includes surgical excision with 1−2-cm margins. Mohs micrographic surgery (MMS) is fast becoming the criterion standard for management of cutaneous carcinomas, offering maximal tissue conservation and high cure rates. We present a brief review of the evolution of MMS, highlight changing practice patterns and introduce a new therapeutic option for PMC. MMS was developed in the 1930s by Frederic E. Mohs. Initially referred to as "chemosurgery," Dr. Mohs implemented fixed tissue techniques using a chemical cauterant, zinc chloride (ZnCl). He discovered that tissue injected with ZnCl remained histologically preserved. He microscopically examined horizontal sections of fixed tissue from various tumors thereby developing the basic premise of MMS. In 1936, he successfully treated the first squamous cell carcinoma of the lower lip using MMS. The technique has since evolved and is currently applied to various cutaneous malignancies. Our extensive PubMed literature review revealed that the majority of PMC cases are treated with traditional surgical excision (85.5%) and only few with MMS (9.4%). The first case of PMC treated with MMS was published in 1988 with only 20 cases reported in total. Published data reveals lower recurrence rates of PMC treated with MMS (0%-7%) versus excision (30%-40%). In conclusion, MMS appears to be superior to standard excision for PMC and should be considered as first line therapy for primary and recurrent lesions especially in cosmetically sensitive areas.

Commercial disclosure: None identified.

17852

Perils and pearls of purchasing sun protection over the internet: A Google project

Elissa Tong, BMed, Royal North Shore Hospital; Kevin Phan, MD, Liverpool Hospital; Saxon D. Smith, MBChB, MHL, PhD, FACD, Discipline of Dermatology, Northern Clinical School, Sydney Medical School, University of Sydney, Australia

Background: Sunscreen use has been shown to reduce the incidence of skin cancers. Internet purchasing allows access to internationally sourced sunscreens, despite varying accepted active ingredients and regulations around the world.

Methods: Six sunscreen-related search queries were executed on Google from January to November 2018. Qualitative analysis of the search results to determine compliance with the current Australian sunscreen standard (AS/NZS 2604:2012) was performed by collecting descriptive data, including listed active ingredients of each advertised product. These were compared against the AS/NZS 2604:2012 list of permitted active ingredients. The compliance status of each product, and reasons for non-compliance were annotated. A multiple regression contingency table test was performed to determine whether compliance was associated with the products' country of origin, and a post hoc analysis was performed to identify countries with significant differences in discrepancy in compliance rate.

Results: Execution of the sunscreen-related search queries on Google generated 1350 results. Only 613 of the 1291 (47.5%) included products were compliant with the AS/NZS 2604:2012 permitted sunscreen active ingredients. 552 of 1291 products were noncompliant due to insufficient information advertised. Australia, India, and South Korea had significantly lower than expected compliance rates.

Conclusions: Online marketing of international sunscreen products has a significantly lower than expected compliance rate with the AS/NZS 2604:2012 permitted sunscreen active ingredients, with many lacking the disclosure of the active ingredients. Advertising regulations for online suppliers need to be tightened to ensure that online consumers purchasing sunscreen products can make informed decisions, as the international E-commerce market rapidly expands.

Commercial disclosure: None identified.