15021

The family impact of atopic dermatitis in children aged 6-11 years: A cross-sectional study in the United States, Canada, Europe, and Japan

Sebastien Barbarot, Department of Dermatology, Nantes University Hospital; Jonathan I. Silverberg, MD, PhD, MPH, George Washington University School of Medicine; Abhijit Gadkari, Regeneron Pharmaceuticals; Eric L. Simpson, MD, MCR, Stephan Weidinger, Oregon Health & Science University; Paola Mina-Osorio, MD, PhD, Regeneron Pharmaceuticals; Tarek Mnif, PharmD, Kantar Health Division; Isabelle Guillemin, PhD, Miriam C. Fenton, MPH, PhD, Laurent Eckert, PhD, Sanofi

Background: Few published multinational reports on impact of AD on children and their family exist.

Methods: This cross-sectional, web-based survey was performed in the United States (US), Canada, France, Germany, Italy, Spain, the United Kingdom (UK), and Japan. Children with AD (caregiver-report of physician diagnosis of AD [eczema with/-without skin allergy] plus positive on ISAAC criteria) were stratified according to mild/moderate/severe AD based on Patient Global Assessment during past week: US, n = 187/83/13; Canada, n = 52/25/6; France, n = 163/89/9; Germany, n = 42/33/1; Italy n = 208/111/13; Spain, n = 152/60/10; UK, n = 152/62/6; Japan, n = 156/43/5. Caregivers reported impact of living with children with AD (Dermatitis Family Impact [DFI, total score range 0-30] questionnaire, higher score = higher impact), time spent on AD-related care during past week, and AD-related time off work during past 4 weeks.

Results: The samples were representative of the general populations for age, gender, regions, and urban/rural split. Impact on family of childhood AD was substantial, increasing with disease severity. Mean DFI total score among families of children with moderate AD ranged from 7.6-14.3; families of children with severe AD reported a higher range (10.8-21.0). Families of children with moderate/severe AD spent, on average, 5.5-12.0 and 2.0-17.8 hours, respectively, during past week, on AD-related care. 47.7%-83.6% and 49.7%-100.0% of employed caregivers of children with moderate/severe AD, respectively, missed ≥1 day of work during past 4 weeks.

Conclusions: Moderate to severe AD had a critical impact on the life of families of affected children (6-11 years). Caregivers reported substantial impact on family life, time spent on AD-related care, and work.

Commercial disclosure: This study was funded by Sanofi and Regeneron Pharmaceuticals (100%).

15033

Evaluation of QM1114, a novel ready-to-use liquid botulinum toxin, in esthetic treatment of glabellar lines

Gary Monheit, MD, Total Skin and Beauty Dermatology Center; Mark Nestor, MD, PhD, Joel L. Cohen, MD, Mitchel P. Goldman, MD, Michael H. Gold, MD, Cosmetic Laser Dermatology: A West Dermatology Company; Elizabeth Tichy, MD, Leonard Swinyer, MD, Matthew Meckfessel, PhD

Introduction: Reconstitution of botulinum toxin type A formulations is typically required before injection. QM1114 is a novel ready-to-use liquid botulinum toxin type A formulation. The objective of this study was to evaluate efficacy and safety of 3 doses of QM1114 in esthetic treatment of glabellar lines (GLs).

Methods: Toxin-naïve subjects with moderate-to-very severe GLs at maximum frown and at least mild GLs at rest were eligible for this multicenter, double-blind 6-month phase II study (NCT02236312). Single treatment with QM1114 (total dose: 30, 45, or 60 units) or placebo was randomly assigned. Assessments included wrinkle severity, subject satisfaction and treatment-emergent adverse events (TEAEs).

Results: 359 subjects aged 23-79 years received QM1114 or placebo. Day 14 responder rates (≥2-grade improvement in wrinkle severity) were high at maximum frown across all QM1114 groups (investigators'/subjects' assessment: 87%/75% [30 units], 83%/73% [45 units], 91%/86% [60 units], 6%/8% [placebo]). Changes in wrinkle severity from baseline at maximum frown were significantly higher for all QM1114 groups versus placebo throughout the 6 months. Duration of response was at least 175-181 days or longer. In all QM1114 groups, satisfaction with treatment ('satisfied' or 'very satisfied') was high at month 1 (90%-98%) through month 6 (72%-80%). Treatment-related TEAEs which affected ≥1% of subjects in any QM1114 group were mild to moderate injection-site pain, headache, eyelid ptosis, injection-site pruritus, injection-site swelling, and eyelid oedema. No serious treatment-related TEAEs were observed.

Conclusions: At all doses, esthetic GL treatment with QM1114 was highly effective with long duration, high subject satisfaction and an acceptable safety profile.

Commercial disclosure: Galderma provided funding for this study as well as development of the abstract and poster.

15036

Pregnancy outcomes in women exposed to guselkumab: Experience from the clinical development program

Alex B. Kimball, Depart of Dermatology, Harvard Medical School, Mass General Hospital; Laura Ferris, MD, PhD, UPMC, April W. Armstrong, MD, MPH, Keck School of Medicine, University of Southern California; Michael Song, MD, Paraneedharan Ramachandran, MD, Connie B. Lin, PhD, RPh, Janssen R&D; Shu Li, PhD, Johnson & Johnson; Richard Langley, Dalhousie University

Objective: Animal studies have demonstrated that monoclonal antibodies like guselkumab (GUS) cross the placenta. Although pregnant women and women who intend to become pregnant were excluded from participation in GUS clinical trials, some female patients still became pregnant during the study period and discontinued GUS. Here, we report these pregnancy experiences.

Methods: Pregnancy data were reported in company-sponsored GUS interventional clinical trials for psoriasis, psoriatic arthritis, palmoplantar psoriasis and in studies with healthy participants, through 12 July 2019, with suspected exposure to GUS in female participants either during anytime of pregnancy or within 3 months before conception.

Results: 24 maternal pregnancies were reported. Mean maternal age at the time of pregnancy was 30.1 years (range 19-40 years, n = 23) and mean duration of GUS exposure prior to the reported pregnancy was 105.9 ± 70.5 wks (n = 21). In all pregnancies, suspected exposure to GUS occurred during the first trimester. Outcomes were known for 12 (50%) pregnancies, which included 7 (58.3%) live births (LBs), 2 (16.7%) spontaneous abortions (SAs), 2 (16.7%) elective abortions, and 1 (8.3%) unspecified abortion. Of the LB cases, mean gestational age was 40.1 ± 0.8 wks (n = 5), mean 5 min-APGAR was 9.7 ± 0.6 (n = 3), and mean birth weight was 7.8 ± 1.0 pounds (n = 5); no congenital anomalies were reported (n = 7). Among the 2 SA cases, 1 involved a 38-year-old woman who had a history of 2 elective abortions, while no risk factors were reported in the other case.

Conclusions: To date, no safety signals in pregnancy outcomes have been observed based on limited data from the GUS clinical development program. Additional pregnancy outcome results from real-world/post-authorization experience are needed.

Commercial disclosure: This study was sponsored by Janssen Research & Development.

15043

Topical 15% resorcinol in hidradenitis suppurativa: Patient satisfaction

Alexandre Docampo-Simón, José C. Pascual, Dermatology Department, Hospital General Universitario de Alicante; Iván Beltrá-Picó, Rosa Fuster Ruiz de Apodaca, Juan Selva Otaolaurruchi

Background and Objective: Topical 15% resorcinol is frequently used for the treatment of hidradenitis suppurativa (HS). It has been shown to be effective in two small open studies. Nevertheless, studies on satisfaction perceived by patients are lacking. The Treatment Satisfaction Questionnaire for Medication (TSQM) is a validated measure of patient satisfaction. The objective of this study is to obtain data from HS patients regarding resorcinol treatment satisfaction and its relationship with clinical and epidemiologic variables.

Methods: TSQM version 1.4 were provided to HS patients who had been prescribed topical resorcinol during the previous 24 months. Epidemiologic and clinical data were collected.

Results: We identified 115 patients who met the inclusion criteria; 92 of them (80%; 74% women, overall mean age 34 years) agreed to answer the questionnaire. The mean total score was 317.5. (71.0 points in effectiveness, 93.6 in side effects, 79.3 in convenience and 73.2 in global satisfaction). Most patients (65, 70.6%) denied having any side effect. Higher scores on convenience were seen in patients who were not overweight or with lesions localized on the abdomen. We did not find differences on scores within sexes or ages, nor depending on HS severity, toxic consumption or concomitant medications. 78 (84.8%) of the patients would recommend the treatment.

Conclusions: Most patients were satisfied with resorcinol treatment and scores were high among the different subgroups. Although controlled clinical trials are needed, topical resorcinol is a promising treatment for HS patients with scarce side effects.

Commercial disclosure: None identified.