9-1-2022

33463 Pooled efficacy and safety results from the DERMIS-1 and DERMIS-2 phase 3 trials of once-daily roflumilast cream 0.3% by baseline body surface area

Linda F. Stein Gold

Jerry Bagel

James Del Rosso

Lawrence J. Green

Mark Lebwohl

See next page for additional authors

Authors

Linda F. Stein Gold, Jerry Bagel, James Del Rosso, Lawrence J. Green, Mark Lebwohl, Leon H. Kircik, Amy Feng, Scott Snyder, Robert C. Higham, Patrick Burnett, and David R. Berk

35389

Polidocanol: A review of clinical uses

Carly Stender, BS, McGovern Medical School, The University of Texas Health Science Center at Houston; Delfina Bur, BA, McGovern Medical School, The University of Texas Health Science Center at Houston; Quoc-Bao Nguyen, MD, MBA, Department of Dermatology, UTHealth McGovern Medical School at Houston; Sirunya Silapunt, MD, Department of Dermatology, UTHealth McGovern Medical School at Houston

Polidocanol is a nonionic detergent sclerosant that disrupts the intimal lining of blood vessels by inducing a negative charge on endothelial surfaces. Ultimately, thrombotic occlusion at the site of endothelial damage gives rise to endovascular fibrosis and effective obliteration of the target vessel. Polidocanol is FDA-approved for the treatment of uncomplicated spider veins and reticular veins in the lower extremity. Despite its limited indication, there are numerous reports of polidocanol's use for a variety of off-label conditions. The purpose of our study was to describe the dermatologic clinical uses of polidocanol and to characterize efficacy and adverse effects associated with its various applications. In a review of literature searchable on PubMed from 2004 to 2020, polidocanol has shown efficacy in the treatment of varicose veins, hemangioma, mucocele of the minor salivary gland, pyogenic granuloma, lymphangioma circumscriptum, digital mucus cyst, mixed skin ulcer, cutaneous focal mucinosis, seroma, glomovenous malformation, acne cyst, and lymphocele. Commonly reported complications of polidocanol therapy include pain, edema, ecchymosis, ulceration, tissue necrosis, and thrombosis of the treated vein. Although not always first-line therapy, polidocanol may be chosen as a treatment method for off-label conditions due to its low cost, ease of use, and adaptability to difficult anatomic locations.

Commercial Disclosure: None identified.

33463

Pooled efficacy and safety results from the DERMIS-1 and DERMIS-2 phase 3 trials of once-daily roflumilast cream 0.3% by baseline body surface area

Linda Stein Gold, Henry Ford Medical Center; Jerry Bagel, Psoriasis Treatment Center of Central New Jersey; James Del Rosso, JDR Dermatology Research Center; Lawrence J. Green, George Washington University School of Medicine; Mark Lebwohl, Icahn School of Medicine at Mount Sinai; Leon H. Kircik, Icahn School of Medicine at Mount Sinai, Indiana Medical Center, Physicians Skin Care, PLLC, and Skin Sciences, PLLC; Amy Feng, Arcutis Biotherapeutics, Inc; Scott Snyder, Arcutis Biotherapeutics, Inc; Robert C. Higham, Arcutis Biotherapeutics, Inc; Patrick Burnett, Arcutis Biotherapeutics, Inc; David R. Berk, Arcutis Biotherapeutics, Inc

Roflumilast cream 0.3% is a selective and potent phosphodiesterase-4 inhibitor under investigation as a once-daily treatment for psoriasis. Here we describe pooled efficacy and safety results from 2 identical phase 3 randomized controlled trials of roflumilast cream (DERMIS-1: NCT04211363 and DERMIS-2: NCT04211389) analyzed by baseline body surface area (BSA) affected (10%). Patients (≥2 years) with psoriasis involving 2-20% BSA were randomized to roflumilast (n = 576) or vehicle (n = 305) for 8 weeks. Overall, significantly more roflumilast- vs. vehicle-treated patients achieved the primary efficacy endpoint of Investigator Global Assessment (IGA) Success (Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline) at Week 8 (39.9% vs. 6.5%; $P < .0001$). More roflumilast-treated patients achieved IGA Success at Week 8 with generally consistent rates (36.5%-46.7% with roflumilast vs. 1.8%-8.5% with vehicle) across all BSA categories ($P < .0001$ for all). Differences favoring roflumilast were also observed for percentages achieving 75% reduction in Psoriasis Area Severity Index (38.1%-47.8% with roflumilast vs. 1.8%-9.4% with vehicle) across all BSA categories. Percentages with baseline Worst Itch-Numeric Rating Scale ≥4 achieving a 4-point reduction favored roflumilast ($P \leq .0001$ for all BSA subgroups). Overall incidence of treatment-emergent adverse events (TEAE), serious adverse events, and TEAEs leading to discontinuation were low with similar rates between roflumilast and vehicle. Local tolerability was highly favorable on patient and investigator assessments. Once-daily roflumilast cream 0.3% provided superior improvement across multiple efficacy endpoints and favorable safety and tolerability in patients with psoriasis in 2 phase 3 trials regardless of BSA affected.

Commercial Disclosure: 100% sponsored by Arcutis Biotherapeutics, Inc.

34346

Pooled safety analysis of respiratory tract infections, including COVID-19, in psoriasis patients treated with secukinumab

Hendrik Schulze-Koops, Division of Rheumatology and Clinical Immunology, Department of Medicine IV, Ludwig-Maximilians-University, Munich, Germany; Atul Deodhar, Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland, OR; Reinhard E. Voll, Department of Rheumatology and Clinical Immunology, Medical Center-University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany; Jan Leipe, Division of Rheumatology, Department of Medicine V, University Hospital Mannheim, Medical Faculty Mannheim of the University Heidelberg; Andrew Blauvelt, Oregon Medical Research Center, Portland, OR; Craig Leonardi, Department of Dermatology, St Louis University, St Louis, MO; Effie Pournara, Novartis Pharma AG, Basel, Switzerland; Ivette Alarcon, Novartis Pharma AG, Basel, Switzerland; Weibin Bao, Novartis Pharma AG, Basel, Switzerland; Vivek Trivedi, Novartis Pharma AG, Basel, Switzerland; Philip J. Mease, Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, WA

Objective: To assess risk of respiratory tract infections (RTIs) in secukinumab treated psoriasis patients, evaluate potential association of COVID-19 risk factors [age >65, diabetes, obesity (BMI >40), heart and respiratory disease] with RTI incidences and report COVID-19 cases from Periodic Safety Update Report (PSUR: 26-Dec-2019−25-Dec-2020).

Methods: Pooled data from clinical trials and postmarketing safety surveillance, including patients who received ≥1 secukinumab dose, were analyzed. RTIs were reported as exposure-adjusted incidence rates (EAIRs) per 100 patient-years.

Results: EAIR (95% CI; n) for 'any RTI' with secukinumab 150 mg/300 mg/150 mg+300 mg, was 42.1 (39.6−44.8; n = 2117)/47.5 (46.1−48.9; n = 9704)/46.6 (45.3−48.0; n = 11232). EAIR for 'viral RTI' at same doses was 7.1 (6.2−8.0)/7.4 (6.9−7.9)/7.3 (6.9−7.7), and for 'other RTI' was 34.3 (32.1−36.6)/38.8 (37.5−40.1)/ 37.7 (36.6−38.9). EAIR ratios in obese versus nonobese patients for viral pharyngitis/streptococcal pharyngitis/bacterial sinusitis with secukinumab 150 mg+300 mg were 4.2 (1.2−15.1)/3.4 (1.7−7.0)/6.9 (2.1−22.3), respectively. Strong associations with other COVID-19 risk factors were not observed. Of 952 COVID-19 cases retrieved, outcome was reported in 416 cases: completely recovered (n = 101), recovered with sequelae (n = 7), condition improving (n = 68), unchanged (n = 165), deteriorated (n = 54) and fatal (n = 21). Overall, 221 cases were confounded by risk factors (age >65, comorbidities, or concomitant use of immunosuppressant). Of 21 COVID-19 fatal cases, 14 had risk factors (age >65, comorbidities and smoking) whereas 7 had limited information.

Conclusion: RTIs in secukinumab treated psoriasis patients from pooled clinical trials and postmarketing surveillance data were consistent with previous publications. In this analysis, obesity increased the risk for RTIs. COVID-19 cases in the PSUR revealed no new safety signals regarding known risk of 'infections and infestations.'

Commercial Disclosure: This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland. The editorial and medical writing support was funded by Novartis Pharma AG, Switzerland in accordance with GPP3 guidelines.

32315

Postoperative care consideration: Cold panniculitis induced by cooling device after knee surgery

Amy Zavell, MD, University of Missouri; Ashley Jenkins, MD, University of Missouri

A 52-year-old woman presented with 1-week history of an asymptomatic eruption on the right knee. This started as blanched patches which progressed over a few days to raised urticarial papules. Prior to the onset of the eruption, she had been using a cold therapy device on this knee for three weeks after arthroscopy and medial meniscus repair. On examination, there were smooth indurated round papules localized to the right anterior knee. A punch biopsy was obtained revealing a superficial and deep perivascular lymphocytic infiltrate extending into the subcutis, consistent with cold panniculitis. Cold panniculitis refers to inflammation of the fat following exposure to very cold temperatures. It is most common in the cheeks of young children but has rarely been reported in adults, including in female equestrians and after use of ice packs for chronic lower back pain. There has also been a report of cold panniculitis after use of a cold device after shoulder surgery. Treatment frequently involves removing the source of thermal injury. Our patient was instructed to stop using her cold therapy device and over time her lesions resolved. Given the development and increased availability of such devices, it is possible a similar clinical picture may present more frequently in dermatology clinics in the future.

Commercial Disclosure: None identified.