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Safety and efficacy of VP-102 in molluscum contagiosum (MC) by lesion count quartile: Pooled results of two phase 3 multicenter, randomized, vehicle-controlled trials for the topical treatment of MC

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Background: Two phase 3 trials were completed using VP-102, a proprietary drug-delivery device combination containing cantharidin (0.7% w/v) for the treatment of molluscum contagiosum (MC). This pre-specified exploratory analysis aimed to determine if lesion count at baseline affected the safety and efficacy outcomes in response to VP-102 by pooling data from both trials.

Methods: Subjects ≥2 years of age with MC were enrolled in two trials with identical protocols and randomized 3:2 to topical administration of VP-102 or vehicle applied to all baseline and new lesions once every 21 days until clear, or a maximum of 4 applications. Lesion counts were recorded by assessors blinded to treatment at days 21, 42, 64, and at end of the study visit (day 84). Adverse events (AE) were documented throughout the study with a specific focus on local site reactions. Patients were separated into quartiles by baseline lesion count.

Results: For the ITT population, VP-102 n = 309. Quartiles (Q) were as follows: Q1: 1-7 lesions (n = 92); Q2: 8-14 lesions (n = 82); Q3: 15-28 lesions (n = 67); Q4: ≥29 lesions (n = 68). In patients treated with VP-102 complete clearance at D84 was similar and statistically significant compared with vehicle for all quartiles (range 43%-63%). Reduction in percent change in lesion count was similar in all quartiles, and highest in Q4 at D84 (−89.8%). Most common AEs including application site vesicles, pain, erythema, and pruritus were similar across groups.

Conclusions: Treatment of MC with VP-102 showed similar safety and efficacy across all lesion count groups.

Commercial disclosure: The trials were 100% funded by Verrica Pharmaceuticals.

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Lichen planopilaris in women: A retrospective review of 232 women seen at Mayo Clinic from 1992 to 2016

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Background: Lichen planopilaris (LPP) is a primary cicatricial alopecia. Large single-center studies on clinicopathologic characteristics, associated disorders, treatments, and clinical courses are sparse.

Design: Retrospective review of women with LPP at Mayo Clinic from 1992 to 2016.

Methods: A total of 846 female patients were reviewed (476 from medical records and 370 from dermatopathology). Clinical notes, pathology reports, laboratory data, and photographs were reviewed to confirm the diagnosis of LPP. Patients were included if they met diagnostic criteria for LPP based on clinicopathologic correlation (CPC). A total of 232 patients met the inclusion criteria, with 217 confirmatory biopsies

Results: We identified 232 women with LPP (mean age 59.8 years). 92.7% presented with hair loss. 23.7% had preceding inflammation. 31% had thyroid disease, including hypothyroidism (23%). 9.4% had vitamin D deficiency. Incidence of depression and anxiety was 45.7% and 41.8%, respectively. 16.8% and 16.4% had hysterectomy/bilateral salpingo-oophorectomies (TAH/BSO) and hormone replacement therapy (HRT), respectively. Lichen planus at other body sites occurred in 16.4% of patients. 60.2% had disease stabilization often requiring combination therapies, with 87% experiencing a recurrence (mean 1.8 years). The mean time to remission was 1.1 years.

Conclusions: As previously reported, LPP is associated with thyroid disease. We also found higher rates of depression, anxiety, nutritional deficiencies, and skin cancer than reported in the general population. In contrast to women with frontal fibrosing alopecia, women with LPP reported fewer TAH/BSO and less frequent HRT.

Commercial disclosure: None identified.

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Development and validation of a multigene signature for identification of cutaneous squamous cell carcinoma patients at high risk for regional or distant metastases

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Cutaneous squamous cell carcinoma (cSCC) exhibits overall favorable prognosis with most cases cured by surgical intervention. However, due to an annual incidence of nearly 1 million patients diagnosed, the estimated deaths attributed to cSCC approach or surpass those from melanoma. Management decisions for high-risk cSCC are complicated by the limited accuracy of current staging systems, highlighting a need for additional prognostic biomarkers. The objective of this study was to develop a gene expression profile (GEP) test that identifies patients at low or high risk for nodal or distant metastasis. Primary cSCC tumors with known patient outcomes were collected as part of a multicenter, IRB-approved study. Deep learning methods were applied to gene expression data from a training set of cSCC tumors (n = 122) to develop a prognostic GEP algorithm for metastatic risk. Preliminary validation of the algorithm in an independent cohort (n = 165) demonstrated: 1) a statistically significant difference in 3-year metastasis-free survival rates between GEP risk groups using Kaplan-Meier analysis ($P < .001$); 2) independent prognostic value of the GEP in multivariate regression models that included two current staging methods ($P < .05$); and 3) accurate identification of tumors deemed low-risk by histopathologic staging that ultimately metastasized. This study showed that tumors with different metastatic potential can be stratified based on the GEP signature of a patient's primary cSCC tumor. Use of this GEP to complement existing staging methods and improve upon risk prognostication has the potential to inform clinical decision-making for cSCC patients, and further archival and prospective validation is in progress.

Commercial disclosure: Castle Biosciences provided funding for tissue and clinical data retrieval.

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Apremilast in the treatment of recalcitrant seborrheic dermatitis

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Background: Seborrheic dermatitis (SD) is one of the most prevalent inflammatory cutaneous conditions. Its incidence ranges from 1%-3% in the general population. Mild disease is adequately treated with topicals. However, extensive disease is often recalcitrant to FDA approved treatments, providing a therapeutic challenge.

Methods: Three patients with extensive SD presented to the Department of Dermatology at Tufts Medical Center. Each patient failed multiple standard topical treatment regimens. Consequently, off-label oral apremilast was prescribed in the standard 5-day titration to 30 mg twice a day.

Results: Significant disease improvement was noted after 3 months of treatment in all patients. No side effects from apremilast were noted except for tolerable nausea in one patient.

Discussion: Patients with severe SD are often recalcitrant to topical therapies. Although topical antifungals and corticosteroids are the mainstays of therapy, topical calcineurin inhibitors, isotretinoin, homeopathic minerals, and tacalcitol have also been reported as effective. Apremilast is a phosphodiesterase-4 (PDE4) inhibitor which is FDA approved for the treatment of psoriasis and psoriatic arthritis. In further support of the strategy of apremilast for SD, crisaborole, a topical PDE4 inhibitor has been successfully reported in treating SD. Patients with comorbidities such as HIV, Parkinson disease, and psychiatric disorders have a higher risk of SD and may present with more severe and recalcitrant disease. Apremilast could be a possible new indication as the first systemic treatment for SD in patients who cannot achieve appropriate control of their disease.

Commercial disclosure: None identified.