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#### PSN<sub>2</sub>

### EFFECTIVITY AND SAFETY OF TACALCITOL IN PSORIASIS VULGARIS IN SPANISH PATIENTS

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OBJECTIVES: To analyse the effectivity and safety of tacalcitol in real daily conditions. METHODS: An epidemiological, observational, prospective and multicenter study of a cohort of patients with mild to moderate Psoriasis vulgaris has been performed. Treatment with tacalcitol ointment (4 mg/g) was prescribed. Anthropometric and demographic characteristics of patients were recorded in addition to percentage of affected area and previous and current treatments. A lesion was selected as target for evaluation, of symptoms (erythema, desquamation and thickness) by a scale from 0 (absent) to 4 (maximum intensity of symptom). At follow-up (30 and 60 days) symptomatology and appearance of adverse events were evaluated. Psoriasis Area Severity Index (PASI) was calculated. RESULTS: Eight hundred twentyone patients with mild to moderate Psoriasis vulgaris, (45.67% were men and 45.33% were women, mean age  $43.59 \pm 15,48$  years) were included. After 2 months of treatment, patients showed a decrease of mean percentage of affected area of 7.83  $\pm$  12.3 (from 15.97%  $\pm$ 16.02% to  $8.14 \pm 10.59$ ). PASI decreased from  $10.11 \pm$ 7.89 to 3.00  $\pm$  3.79 (p < 0.01). Percentage of patients without symptoms increased up to 85.44% for erythema, 93.11% for desquamation and 96.16% for thickness. Six adverse events were reported (1% of sample). Seventyeight percent of investigators and 80% of patients evaluated effectivity of treatment as satisfactory. CON-CLUSIONS: Tacalcitol was effective in symptomatic treatment of psoriasis. Treatment achieved improvement on affected area and intensity of symptoms as well. Excellent tolerability of tacalcitol was corroborated by the low rate of adverse events reported.

#### **SKIN DISORDERS—Cost Studies**

### PSN 3

## MANAGEMENT AND SOCIO ECONOMIC IMPACT OF ATOPIC DERMATITIS (AD) IN FRANCE: THE ELIPANEL STUDY

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**OBJECTIVE:** To evaluate the management and socioeconomic consequences of AD on patients and parents of children with AD in France. **METHODS:** Retrospective crossectional study in a representative national sample of patients suffering from AD has been conducted between March and June 2002. One hundred children and 90 adults have been recruited from a representative panel of 4012 individuals of the general population. Data was col-

lected on aspects of the disease, medical resource use and Quality of Life (QoL). RESULTS: On average, the mean time spent with AD during the last year was 131 days; 26% of patients reported having symptomatic AD all the time, the other patients had 5.5 flares on average. Mean duration of the last flare in the overall sample was 21 days. Ninety percent of the patients consulted a physician during the last year for their AD. Sixty-two percent of adults had usually seen a general practitioner (GP) and/or a dermatologist (57%). Fourty-one percent of adults and 42% of children had seen a GP exclusively. None of the patients interviewed were hospitalized for AD during the last 12 months. We estimated the annual medical and non-medical cost of AD in France at €128 million per year, physician consultations accounting for 59% of this cost. AD impairs significantly the patients and parents QoL. Adults declared having no relieve from it (40%), being worried about their appearance (36%), finding it hard to relax (33%), having no self-confidence (24%). Parents reported having no control over the disease (53%), are worried about the future of their children (17%) and 13% said AD created much tension in the family. CONCLUSION: This unprecedented study shows that AD signs and symptoms affect patients for one-third of the year on average, producing a significant socioeconomic burden on the patients and their family

PSN4

## ECONOMIC EVALUATION OF TACROLIMUS OINTMENT VERSUS CURRENT CARE IN MODERATE TO SEVERE ATOPIC DERMATITIS

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OBJECTIVES: Topical steroids are the corner-stone of current treatment for atopic dermatitis (AD), a chronic fluctuating inflammatory skin disease. However, steroids carry a risk of local and systemic side effects limiting their long term use and effectiveness. The objective was to assess the incremental cost-effectiveness ratio (ICER) of the new topical immunomodulator Tacrolimus in moderate to severe AD. Tacrolimus has shown significant clinical improvement, maintained with long term intermittent treatment up to four years. METHODS: A Markov model was developed in MS-Excel. Model health states represent severe, moderate, mild, and virtually cured AD as defined by the Eczema Area and Severity Index (EASI). Based on prevalence data, 82% start with moderate, 18% with severe AD. The model simulates monthly severity fluctuations. Transitions among health states were calculated from two 1-year observational trials (Tacrolimus n = 93, current care n = 120). Tacrolimus consumption was obtained from the clinical trial, other resource utilisation from a two-round Delphi consensus panel (n = 8). Unit costs from the Belgian health care payers perspective were applied. Effects are expressed in "disease controlled days", defined as days with mild or virtually cured AD. The time horizon was from 1 (basecase) to 3 years.

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RESULTS: By the end of the first year, Tacrolimus increases the number of 'disease controlled days' with 59 days at an IC of €60, implying an ICER of 1€/disease controlled day. Better ICERs are obtained in severe AD, when taking into account UV light therapy costs in the steroid arm, currently not reimbursed in Belgium. Due to the long term clinical improvement, the ICER decreases with treatment duration and Tacrolimus ointment is estimated to become cost-saving as from 2 years treatment duration. CONCLUSION: Tacrolimus is a cost-effective treatment for moderate to severe AD, providing potential savings to the health care system during long term maintenance treatment.

PSN5

# THE COST-UTILITY OF CALCIPOTRIOL/BETHAMETHASONE (DOVOBET) OINTMENT IN THE TREATMENT OF PSORIASIS VULGARIS IN THE UNITED KINGDOM

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OBJECTIVES: To evaluate the cost and utility of calcipotriol/bethamethasone (Dovobet) compared to calcipotriol (Dovonex) in the treatment of psoriasis vulgaris. METHODS: A four-state Markov model was designed to estimate the cost and utilities associated with psoriasis treatment over a full year. The model consists of four mutually exclusive health states: Controlled psoriasis, and three states of uncontrolled psoriasis: Initial treatment, subsequent treatment, and no treatment. Various sources were used to estimate the parameters of the model, but the primary source for utility scores and transition probabilities was an international phase III trial, estimating efficacy and the quality of life for 737 patients randomised to one of four different treatment options. Among the treatment options were calcipotriol/ bethamethasone (Dovobet) once daily and the currently most frequently prescribed topical antipsoriatic in the UK, calcipotriol (Dovonex). RESULTS: In the baseline model, the average annual cost to the NHS associated with treatment of a psoriasis patient with calcipotriol/ bethamethasone (Dovobet) once daily amounted to £64.7. The cost of calcipotriol twice-daily treatment in the same period would amount to £120.3. In terms of number of QALYs gained in a year, calcipotriol/ bethamethasone (Dovobet) once daily patients on average accumulated 0.7719 QALYs, compared to calcipotriol twice daily patients who accumulated only 0.7599 QALYs. Thus, in the baseline model treatment with calcipotriol/bethamethasone (Dovobet) twice daily is both less costly and more effective than the current standard therapy of calcipotriol twice daily. These results were robust to extensive sensitivity analysis of important assumptions. CONCLUSION: Looking at a full year of treatment, the cost-utility analysis showed that calcipotriol/bethamethasone (Dovobet) once daily was both

less expensive and yielded more QALYs than the current standard therapy (calcipotriol).

PSN6

### CHILDREN'S ATOPIC DERMATITIS: PHARMACOECONOMIC COST ANALYSIS

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Atopic dermatitis is considered in modern society to be a disease leading to large expenses of the state, person and family. OBJECTIVE: Pharmacoeconomic analysis of family expenses and losses connected with child's atopic dermatitis. METHODS: cost and expenses analysis of the disease was conducted with account of expenses on pharmacotherapy, hospital and ambulance treatment, disablement pensions, temporary disability of parents and evaluation of the disease influence on the standard of life of the child and the whole family. In 2000-2003 we have conducted polling of families with children having atopic dermatitis, analysis of ambulatory cards and case histories in Vladivostok Children's Municipal Clinic Hospital. Also, life standard questionnaires were filled in. RESULTS: Family expenses on the child's disease treatment in 2000 were 9658.9 rubles (\$311.5), in 2001— 12142.1 rubles (\$379), in 2002—13400 rubles (\$446), which made from 9.6 to 13.4% of family annual income. The largest specific weight of expenses (36.1%) was shown by drugs purchase: in 2000-3486.8 rubles (\$112), in 2001—4383.2 (\$136), 2002—4837.4 rubles (\$161). In 2000 atopic dermatitis caused hospitalization of the child in average in  $1.54 \pm 0.2$  cases in a year, period of treatment  $15.62 \pm 1.02$  days. In 2002 share of expenses on basis antiinflammatory therapy and consultations of allergist and dermatologist increased, while number of hospitalization cases reduced to 1.01  $\pm$  0.1, duration of hospitalization reduced down to  $10.37 \pm 0.94$  days per one child in average during a year. Atopic dermatitis detected decrease in life quality not only of the child but also of the family as a whole. CONCLUSIONS: Effective pharmacotherapy and observance of hypoallergic every day life regulations led to improvement of children life quality, reduced expenses on hospital assistance, temporary disability and disablement but increased the burden of family expenses on drugs.

PSN7

# TREATMENT OF PSORIASIS WITH CONVENTIONAL SYSTEMIC AGENTS IS ASSOCIATED WITH HIGH MEDICAL COSTS AND FREQUENT TREATMENT FAILURE

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