

## **1.0 Abstract**

### **Title**

Post-authorization, observational study to evaluate the effectiveness of adalimumab (HUMIRA<sup>®</sup>) on moderate-severe psoriasis under conditions of normal clinical practice in Spain.

### **Keywords**

Adalimumab, effectiveness, safety, moderate-severe psoriasis, clinical practice.

### **Rationale and Background**

Co-morbidities associated to psoriasis exert a negative impact on patient's quality of life and productivity. Adalimumab has proved to be efficacious for moderate-severe plaque psoriasis (MSPPS) in clinical trials.

### **Research Question and Objectives**

To determine the impact of the clinical and therapeutic profile of the patient on the effectiveness of treatment with adalimumab in adult patients diagnosed with moderate to severe chronic plaque psoriasis administered under conditions of normal clinical practice in Spain.

To determine the handling of treatment with adalimumab in adult patients diagnosed with moderate to severe chronic plaque psoriasis administered under conditions of normal clinical practice in Spain.

To expand the knowledge of the safety profile of treatment with adalimumab in adult patients diagnosed with moderate to severe chronic plaque psoriasis administered under conditions of normal clinical practice in Spain.

To determine the impact of treatment with adalimumab (Humira<sup>®</sup>) on health-related quality of life in adult patients diagnosed with moderate to severe chronic plaque psoriasis under conditions of normal clinical practice in Spain.

### **Study Design**

Post-authorization, observational, multi-center, uncontrolled study in adult patients with chronic plaque PS treated with Humira<sup>®</sup> in routine clinical practice.

## **Setting**

Fifty nine hospital dermatologists with experience in clinical and therapeutic treatment of moderate-severe psoriasis.

## **Subjects and Study Size, Including Dropouts**

Between February 2010 and February 2012, 547 patients fulfilling the following criteria were included: diagnosed of MSPPs, initiating treatment with adalimumab, aged 18 or older, and giving written informed consent. Patients who could not be treated with adalimumab, that were participating in another clinical trial or that were unable to fill in any of the questionnaires were excluded. A total of 532 evaluable patients for the effectiveness analysis and 542 evaluable patients for the safety analysis were included.

## **Variables and Data Sources**

The following sociodemographic and clinical data were collected at baseline: age, gender, BMI, employment status, smoking and alcoholic habit, time since diagnosis, joint pain and inflammation, previous Ps treatment, concomitant diseases, hospital stays and loss of working days due to Ps. In order to assess adalimumab effectiveness, Ps severity was determined at baseline and each monitoring visit through the PASI, BSA, and Physician's Global Assessment (PGA) on a 0 to 5 scale (0 denoting Ps absence and 5 denoting severe Ps); as well as presence of Ps in palms, soles, nails and scalp. Also, in order to determine evolution of patient's HRQoL and productivity, they were asked to fulfil the following questionnaires: Dermatology Life Quality Index (DLQI), EuroQoL-5D and Work productivity and Activity Impairment Questionnaire (WPAI-SHP:PSO), at visits closest to months: 6, 12, 18 and 24. Results regarding palms, soles, nails and scalp Ps, HRQoL and productivity are being published elsewhere.

## **Results**

On the effectiveness population, 61.1% of patients were male, mean (SD) age was 46.5 (13.3) years, 104 (19.5%) of patients presented palmoplantar PS (PPP); 146 (27.5%) of patients exhibited NPGA of 2-4 with a mean (SD) of 12.0 (6.7) nails with PS and 235 (44.2%) of patients presented Scalp IGA 3-5. EQ-5D pain/discomfort dimension was reported by 63.5% of patients.

After 24 months under ADA, 64.4%, 47.1% and 32.7% of patients in the ITT population reached a PASI75, PASI90 and PASI100, respectively; when considering

PP population these results were slightly higher: 78.9%, 59.2% and 44.2% presenting a PASI75, PASI90 and PASI100, respectively. 64.2% (ITT) and 79.3% (PP) presented a BSA<5%. 61.5 % (ITT) and 77% (PP) of patients reported a PGA 0–1. Mean (SD) DLQI score was also reduced in 6.0 (7.4) (ITT) and 7.6 (7.1) (PP) points (p<0.001). At 24 months there was also a reduction of patients with PPP of 76% (ITT) and 86.6% (PP). A reduction of 75% (ITT) and 89.7% (PP) of patients with NPGA 2-4 was reported, with the number of affected nails being reduced to a mean (SD) of 3.8 (6.7) (ITT) and 2.1 (5.3) (PP). 81.3% (ITT) and 97% (PP) of patients with Scalp IGA 3-5 presented Scalp IGA 0-1 at the end of treatment.

During 24 months of study duration, 63.8% of patients reported an adverse event (AE); only 4.4% and 8.3% reported an AE classified as severe or of especial interest, respectively; opportunist infections (3.5/100 patients/year) and malignant neoplasms (1.3/100 patients/year) were reported.

Positive results were also observed in terms of general PS evolution (PASI, BSA and PGA), QoL (DLQI and EQ-5D) and productivity (WPAI). Patients claimed improved QoL perception through the EQ-5D questionnaire; not only on the basis of issues related to their disease reported through its visual analogical scale, but also through the scores reported in all 5 dimensions, especially the one referring to pain/discomfort with 40% reduction of patients suffering pain/discomfort. Productivity and working hours lost due to PS were reduced in 12.9% and 2.3%, respectively.

## **Discussion**

Further reinforcing previous results, the study concludes that patients with moderate-severe plaque psoriasis who received ADA for 24 months exhibited a statistically significant improvement in terms of PS severity translated into an increased quality of life. No new safety signals were observed

Consistent with previous results, the present study concludes that patients with moderate-severe plaque psoriasis who received ADA for 24 months exhibited improvements in PS severity, and particularly in terms of palmoplantar, nails and scalp PS, which translated into an increased quality of life. No new safety signals were observed

## **Marketing Authorisation Holder(s)**

AbbVie Spain, (AbbVie)