# Demography, baseline disease characteristics and treatment history of patients with psoriasis enrolled in a multicentre, prospective, disease-based registry (PSOLAR)*

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# Demography, baseline disease characteristics and treatment history of patients with psoriasis enrolled in a multicentre, prospective, disease-based registry (PSOLAR)*

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## Summary

*Background* Psoriasis is associated with several comorbidities and behavioural risk factors.
*Objectives* To evaluate demographic and disease characteristics in patients enrolled in the Psoriasis Longitudinal Assessment and Registry (PSOLAR).
*Methods* PSOLAR is a global, prospective, longitudinal, disease-based registry that includes a postmarketing commitment to evaluate safety in patients with psoriasis. Enrolled patients had to be receiving, or be eligible to receive, conventional systemic or biological agents. Demographic/disease characteristics, medical histories, lifestyle risk factors and previous treatments are collected at enrolment. Efficacy and safety data are collected every 6 months for 8 years, and data are extracted annually. Selected parameters are evaluated by age quartile using post hoc analyses.
*Results* As of 23 August 2012, 11 900 patients were enrolled at 301 sites in North America, Europe and Latin America. Over half of the PSOLAR population (54·7%) is male, with a mean age of 48·6 years and mean body mass index of 30·9 kg $m^{-2}$ at enrolment. Mean duration of disease at enrolment was 17·5 years, and mean Physician's Global Assessment score was 2·0. Psoriatic arthritis (35·5%) and cardiovascular diseases (38·2%) were highly prevalent. Diabetes mellitus type II was reported in 11·4% of patients. Depression and anxiety were noted in 14·7% and 11·1% of patients, respectively; 79·0% reported any alcohol use and 56·7% reported smoking or a history of smoking. The occurrence of most comorbidities, including cardiovascular disease and risk factors, increased with age.
*Conclusions* In the PSOLAR population, multiple and age-appropriate comorbidities are associated with psoriasis and may affect the selection of psoriasis treatments.

### What's already known about this topic?

- Psoriasis is a complicated disorder, often accompanied by multiple comorbidities.
- Demographic and disease characteristics of patients with psoriasis reported from large claims datasets may be affected by misclassification bias or coding errors.
- In clinical trials, many patients are excluded owing to strict inclusion criteria.

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### Conflicts of interest
*See Appendix 1.*

*Plain language summary available online

**PSOLAR Steering Committee members are listed in Appendix 2.

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**What does this study add?**

- Data collected by the Psoriasis Longitudinal Assessment and Registry reveal that the demographics and disease characteristics of patients with psoriasis who are receiving, or are candidates for, systemic therapy in actual clinical care resemble those reported in clinical trials.
- Most comorbidities occur more frequently in older patients, who, in turn, may require more comprehensive overall medical care.

Psoriasis is a common, chronic, inflammatory, immune-mediated disease that manifests with scaly, erythematous plaques on the skin.[1] Psoriatic disease is often associated with a variety of comorbid conditions, including psoriatic arthritis (PsA), which has been estimated to occur in one-third of patients with psoriasis.[2] Likewise, cardiovascular conditions and risk factors, including diabetes, hypertension, hyperlipidaemia, obesity and metabolic syndrome, as well as chronic pulmonary disease and Crohn disease, are commonly reported among patients with psoriasis.[3–10] Patients with psoriasis have an increased risk of depression and anxiety compared with the general population,[11] and lifestyle risk factors that may exacerbate psoriasis itself or complications of the disease, such as smoking and alcohol use, are highly prevalent in this patient population.[12]

Current understanding of the typical profile of a patient with psoriasis, including demographic and disease characteristics, as well as common comorbidities and standard-of-care treatment, is based mainly on large datasets derived from claims databases or populations enrolled in clinical trials. However, such studies have limitations, including coding accuracy and criteria required for enrolment, respectively.[13] Although patient registries may also have limitations, such as participation, recall and other forms of bias, such observational studies allow for the collection of valuable data during continuous treatment in actual practice settings.[14,15]

The Psoriasis Longitudinal Assessment and Registry (PSOLAR) is a large, international, longitudinal, disease-based registry with prospective enrolment of patients with psoriasis who are receiving, or are candidates for treatment with, systemic therapies.[16] This observational study, which supports a postmarketing commitment of the sponsor (Janssen Scientific Affairs, LLC, Horsham, PA, U.S.A.), provides the opportunity to collect epidemiological data on patients with psoriasis who are treated in real-life dermatological practices primarily in North America and Europe. This report provides a comprehensive description of demographics, disease characteristics, medical history, lifestyle risk factors (i.e. alcohol use and smoking) and treatments prior to enrolment in PSOLAR. These data are further analysed to determine how the prevalence of certain comorbidities and social behaviours commonly observed in patients with psoriasis may vary with age.

## Methods

PSOLAR is a prospective, 8-year, longitudinal, disease-based registry designed to collect safety, clinical outcome, quality of life and comorbidity data from patients with psoriasis who are receiving, or are eligible to receive, conventional systemic or biological therapies. PSOLAR patients are enrolled at nearly 300 academic, community-based and hospital-affiliated clinical practices in 16 countries.[16] To meet the need for postmarketing surveillance of the long-term safety of psoriasis therapies developed by the sponsor within the registry population, enrolment was planned for approximately 12 000 patients and to accommodate patients exposed to not only sponsor-produced biologics (i.e. ustekinumab and infliximab), but also other biological agents (e.g. adalimimumab and etanercept), as well as other nonbiological therapies (e.g. immunomodulators and/or phototherapy).

The design and utility of PSOLAR, as well as the role of the chartered Steering Committee (see Appendix 2), have been reported previously.[16] PSOLAR was conducted in accordance with guidelines from the Agency for Healthcare Research and Quality.[17] Briefly, eligible patients (aged $\geq$ 18 years) must have had a diagnosis of moderate-to-severe plaque or other form of psoriasis for which they were receiving, or were candidates for receiving, treatment with systemic therapies. As with all observational studies, study physicians prescribe treatment based solely on the usual practices of care. The registry does not allocate patients to specific treatment or restrict the use of commercially available medications as monotherapy or in combination. Sites collect a core set of data that includes demographics, disease activity, medical history and previous medications at enrolment; safety data are collected at each study visit every 6 months for a minimum of 8 years.

Specified data are collected by site personnel using the following methods: (i) direct contact (i.e. office visit or, in limited circumstances, by telephone) with the patient; (ii) review of the patient's medical records; or (iii) contact with the patient's primary care physician or specialty physician involved in the patient's medical care. Data collected at each site include demographic and disease characteristics, medical histories, lifestyle risk factors, and previous medication exposure using electronic case report forms, which were designed to query for specific parameters and offered the option to provide additional information for certain queries. For example, patients were queried for the presence of PsA and, if present, they were asked if the diagnosis of PsA had been confirmed by a joint specialist.

For this report, epidemiological data (i.e. demographic and disease characteristics, individual and family medical history,

social activity history and psoriasis treatment history) at enrolment, as well as history of infection requiring prescription treatment in the 3 years prior to enrolment, were summarized using descriptive statistics. Selected parameters [i.e. body mass index (BMI), medical history and social activity] were summarized by age quartiles of 18–35 years (Q1), 36–50 years (Q2), 51–65 years (Q3) and > 65 years (Q4). This report includes data for patients enrolled prior to the annual database extract on 23 August 2012.

## Results

As of the 23 August 2012 PSOLAR data extract, 11 900 of the 12 000 targeted patients were enrolled at 301 global sites in North America, Europe and Latin America. The first patient was enrolled on 20 June 2007. More than 90% of sites are located in North America (i.e. approximately 75·0% in the U.S.A. and approximately 16·0% in Canada) (Fig. 1).

At enrolment, the mean patient age was 48·6 years and the mean BMI was 30·9 kg $m^{-2}$ (Table 1). Just over half of the PSOLAR population at this time were men (54·7%), with the majority being white (83·1%). Approximately 80·0% of patients in PSOLAR were either overweight or obese at enrolment. Based on the National Heart, Lung, and Blood Institute Obesity Education Initiative criteria, nearly half of the patients were obese at enrolment: 24·3% were of class I obesity status (BMI 30·0–34·9), 13·1% were of class II obesity status (BMI 35·0–39·9) and 10·8% were of class III obesity status (BMI ≥ 40); an additional 32·1% of patients were overweight.

### Disease characteristics

The mean percentage of body surface area (BSA) affected by psoriasis was 12·1% at enrolment, which is significantly lower than the mean BSA affected at peak historical disease activity (29·7%) (Table 2). This finding is consistent with the fact that many patients were receiving treatment for psoriasis at the time of registry enrolment. Similarly, the mean Physician's Global Assessment (PGA) score was 2·0 at entry compared with 3·1 at peak activity. Approximately three quarters of patients had a mean PGA score indicative of minimal (1), mild (2) or moderate (3) psoriasis at enrolment (23·2%, 28·1% and 27·5%, respectively), whereas almost all patients had moderate (46·4%), marked (26·4%) or severe (7·0%) psoriasis at peak disease activity. Overall, 96·9% of patients enrolled in PSOLAR had plaque psoriasis (Table 1). The mean time since psoriasis had been diagnosed was 17·5 years, and the mean time since the highest degree of disease activity was 3·3 years.

**Table 1** Demographic and disease characteristics at enrolment (enrolled patients)

| Patients enrolled | n = 11 900 |
|---|---|
| Sex, male | 6513 (54·7) |
| Race, white | 9890/11 898 (83·1) |
| Age (years) | 48·6 ± 13·9 |
| BMI (kg $m^{-2}$) | 30·9 ± 7·2 |
| BMI category[a] | 11 703 |
| Underweight (BMI < 18·5) | 59 (0·5) |
| Normal (BMI 18·5–24·9) | 2235 (19·1) |
| Overweight (BMI 25·0–29·9) | 3762 (32·1) |
| Obesity class I (BMI 30·0–34·9) | 2845 (24·3) |
| Obesity class II (BMI 35·0–39·9) | 1537 (13·1) |
| Obesity class III (BMI ≥40·0) | 1265 (10·8) |
| Psoriasis type | 11 854 |
| Plaque | 11 491 (96·9) |
| Other | 1089 (9·2) |
| Duration of psoriasis (years) | 11 777 |
| Mean ± SD | 17·5 ± 13·5 |

Values are n (%) of patients or mean ± SD. BMI, body mass index. [a]Obesity class based upon National Heart, Lung, and Blood Institute Obesity Education Initiative (http://www.nhlbi.nih.gov/about/oei/).

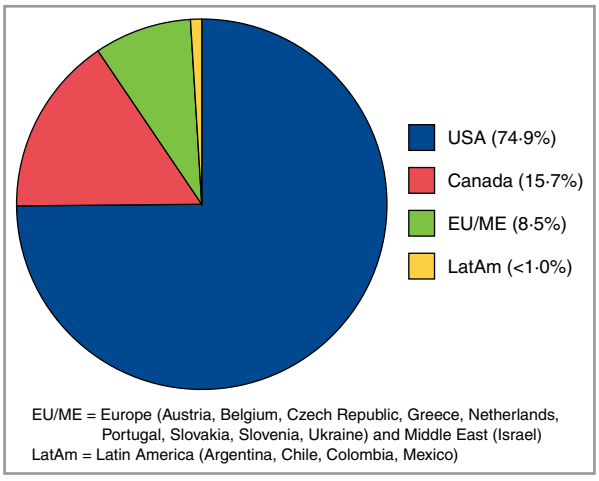


**Fig 1.** Proportion of patients enrolled in the Psoriasis Longitudinal Assessment and Registry by country.

### Comorbidities and family history

Approximately one-third of patients (35·5%; n = 4226) reported a history of PsA at the time of enrolment in PSOLAR (Table 3), with 1664 patients (14·1%) having their diagnosis confirmed by a joint specialist. A family history of psoriasis was reported by 45·5% of patients, while 10·3% noted a family history of PsA (Table 4). There was a high proportion of patients (38·2%) with a history of cardiovascular disease [e.g. myocardial infarction (2·4%), transient ischaemic attack or stroke (1·2%), and congestive heart failure (1·0%)] and risk factors [e.g. hypertension (29·7%), hyperlipidaemia (18·6%) and diabetes mellitus type II (11·4%)] (Table 3), with a family history of cardiovascular disease reported by 44·7% of patients (Table 4).

A history of pulmonary conditions was reported for 14·4% of patients [e.g. asthma (8·0%) and sleep apnoea (5·7%)], while a history of hepatic conditions [e.g. cirrhosis (0·8%), hepatitis B (0·5%) and hepatitis C (1·1%)] was noted in < 5·0% of patients (Table 3). Liver biopsies had been per-

**Table 2** Disease activity at enrolment and peak historical level (enrolled patients)

| | All patients | Patients with peak historic data | |
|---|---|---|---|
| | | Enrolment[a] | Peak historic |
| BSA by palm method | 11 756 | 6746 | 6772 |
| Mean ± SD | 12·1 ± 17·5 | 13·6 ± 19·04 | 29·7 ± 24·8 |
| PGA score | 11 360 | 6606 | 6845 |
| Mean ± SD | 2·0 ± 1·2 | 2·0 ± 1·22 | 3·1 ± 1·0 |
| PGA score distribution | 11 360 | 6606 | 6845 |
| 0 = clear | 1335 (11·8) | 767 (11·6) | 171 (2·5) |
| 1 = minimal | 2633 (23·2) | 1544 (23·4) | 258 (3·8) |
| 2 = mild | 3196 (28·1) | 1782 (27·0) | 959 (14·0) |
| 3 = moderate | 3125 (27·5) | 1835 (27·8) | 3174 (46·4) |
| 4 = marked | 873 (7·7) | 548 (8·3) | 1807 (26·4) |
| 5 = severe | 198 (1·7) | 130 (2·0) | 476 (7·0) |

Values are n (%) of patients or mean ± SD. BSA, body surface area affected by psoriasis; PGA, Physician's Global Assessment. [a]Includes patients for whom data were also collected for peak disease activity.

formed in 1·9% of the patients (n = 223), and only 0·3% of patients (n = 31) had a history of alcoholic liver disease. A history of ulcerative colitis (0·8%) or Crohn disease (0·5%) was rarely noted. Similarly, low proportions of patients with neurological conditions, including demyelinating disease (0·2%) and multiple sclerosis (0·1%), and other autoimmune conditions, such as lupus (0·3%), were observed.

Overall, 24·6% of patients reported significant infections requiring prescription medication within the 3-year interval before enrolment. Most prior infections were bacterial in nature (21·6%); opportunistic infections (as defined by the site investigator) were uncommon (1·2%). A history of basal cell (BCC) and squamous cell carcinoma (SCC) was reported for 3·8% and 2·4% of patients, respectively, and a history of other cancers was reported in 3·7% of patients (Table 3), including lymphoma (n = 14) in approximately 0·1% of patients. A history of psychiatric disease was noted in 20·7% of patients. Among the psychiatric conditions commonly associated with psoriasis, depression was reported for 14·7% of patients and anxiety for 11·1% (Table 3). High proportions of patients reported current or previous alcohol use of any kind (79·0%), or smoking in any capacity (56·7%) (Table 5).

### Previous treatment

At enrolment, 97·3% of patients had been treated with topical therapy, 54·6% with phototherapy and 43·6% with retinoids, such as acitretin (19·9%), and 47·6% with immunomodulators, such as methotrexate (40·6%) and ciclosporin (15·6%) (Table 6). Nearly three-quarters (72·1%) had received biological therapy prior to entry into the registry: 39·0% had received one biological agent and 29·3% had received two or three biological agents. Specific biological agents received by patients enrolled in PSOLAR prior to enrolment included etanercept (40·5%), adalimumab (29·4%), ustekinumab (18·7%), infliximab (15·2%), efalizumab (11·2%), alefacept (5·8%) and/or others (2·3%).

### Baseline characteristics by age quartile

Selected baseline characteristics were analysed by age quartiles of 18–35 years (Q1), 36–50 years (Q2), 51–65 years (Q3) and > 65 years (Q4). Mean BMI values were comparable in the Q1 (29·5), Q2 (31·4), Q3 (31·5) and Q4 (30·1) groups (Table 7). The proportions of patients with class I obesity status increased consistently with age, but only by a few percentage points, while the Q1 (youngest) and Q4 (oldest) groups had similar and slightly lower proportions of patients with class II/III obesity status.

The proportion of patients that reported PsA was lowest in the Q1 group (23·6%), and comparably higher among the Q2 (37·2%), Q3 (40·7%) and Q4 (35·0%) groups (Table 8). The proportion with a history of cardiovascular disease and risk factors generally increased with age. The same trend was observed for most other medical history categories and individual diseases. Of note, the proportion of patients with diabetes mellitus II was noticeably lower for the Q1 (2·3%) and Q2 (7·1%) age groups compared with the Q3 (17·5%) and Q4 (21·2%) age groups, as were those with hypertension and hyperlipidaemia.

Finally, the proportions of patients with a history of overall psychiatric disease increased slightly with age across the Q1, Q2 and Q3 groups; a similar pattern was observed for history of depression (Table 9). In contrast, generally similar proportions of patients with a history of anxiety, bipolar disorder and suicidal ideation were observed across age groups. The proportions of patients reporting current use of alcohol or identified as current smokers generally decreased with age, while the proportions of those who had stopped using alcohol or smoking consistently increased with age (Table 9).

## Discussion

PSOLAR, which began in 2007, is a prospective, longitudinal, disease cohort study for patients with psoriasis who are eligi-

**Table 3** Medical history at enrolment (enrolled patients)

| Patients enrolled[a] | n = 11 900 |
|---|---|
| Psoriatic arthritis | 4226 (35·5) |
| Cardiovascular disease | 4545 (38·2) |
| Hypertension | 3527 (29·7) |
| Hyperlipidaemia | 2215 (18·6) |
| Atherosclerotic disease | 417 (3·5) |
| Coronary artery disease | 355 (3·0) |
| Myocardial infarction | 290 (2·4) |
| Angina[b] | 165 (1·4) |
| TIA/stroke | 148 (1·2) |
| Congestive heart failure | 122 (1·0) |
| Peripheral arterial disease | 68 (0·6) |
| Psychiatric disease | 2460 (20·7) |
| Depression | 1751 (14·7) |
| Anxiety | 1318 (11·1) |
| Bipolar | 181 (1·5) |
| Suicidal ideation | 114 (1·0) |
| Endocrine disease | 2233 (18·8) |
| Diabetes mellitus type II | 1357 (11·4) |
| Thyroid dysfunction | 910 (7·7) |
| Diabetes mellitus type I | 145 (1·2) |
| Pulmonary disease | 1710 (14·4) |
| Asthma | 952 (8·0) |
| Sleep apnoea | 680 (5·7) |
| COPD | 241 (2·0) |
| NMSC[c] | 657 (5·5) |
| Basal cell carcinoma | 446 (3·8) |
| Squamous cell carcinoma | 287 (2·4) |
| Melanoma skin cancer | 103 (0·9) |
| Other types of cancer[d] | 439 (3·7) |
| Hepatic disease | 485 (4·1) |
| Hepatitis C | 129 (1·1) |
| Cirrhosis | 90 (0·8) |
| Drug-induced[e] | 71 (0·6) |
| Hepatitis B | 65 (0·5) |
| Inflammatory bowel disease | 273 (2·3) |
| Indeterminate colitis | 106 (0·9) |
| Ulcerative colitis | 96 (0·8) |
| Crohn disease | 58 (0·5) |

Values are n (%) of patients for conditions occurring at an incidence of at least 0·5%. TIA, transient ischaemic attack; COPD, chronic obstructive pulmonary disease; NMSC, nonmelanoma skin cancer. [a]On the case report form all patients (n = 11 900) provided a response regarding psoriatic arthritis status, whereas 11 888 patients reported the presence of other relevant medical history. [b]May include noncardiac angina (e.g. bowel angina) if not specified by site. [c]Some patients had both basal and squamous cell carcinoma, accounting for the discrepancy between the total proportion with NMSC and the proportions with individual types of skin cancer. [d]Other types of cancer were entered manually on the case report form at each study site. A history of other cancers reported in a total of five or more patients included lymphoma (n = 14), breast (n = 13), gynaecological (n = 10), cervical (n = 8), colorectal (n = 8), prostate (n = 7), bladder (n = 6), kidney (n = 6) and sarcoma (n = 6). [e]Includes drug-induced hepatic disease related to psoriasis or other treatment.

**Table 4** Family medical history at enrolment (enrolled patients)

| Number of patients with family history data | n = 11 540 |
|---|---|
| Psoriasis | 5246 (45·5) |
| Psoriatic arthritis | 1193 (10·3) |
| Cardiovascular disease | 5158 (44·7) |
| NMSC | 1250 (10·8) |
| Melanoma skin cancer | 624 (5·4) |
| Other cancer | 3839 (33·3) |
| Diabetes | 4450 (38·6) |
| Inflammatory bowel disease | 762 (6·6) |
| Indeterminate colitis | 200 (1·7) |
| Ulcerative colitis | 153 (1·3) |
| Crohn disease | 199 (1·7) |
| Sprue/coeliac disease | 42 (0·4) |

Values are n (%) of patients. NMSC, nonmelanoma skin cancer.

**Table 5** Social activity at enrolment (enrolled patients)

| Patients enrolled | n = 11 900 |
|---|---|
| Alcohol | 11 875 |
| Never used | 2500 (21·1) |
| Current use | 7678 (64·7) |
| Have used alcohol and stopped | 1697 (14·3) |
| Smoking | 11 882 |
| Never smoked | 5139 (43·3) |
| Current smoker | 2831 (23·8) |
| Have smoked and stopped | 3912 (32·9) |

Values are n (%) of patients.

ble for systemic therapy. With 11 900 patients enrolled at 301 global centres as of the August 2012 database extract, PSOLAR represents the largest, international, industry-sponsored collection of data from a disease-based registry of patients with psoriasis. As part of postmarketing commitments to evaluate safety, a primary objective for PSOLAR is to provide pharmacovigilance reports to regulatory agencies for individual sponsor products. However, the registry also provides data on patients receiving multiple other therapies and offers relevant information about the disease to the community of healthcare providers treating patients with psoriasis. Our findings confirm that psoriasis is a complex disease frequently associated with multiple and age-appropriate comorbidities, which should be considered when evaluating treatment for psoriasis.

The PSOLAR population represents one with substantial disease, as indicated by peak historic disease activity (mean PGA score 3·1, but mean BSA of 29·7%) which, on average, predated enrolment by about 3 years. At entry, patients had somewhat less severe disease compared with peak historic levels (mean PGA 2·0, mean BSA 12·1%), a not unexpected finding given that the majority of patients were receiving treatment for psoriasis at the time of enrolment. The majority of patients had plaque psoriasis, and nearly half (45·5%) had a family history of psoriasis. Overall, 35·5% reported a history of PsA at enrolment, consistent with similar populations with

**Table 6** Previous medication use at enrolment (enrolled patients)

| Patients enrolled | n = 11 900 |
|---|---|
| Number of patients with data available | 11 866 |
| Topical therapy | 11 542 (97·3) |
| Tazarotene | 1309 (11·0) |
| Calcipotriene/betamethasone | 2904 (24·5) |
| Topical steroid therapy | 11 267 (95·0) |
| High potency | 9570 (80·7) |
| Medium potency | 7032 (59·3) |
| Low potency | 4576 (38·6) |
| Phototherapy | 6482 (54·6) |
| Psoralen plus UVA | 2028 (17·1) |
| UVB | 5438 (45·8) |
| Systemic steroids | 2782 (23·4) |
| Retinoids | 5176 (43·6) |
| Acitretin | 2359 (19·9) |
| Immunomodulators | 5646 (47·6) |
| Ciclosporin | 1855 (15·6) |
| Methotrexate | 4819 (40·6) |
| Other immunomodulators | 317 (2·7) |
| Biological agents(s) | 8583 (72·1) |
| Infliximab | 1808 (15·2) |
| Ustekinumab | 2220 (18·7) |
| Adalimumab | 3495 (29·4) |
| Alefacept | 696 (5·8) |
| Efalizumab | 1328 (11·2) |
| Etanercept | 4814 (40·5) |
| Other biological agents | 277 (2·3) |
| Number of biological agents used prior to entry | |
| 0 | 3317 (27·9) |
| 1 | 4645 (39·0) |
| 2–3 | 3490 (29·3) |
| 4–7 | 448 (3·8) |

Values are n (%) of patients for treatments received by at least 2·0% of patients. UVA, ultraviolet A; UVB, ultraviolet B.

moderate-to-severe psoriasis.[2,18] About 10·0% reported a family history of PsA, although only about 15·0% of patients had PsA diagnosed by a joint specialist. PSOLAR includes a broad spectrum of patients with psoriasis who may or may not be normally eligible for clinical trials. Many demographic features of the PSOLAR population reported at enrolment (e.g. age) and disease characteristics (e.g. % BSA) reported at peak historic levels are generally similar to those reported in phase III clinical trials and other observational studies of biologics in psoriasis, while others (e.g. male : female ratio) may differ.[19–27] Interestingly, the proportion of women enrolled in PSOLAR and other observational studies of biological agents was 10·0–15·0% higher than that reported in many clinical trials, which may be because women of childbearing age are less inclined to participate in studies of experimental agents.

Based upon National Heart, Lung, and Blood Institute Obesity Education Initiative criteria, about 20% of patients were of normal body weight status at enrolment in PSOLAR, while a remarkable 80% were overweight or obese. Furthermore, the rate of obesity at entry into PSOLAR (48·2%) is higher than published rates for adults in the U.S.A. and Canada (nearly 25·0% and 35·0%, respectively).[28] This is particularly notable because increased BMI is an established risk factor for cardiovascular disease,[29] may impact response to treatment, and could further burden patients with anxiety, depression and sleep impairment.[30] Interestingly, the prevalence of weight problems did not differ much across age quartiles, while the prevalence of cardiovascular risk factors varied substantially, suggesting a tendency towards accumulation of these comorbidities over time.

There was a high prevalence of cardiovascular disease (38·2%) and other cardiovascular risk factors, including hypertension (29·7%), hyperlipidaemia (18·6%) and diabetes mellitus type II (11·4%), all of which, along with obesity, are components of metabolic syndrome. These results are consistent with the reported association between psoriasis and both cardiovascular risk factors and metabolic syndrome.[31–33] Of note, the prevalence of cardiovascular risk factors increased substantially with increasing age, which indicates, as expected, that cardiovascular comorbidities tend to accumulate over time in the psoriasis population. Furthermore, high proportions of patients reported a family history of cardiovascular disease (44·7%) and diabetes (38·6%), likely indicative of a predisposition to such diseases in certain patients with psoriasis.

Some patients reported a history of pulmonary diseases [e.g. asthma (8·0%), sleep apnoea (5·7%) and chronic

**Table 7** Body mass index (BMI) and obesity class by age quartiles (enrolled patients)

| Age (years) | 18–35 | 36–50 | 51–65 | > 65 |
|---|---|---|---|---|
| BMI (kg $m^{-2}$) | 2285 | 4003 | 4073 | 1339 |
| Mean ± SD | 29·5 ± 7·58 | 31·4 ± 7·57 | 31·5 ± 6·86 | 30·1 ± 6·17 |
| Obesity class[a] | 2285 | 4003 | 4073 | 1339 |
| Underweight (BMI < 18·5) | 28 (1·2) | 18 (0·4) | 6 (0·1) | 7 (0·5) |
| Normal (BMI 18·5–24·9) | 682 (29·8) | 685 (17·1) | 622 (15·3) | 246 (18·4) |
| Overweight (BMI 25·0–29·9) | 676 (29·6) | 1293 (32·3) | 1310 (32·2) | 481 (35·9) |
| Obesity class I (BMI 30·0–34·9) | 444 (19·4) | 968 (24·2) | 1071 (26·3) | 361 (27·0) |
| Obesity class II (BMI 35·0–39·9) | 243 (10·6) | 532 (13·3) | 619 (15·2) | 143 (10·7) |
| Obesity class III (BMI ≥40·0) | 212 (9·3) | 507 (12·7) | 445 (10·9) | 101 (7·5) |

Values are n (%) of patients, unless otherwise noted, for conditions occurring at a total incidence of at least 0·5% in any quartile. [a]Obesity class based upon National Heart, Lung, and Blood Institute Obesity Education Initiative (http://www.nhlbi.nih.gov/about/oei/).

**Table 8** Medical history by age quartiles (enrolled patients)

| Age (years) | 18–35 | 36–50 | 51–65 | > 65 |
|---|---|---|---|---|
| Patients with PsA data available (n) | 2322 | 4075 | 4147 | 1352 |
| Patients with PsA (n) | 548 (23·6) | 1517 (37·2) | 1687 (40·7) | 473 (35·0) |
| Patients with relevant medical history data (n) | 2321 | 4068 | 4144 | 1352 |
| Cardiovascular disease | 223 (9·6) | 1193 (29·3) | 2213 (53·4) | 916 (67·8) |
| Hypertension | 160 (6·9) | 880 (21·6) | 1747 (42·2) | 740 (54·7) |
| Hyperlipidaemia | 86 (3·7) | 560 (13·8) | 1109 (26·8) | 460 (34·0) |
| Atherosclerotic disease | 3 (0·1) | 49 (1·2) | 217 (5·2) | 148 (10·9) |
| Peripheral arterial disease | 0 | 7 (0·2) | 36 (0·9) | 25 (1·8) |
| Coronary artery disease | 3 (0·1) | 40 (1·0) | 183 (4·4) | 129 (9·5) |
| Myocardial infarction | 2 (0·1) | 46 (1·1) | 137 (3·3) | 105 (7·8) |
| Angina[a] | 3 (0·1) | 18 (0·4) | 90 (2·2) | 54 (4·0) |
| TIA/stroke | 2 (0·1) | 23 (0·6) | 64 (1·5) | 59 (4·4) |
| Congestive heart failure | 6 (0·3) | 17 (0·4) | 53 (1·3) | 46 (3·4) |
| Endocrine disease | 135 (5·8) | 535 (13·2) | 1112 (26·8) | 450 (33·3) |
| Diabetes mellitus II | 54 (2·3) | 290 (7·1) | 726 (17·5) | 286 (21·2) |
| Thyroid dysfunction | 73 (3·1) | 233 (5·7) | 420 (10·1) | 184 (13·6) |
| Diabetes mellitus I | 14 (0·6) | 47 (1·2) | 62 (1·5) | 22 (1·6) |
| Pulmonary disease | 246 (10·6) | 526 (12·9) | 678 (16·4) | 260 (19·2) |
| Asthma | 207 (8·9) | 302 (7·4) | 318 (7·7) | 125 (9·2) |
| Sleep apnoea | 39 (1·7) | 225 (5·5) | 325 (7·8) | 91 (6·7) |
| COPD | 3 (0·1) | 30 (0·7) | 132 (3·2) | 76 (5·6) |
| NMSC[b] | 6 (0·3) | 80 (2·0) | 327 (7·9) | 244 (18·0) |
| Basal cell carcinoma | 5 (0·2) | 60 (1·5) | 227 (5·5) | 154 (11·4) |
| Squamous cell carcinoma | 1 (< 0·1) | 20 (0·5) | 137 (3·3) | 129 (9·5) |
| Other types of cancer[c] | 13 (0·6) | 60 (1·5) | 204 (4·9) | 162 (12·0) |
| Hepatic disease | 37 (1·6) | 140 (3·4) | 231 (5·6) | 77 (5·7) |
| Hepatitis C | 5 (0·2) | 41 (1·0) | 71 (1·7) | 12 (0·9) |
| Cirrhosis | 5 (0·2) | 20 (0·5) | 48 (1·2) | 17 (1·3) |
| Drug-induced[d] | 9 (0·4) | 21 (0·5) | 30 (0·7) | 11 (0·8) |
| Hepatitis B | 1 (< 0·1) | 26 (0·6) | 30 (0·7) | 8 (0·6) |
| Inflammatory bowel disease | 37 (1·6) | 77 (1·9) | 117 (2·8) | 42 (3·1) |
| Crohn disease | 17 (0·7) | 22 (0·5) | 18 (0·4) | 1 (0·1) |
| Ulcerative colitis | 10 (0·4) | 28 (0·7) | 41 (1·0) | 17 (1·3) |
| Indeterminate colitis | 9 (0·4) | 25 (0·6) | 52 (1·3) | 20 (1·5) |

Values are n (%) of patients, unless otherwise noted, for conditions occurring at a total incidence of at least 0·5% in any quartile. PsA, psoriatic arthritis; TIA, transient ischaemic attack; COPD, chronic obstructive pulmonary disease; NMSC, nonmelanoma skin cancer. [a]May include noncardiac angina (e.g. bowel angina) if not specified by site. [b]Some patients had both basal and squamous cell carcinoma, accounting for the discrepancy between the total proportion with NMSC and the proportions with individual types of skin cancer. [c]Other types of cancer were entered manually on the case report form at each study site. A history of other cancers reported in a total of five or more patients included lymphoma (n = 14), breast (n = 13), gynaecological (n = 10), cervical (n = 8), colorectal (n = 8), prostate (n = 7), bladder (n = 6), kidney (n = 6) and sarcoma (n = 6). [d]Includes drug-induced hepatic disease related to psoriasis or other treatment.

obstructive pulmonary disease (COPD; 2·0%)] at enrolment. While other reports have suggested an association between COPD and psoriasis, the proportion of patients with a history of COPD observed in PSOLAR is lower than that reported for patients with psoriasis elsewhere.[34,35] Generally, COPD occurs more commonly than asthma, and studies evaluating an association between psoriasis and asthma have been inconclusive.[36] However, in PSOLAR, the higher prevalence of asthma (8·0%) compared with COPD is likely attributable to a reporting bias due to the overlap of clinical symptoms between COPD and asthma. The approximately 6·0% of patients reporting a history of sleep apnoea is likely related to the high prevalence of obesity.

As reported elsewhere, there may be an increase in the background risk of cancer in patients with psoriasis.[36,37] Increased rates of lymphoma have been reported in multiple cohort studies of patients with psoriasis,[4] and the risk of lymphoma with biological agents, in general, remains a topic of debate.[38] In PSOLAR, about 4% of patients had a history of some type of cancer other than melanoma and nonmelanoma

**Table 9** Psychiatric disease history and lifestyle risk factors by age quartiles (enrolled patients)

| Age (years) | 18–35 | 36–50 | 51–65 | > 65 |
|---|---|---|---|---|
| Psychiatric disease[a] | 411 (17·7) | 830 (20·4) | 966 (23·3) | 252 (18·6) |
| Depression | 269 (11·6) | 588 (14·5) | 716 (17·3) | 177 (13·1) |
| Anxiety | 252 (10·9) | 450 (11·1) | 487 (11·8) | 129 (9·5) |
| Bipolar disorder | 40 (1·7) | 69 (1·7) | 62 (1·5) | 10 (0·7) |
| Suicidal ideation | 20 (0·9) | 44 (1·1) | 41 (1·0) | 9 (0·7) |
| Social activity | | | | |
| Alcohol use | 2316 | 4068 | 4140 | 1348 |
| Current use of alcohol | 1585 (68·4) | 2757 (67·8) | 2608 (63·0) | 726 (53·9) |
| Have used alcohol and stopped | 237 (10·2) | 543 (13·3) | 669 (16·2) | 248 (18·4) |
| Smoking | 2320 | 4069 | 4142 | 1348 |
| Current smoker | 700 (30·2) | 1113 (27·4) | 862 (20·8) | 156 (11·6) |
| Have smoked and stopped | 478 (20·6) | 1106 (27·2) | 1651 (39·9) | 677 (50·2) |

Values are n (%) of patients. [a]Includes psychiatric conditions occurring in at least 0·5% of patients.

skin cancer (NMSC), while approximately one-third of patients had a family history of such cancers. A history of NMSC was reported in 5·5% of patients: 3·8% with BCC and 2·4% with SCC, with some patients having had both BCC and SCC. Although the ratio of BCC to SCC in the general population is reported to be 4 : 1[39], exposure to psoralen with ultraviolet A (17·0%), as well as immunosuppressive agents, in some patients in PSOLAR could have increased the risk for SCC,[40] and a potential reporting bias that could lead to underreporting of BCC among dermatologists may have shifted the expected balance between BCC and SCC.

A history of hepatic disorders was noted in < 5% of patients enrolled in PSOLAR, although other reports have suggested a notably higher prevalence of liver diseases, particularly nonalcoholic fatty liver disease, among patients with psoriasis.[41,42] The lower prevalence observed in the PSOLAR population may reflect the design of the case report form, which allows for proactive inquiry about only certain hepatic conditions. Prior liver biopsies were reported in about 2·0% of patients. Although the reason for biopsy was not captured, the majority were presumably performed to monitor for liver toxicity in patients receiving methotrexate, as per published guidelines.[43]

An increased risk of psoriasis has been reported in patients with Crohn disease and ulcerative colitis; common inflammatory, and even genetic, pathways have been implicated as possible causes.[44,45] Among patients enrolled in PSOLAR, the prevalence is 0·5% for Crohn disease and 0·8% for ulcerative colitis. Similar findings were reported in a large, case–control study, in which 0·5% of patients with psoriasis reported a history of ulcerative colitis at baseline compared with 0·3% of age- and sex-matched controls, while the prevalence of Crohn disease among patients with psoriasis was 0·5% vs. 0·2% for controls.[46]

Increased risks of depression, anxiety and suicidality have been linked to psoriasis.[11,12] In PSOLAR, 14·7% and 11·1% of patients reported a history of depression and anxiety, respectively, which is similar to or lower than the proportions reported in phase III studies of biological agents.[47–50] However, the proportion of patients with a history of suicidality in PSOLAR was lower (1·0%) than that reported in large surveys conducted by the National Psoriasis Foundation, which were conducted before a number of biological agents were approved for the treatment of psoriasis.[51] Indeed, recent studies have shown that symptoms of anxiety and depression can be reduced, although not eliminated, in patients with psoriasis treated with adalimumab, etanercept, infliximab and ustekinumab.[46–49] Additionally, data from PSOLAR support the literature, which has shown that certain lifestyle behaviours, such as alcohol use and cigarette smoking, are exhibited more commonly in patients with psoriasis compared with patients without psoriasis and that these behaviours may exacerbate the disease.[4,12,52]

A subanalysis of medical history by age quartile showed that the proportion of patients with certain comorbidities varied with age. As expected, the prevalence of PsA was lowest among younger patients (aged 18–35 years), given that psoriasis typically develops 10–12 years before PsA.[2] PSOLAR provides a long-term opportunity to monitor the incidence of PsA, as well as the potential impact of therapies on the development of PsA, in a large psoriasis population prospectively over time. Also, as expected, the proportions of patients with a history of cardiovascular, endocrine, pulmonary and hepatic diseases, as well as skin cancers and other types of cancer, generally increased with age. The proportions of patients with psychiatric illness (e.g. anxiety and depression) were generally comparable across age quartiles, and the proportions using alcohol or smoking cigarettes decreased with age. These observations indicate that, as observed in the general population, age correlates with the occurrence of various comorbid conditions in patients with psoriasis. Whether the treatment of psoriasis with systemic therapies, such as biological agents, may affect associated comorbidities across age groups remains to be seen.

In general, observational data are subject to multiple forms of bias, including treatment selection and outcome reporting bias. In particular, participation bias on the part of the prescriber and the patient may exist, as patients who

choose not to participate are not represented in the registry, and may be reflected in the baseline demographic and comorbidity data presented in this report. Additionally, exposure at baseline may reflect prior treatment selection bias. Enrolment in PSOLAR was driven primarily by North American sites, with > 90·0% of patients from the U.S.A. and Canada. Nonetheless, the PSOLAR population provides valuable insight into the features of a broad group of patients receiving various treatments for psoriasis in the setting of actual clinical care.

In summary, PSOLAR is a large (approximately 12 000 patients), prospective, disease-based registry that represents a valuable resource for collecting information on patient features, disease characteristics, previous treatments and comorbid conditions to further define a profile of patients with psoriasis treated in real-world settings. Additionally, the baseline demographic features and disease characteristics reported at peak historic levels in the registry are generally similar to those reported in clinical trials of biological agents, although some differences are noted. The data presented here (collected from 2007 to 2012) further substantiate that psoriasis is associated with multiple comorbidities[53] and indicate that patient age should be considered when evaluating patients with psoriasis for the presence of certain coexisting conditions. PSOLAR is an important part of the safety surveillance programme for ustekinumab and infliximab that is also designed to collect safety data for other biological agents and systemic therapies. Consequently, data collected in the PSOLAR registry will be used to monitor and report long-term safety across a spectrum of psoriasis therapies.

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## Appendix 1

## Conflicts of interest

A.B.K. is an investigator and consultant for Amgen, AbbVie, Janssen, Pfizer, Merck and Celgene. She is a consultant to VBL Therapeutics and also has fellowship funding from Janssen. C.L. has served as a consultant, investigator and/or speaker for AbbVie, Amgen, Celgene, Centocor, Eli Lilly, Galderma, Genentech, Genzyme, GlaxoSmithKline, Incyte, Janssen, Maruho, Novartis, Novo Nordisk, Pfizer, Schering Plough, Sirtris, Stiefel, Vascular Biogenics and/or Wyeth. M.S. has received research support or has served as a speaker or advisory board member for Pfizer, AbbVie, Novartis, Janssen-Cilag, MSD and Leo Pharma. W.G. has received speaker honoraria and consulting fees, conducted clinical trials and/or served on Advisory Boards for AbbVie, Amgen, Astellas, Celgene, Janssen, Merck, Novartis and Pfizer. A.M. has received grants and/or honoraria as an advisory board member, consultant, investigator and/or speaker for AbbVie, Allergan, Amgen, ApoPharma, Boehringer, Celgene, Convoy Therapeutics, Inc, Eli Lilly, Genentech, Janssen Biotech, Inc,, LEO Pharma, Novartis, Pfizer, Symbio/Maruho, Syntrix Biosystems, Wyeth, and/or XenoPort. M.C., S.F., K.G. and S.C. are employees of Janssen Scientific Affairs LLC, and W.L. is an employee of Janssen Research & Development, LLC.

## Appendix 2

## Psoriasis Longitudinal Assessment and Registry Steering Committee members

The Psoriasis Longitudinal Assessment and Registry Steering Committee members include M. Augustin, Institute for Health Services Research in Dermatology, University Medical Center Hamburg–Eppendorf, Hamburg, Germany; M. Chevrier, Janssen Scientific Affairs, Horsham, PA, U.S.A.; D. Fiorentino, Stanford University School of Medicine, Stanford, CA, U.S.A.;

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