Secukinumab is effective in treatment of moderate-to-severe plaque psoriasis: real-life effectiveness and safety from the PROSPECT study

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Abstract

Background Secukinumab, a fully human anti-interleukin-17A monoclonal antibody, has demonstrated efficacy and safety in patients with moderate-to-severe psoriasis. Trial protocols specify transition periods and prohibit concomitant psoriasis medication. Data are therefore needed on secukinumab effectiveness and safety in routine clinical practice.

Objectives The PROSPECT study assesses prior and concomitant psoriasis treatments and transition periods in subjects receiving secukinumab. Here, we report interim effectiveness and safety data for secukinumab in the context of prior and concomitant treatments.

Methods PROSPECT is an ongoing 24-week, single-cohort, non-interventional study. Subjects with moderate-to-severe psoriasis with a decision to receive secukinumab 300 mg were included.

Results Of 1988 subjects, 1238/1988 (62.4%) were male, and mean age was 48.1 ± 13.7 years. Mean baseline Psoriasis Area and Severity Index (PASI) score was 17.7 ± 12.5. 90.9% of subjects had prior systemic treatment. Concomitant treatment was recorded in 44.3% of subjects. Median duration of transition period was 14.0, 30.0 and 44.5 days from prior topical, conventional systemic and biologic treatments. At Week 24, PASI75/90/100 was reached by 86.1%, 68.5% and 39.7% of subjects who started secukinumab treatment at baseline. No unexpected safety signals were observed.

Conclusion PROSPECT provides a large prospective real-world analysis of secukinumab treatment and includes prior and concomitant use of psoriasis treatments in subjects receiving secukinumab in a real-world setting. Secukinumab effectiveness and safety were comparable to that seen in the phase 2/3 secukinumab clinical trial programme.

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Conflicts of interest

D. Thaći has served as an investigator and/or consultant/advisor for Abbvie, Almiral, Amgen, Arena, Biogen Idec, Boehringer Ingelheim, Celgene, DS-Biopharma, Eli Lilly, Galapagos, GSK, Leo Pharma, Janssen-Cilag, Mundipharma, Merck Sharp Dohme, Novartis, Pfizer, Roche, Samsung, Sandoz, Target and UCB. A. Körber has served as an investigator and/or consultant/advisor for Abbvie, Biogen Idec, Boehringer Ingelheim, Celgene, Eli Lilly, Leo Pharma, Janssen-Cilag, MSD, Novartis, Pfizer, Grünenthal and Almiral. R. von Kiedrowski has served as an investigator and/or consultant/advisor and/or speaker for Abbvie, Almirall, Amgen, Biogen Idec, Boehringer Ingelheim, Celgene, Eli Lilly, GSK, Leo, Janssen-Cilag, MSD, Novartis, Pfizer, UCB and VBL Pharma. G. Kraehn-Sentlfieben has served as an investigator and/or consultant for Abbvie, Almiral, Leo, Janssen-Cilag and Novartis. U. Amon has served as consultant and/or investigator and/or lecture honorarium for Abbvie, Alma, Astellas, Basilea, Celgene, Eli Lilly, Galdema, GME, Hans Karrer, Janssen-Cilag, Medilux, Novartis, Pierre Fabre and TEVA. M. Augustin has served as consultant for or has been a paid speaker for clinical trials sponsored by companies that manufacture drugs used for the treatment of psoriasis, including Abbvie, Almirall, Amgen,
Introduction
Psoriasis is a chronic immune-mediated inflammatory disease, and long-term management is critical to maintain good control of signs and symptoms and to preserve quality of life. In recent years, the use of biologic therapies in psoriasis has increased as a result of advances in understanding of the pathophysiology of the disease. In clinical trials, subjects are usually required to have long transition periods to wash out all prior treatments, and concomitant treatments are prohibited. However, treatment guidelines usually recommend concomitant treatments for selected subjects.1 For example, topical treatments are often combined with conventional systemic treatments or biologics, and conventional systemic treatments are sometimes combined with biologics.2 Minimal washout periods were recommended by an international consensus for therapy changes due to insufficient disease control.3 There is therefore a need for data on the effect of shorter transition periods, and the use of concomitant treatments, on the effectiveness and safety of biologics in routine clinical practice.

Secukinumab is a fully human monoclonal antibody that selectively neutralizes IL-17A, a cornerstone cytokine involved in the development of psoriasis.4 In clinical trials, secukinumab has shown long-lasting efficacy and safety in the complete spectrum of psoriasis manifestations, including nails, scalp, palms and soles, and psoriatic arthritis.5-8 PROSPECT (Observational, Descriptive Study of Prior and Concomitant Psoriasis Treatments in subjects Receiving Secukinumab in the Routine Treatment of Moderate-to-Severe Plaque-type Psoriasis; EUPAS10715) is an observational study conducted in Germany, designed to assess prior and concomitant use of psoriasis treatments in subjects receiving secukinumab, and the duration of transition periods from prior treatments to secukinumab treatment. The German annual national conference on psoriasis of 2016 encouraged healthcare researchers to provide early real-world data on biologic treatments for psoriasis, in addition to contributing to the German registry Psoriasis Best for improving quality of care on a large scale.9,10

In this interim analysis, we report the exploratory effectiveness and safety endpoints for the first 1988 subjects enrolled in PROSPECT, along with duration of transition periods to secukinumab from prior treatments, prior treatments and reasons for discontinuation, and use of concomitant treatments.

Methods
Study design and endpoints
PROSPECT study design and an interim analysis of the baseline characteristics of the first 800 subjects recruited were previously published.11

PROSPECT is an ongoing single-cohort, non-interventional study (NIS) conducted in 335 sites across Germany with a study duration of 24 weeks, recruiting subjects for whom the decision of treatment with secukinumab for plaque psoriasis has been made before inclusion. Planned recruitment is 2504 subjects. The study collects data from subjects prior to (retrospective period) and during (prospective period) routine secukinumab treatment (Fig. 1).

The primary endpoint of the study is the assessment of the transition period from prior treatments to secukinumab treatment. The transition period from prior treatments to secukinumab was assessed retrospectively, and the application of concomitant treatments was assessed prospectively. PASI was assessed for all subjects as part of routine clinical practice. Investigator’s Global Assessment (IGA), DLQI (Dermatology Life Quality Index) and other measures of clinical effectiveness, if used by the treating physician during routine clinical practice, as well as adverse events, are being documented prospectively.
All subjects provided written informed consent, and the study protocol was approved by the central ethics committee of the University of Lübeck (reference number 15-207).

**Subject selection**
Subjects were aged >18 years old with moderate-to-severe plaque psoriasis, able to provide written informed consent, were candidates for systemic therapy who had routine treatment with secukinumab 300 mg per label planned prior to inclusion and were scheduled to receive at least one dose of secukinumab during the study. Subjects were excluded from the study if they had received marketed secukinumab prior to the day of informed consent; however, prior secukinumab treatment in a clinical trial setting was allowed in a subset of subjects and documented accordingly. Subjects could not be enrolled in any other NIS (including Novartis NIS), but registry enrolment was permitted. Three non-mutually exclusive subgroups were predefined:

1. Subjects with higher disease severity or impact, potentially affecting transition periods and concomitant treatments, defined by one or more of the following characteristics at baseline: severe psoriasis (PASI > 20), affected scalp, face, palms, soles, nails, genitals, joints, diagnosis of psoriatic arthritis (PsA) or signs and symptoms of PsA including but not limited to joint pain, swelling, redness, dactylitis or enthesitis.
2. Subjects who had not participated in a clinical trial with secukinumab prior to inclusion in this NIS and who started secukinumab treatment at baseline
3. Subjects without prior systemic treatments (including Fumaric acid esters, methotrexate, phototherapy, cyclosporine, acitretin, apremilast and all other systemic anti-inflammatory treatments, for example systemic steroids).

**Data collection**
Please see previously published methodology for full details. Data were collected by treating physicians and site staff in electronic case report forms (eCRF); entered data were checked automatically for completeness and accuracy. Data monitoring was conducted via regular site visits and remote monitoring to verify the completeness of patient records, the accuracy of entries on the eCRFs compared with the original patient chart entries and the compliance with the protocol.

Last prior psoriasis treatment was defined as the last prior psoriasis treatment of a subject that ended within 1 year of baseline data collection; if two or more prior psoriasis treatments were given in parallel within 6 months of baseline, each was regarded as the last prior psoriasis treatment.

**Statistical analysis**
Study size was selected to yield adequate precision in assessing transition times to secukinumab while remaining feasible. Targeting a precision [95% CI] of ±7 days (based on methotrexate to secukinumab transition), an overall sample size of 2504 patients was determined. All data were analysed descriptively. Exploratory subgroup and correlation analyses were applied to identify factors that may have influenced the primary and secondary endpoints. A number of non-missing data, mean, SD, minimum, median and maximum were used as sample statistics. All parameters were either nominally or ordinally scaled and were tabulated by absolute and relative frequencies. Percentages were calculated as observed if not otherwise specified. The duration of transition periods from prior treatments to secukinumab (primary endpoint) was analysed by sample statistics [including interquartile range (IQR)] and 95% CIs (for prior treatment categories and groups). The duration of transition period (in days) from a prior psoriasis treatment to secukinumab was defined as the difference between the date of secukinumab first dose and the date of the last dose of the respective prior psoriasis treatment (only calculated for a subject’s last prior psoriasis treatment, excluding secukinumab). PASI and all other assessment of effectiveness and quality of life were analysed descriptively. PASI and DLQI data are presented as observed; no imputation method was used for missing values.

**Subject disposition and baseline characteristics**
During the period specified by this interim analysis (27-Aug-2015 until 27-Mar-2017), 1988 subjects received at least one dose of secukinumab, and 1323 completed the study (to Week 24; Figure S1). There were 155 (7.7%) discontinuations overall, with the most common reasons for discontinuation being adverse events (2.4%), insufficient response (2.1%) and loss to follow-up (1.5%) (Figure S1). This interim analysis includes a total cumulative secukinumab exposure of 746.3 patient years.

Baseline characteristics of the study population were comparable to those of other secukinumab clinical trial subjects. The mean baseline PASI of 17.7 was slightly lower than that typical of clinical trial populations, which is around 20-22. However, unlike clinical trials, the PROSPECT study recruited subjects with PASI < 10, many of whom had short transition times from previous treatments, and some of whom had received secukinumab prior to baseline in clinical trials (Table 1).

Of 296 (14.9%) subjects had previously taken part in a secukinumab clinical trial; 1692 subjects (85.1%) had no previous treatment with secukinumab. Within this group that started secukinumab treatment at baseline, mean baseline PASI was 20.1, mean baseline DLQI was 15.0, and mean time from diagnosis was 17.7 years (Table 1).

Overall, 1808 (90.9%) of subjects had received prior systemic therapy. Subjects who had not received prior systemic therapy had a lower mean time since psoriasis diagnosis than the cohort overall (13.4 ± 14.1 vs. 18.0 ± 13.3 years). In subjects who started secukinumab treatment at baseline, 180 (10.6%) were receiving secukinumab in PROSPECT as a first-line systemic treatment for psoriasis.
Higher disease severity
Out of 1988 subjects, 160 (93.6%) had one or more signs of high disease severity, including severe psoriasis with PASI > 20 (69.0%), affected scalp (64.1%), affected nails (40.3%), affected face (28.6%) or a diagnosis of PsA (18.8%) (Table S1). Overall, 40.0% of subjects had four or more signs of high disease severity (Figure S2).

Prior psoriasis treatments
In patients who started secukinumab treatment at baseline (n = 1692), 10.6% were systemic treatment naïve, 60.7% had received conventional systemic treatments and/or phototherapy, and 28.7% had been previously treated with biologics (Figure S3a). The majority of these subjects (69.5%) had received only one prior biologic treatment, but a small number (3.4%) had over three prior biologic treatments (Figure S3d).

Reasons for previous treatment discontinuation
In subjects who started secukinumab treatment at baseline (n = 1692), the most common reason for previous treatment discontinuation within the 12 months prior to baseline was insufficient response, for topical, conventional systemic or biologic treatments (Table S2). Overall, 63.2%, 62.3% and 61.6% of subjects discontinued topical, conventional systemic and biologic treatments because of insufficient response. Loss of efficacy and adverse events was the next most frequent reasons for discontinuation of previous treatment (Table S2).

Duration of transitional period
The median durations of the transitional periods from other topical, conventional and biologic treatments were 14.0, 30.0 and 44.5 days, respectively (Table 3). Transitional periods from topical, conventional systemic and biologic agents are shown in Table S3a–c.
For subjects with prior biologic treatments, transition periods to secukinumab ranged from a median of 28 days for etanercept to 86 days for ustekinumab (Table S3c). Transition periods from topical treatments ranged from a median of 12.0 days for topical steroids to 42.5 days for other topical treatments (Table S3a). For conventional systemic agents and phototherapy, the median transition time before starting secukinumab ranged from 15 to 19 days for acitretin to 35 days for phototherapy (Table S3c).

Concomitant psoriasis treatment

Overall, 876/1988 (44.1%) patients used concomitant medication in addition to secukinumab. Most concomitant medication was started before baseline, and secukinumab treatment was commenced without a washout period. Out of the 829 subjects with concomitant topical treatments, 601 (72.5%) had started topical treatments before baseline, and 277 (33.4%) began using topical treatments concomitantly with secukinumab after baseline. Conventional systemic agents and phototherapy were used concomitantly by 110 subjects, of whom 77 (70.0%) started treatment before baseline and 36 (32.7%) started after baseline. The most commonly used concomitant topical and conventional systemic treatments were topical steroids and phototherapy (Table S4a,b).

Figure 2  Psoriasis treatment history in subjects who started secukinumab treatment at baseline (n = 1692). (a) Psoriasis treatment history. (b) Last prior psoriasis treatments 12 months before baseline. (c) Last prior psoriasis treatments and concomitant treatments 12 months before baseline. Topical treatments are included from the entire last 12 months prior to baseline.
Clinical response

In subjects who started secukinumab treatment and had a PASI > 0 at baseline, PASI responses at Week 24 (n = 905) were comparable to observed Phase 3 results: PASI75 was attained by 86.1% of subjects at Week 24, PASI90 by 68.5% and PASI100 by 39.7% (Fig. 3a as observed). In patients with PASI > 10 at baseline, PASI75, PASI90 and PASI100 response rates were 88.1%, 71.8% and 39.7%. At Week 24, 56.5% of subjects had an absolute PASI score < 1. PASI < 3 was achieved by 80.9% of subjects, and PASI < 5 by 88.4%.

A high level of response to secukinumab was observed for 83 subjects naïve to systemic therapies, with 92.8%, 84.3% and 66.3% reaching PASI75, 90 and 100, respectively. In subjects previously treated with biologics, PASI response rates were slightly lower than in biologic-naïve subjects, but remained high overall with 78.1%, 54.8% and 29.0% reaching PASI75, 90 and 100, respectively (Fig. 3b). Compared to the overall population, these patients had a higher mean age (49.8 ± 13.3), a higher weight (90.5 ± 21.0 kg), longer disease history and a higher prevalence of PsA symptoms (23.1%). Mean baseline PASI was 18.6 ± 12.2.

DLQI response

A rapid rise in DLQI 0/1 responders, indicating no/minimal impact of psoriasis on quality of life, was observed over the 24 weeks of the analysis (Fig. 4). At Week 24, 59.3% (188/317) of subjects who started secukinumab treatment at baseline reported a DLQI of 0/1, in line with previous trial results with secukinumab.14

Safety

Safety data are summarized in Table 4. Overall, 912/1988 (45.9%) subjects experienced an adverse event while being treated with secukinumab. At the point of this interim analysis, subjects had a mean exposure to secukinumab of 137.0 ± 57.9 days.

There were three deaths during the period covered by this interim analysis. Causes of death were cardiac failure from...
worsening of a pre-existing condition (1), sudden brain death (1, deemed related to patient age and cardiovascular status by investigator) and suicide (1). These three deaths were assessed by the treating physician as not being linked to secukinumab, as there were pre-existing conditions or risk factors for these conditions.

Serious adverse events occurred in 81 (4.1%) subjects, of which 22 (1.1%) were suspected to be related to secukinumab (Table 4). Secukinumab treatment was discontinued (permanently or temporarily, not differentiated in reporting) because of an adverse event in 137 (6.9%) subjects [suspected related to secukinumab treatment in 87 (4.4%) subjects]. The most frequent reasons for discontinuation were drug ineffective [48 subjects (2.4%)], psoriasis [46 subjects (2.3%)] and viral upper respiratory tract infection [10 subjects (0.5%)]. Rates of MACE, malignancy and IBD were consistently low (Table 4).

The most common adverse events were nasopharyngitis (n = 172, 8.7%), pruritus (n = 58, 2.9%) and headache (n = 48, 2.4%) (Table 4). The safety profile of secukinumab was similar to that reported in previous clinical trials,5,12,15 and no new or unexpected safety signals were observed.

**Discussion**

PROSPECT is the first study in Germany to investigate prior and concomitant use of psoriasis treatments in subjects receiving secukinumab as part of routine clinical practice. In contrast to controlled clinical studies, applying strict inclusion and exclusion criteria, PROSPECT collects real-world data from psoriasis subjects treated in clinics and private medical practice.

PROSPECT adds to the body of data collected in psoriasis registries on the safety of biologic treatments in routine clinical care. PROSPECT specifically included and documented in detail subjects receiving concomitant treatment.

The baseline characteristics of the PROSPECT psoriasis patients show that secukinumab interventional trial subjects have generally reflected the population encountered in the clinic, with some important distinctions. The majority of the PROSPECT population had not taken part in a previous clinical trial with secukinumab. However, nearly all had received prior conventional systemic treatments. Although over half of subjects had 3 or more signs of higher disease severity, the mean baseline PASI score was slightly lower than in other studies with secukinumab, both overall and in subjects who started secukinumab treatment at baseline. Some patients had prior treatment with secukinumab in a clinical trial before baseline, making it difficult to assess the effectiveness of secukinumab in terms of relative PASI improvement vs. baseline. Therefore, the effectiveness analysis was performed on subjects who started secukinumab at baseline. However, even in this population, the baseline PASI score cannot be compared with baseline PASI values in clinical trials because some patients were treated with concomitant psoriasis treatments at baseline or had only brief washout periods of prior treatments. These factors contributed to low baseline PASI values, some below 10, in the context of a diagnosis of moderate-to-severe psoriasis as per label for secukinumab treatment.
Table 4 Rates of adverse events and serious adverse events in PROSPECT

|                                | All subjects N = 1988 |
|--------------------------------|------------------------|
| Mean exposure to study treatment, days (mean ± SD) | 137.0 ± 57.9 |
| Entire study period (weeks 0-24) |                        |
| Any AE, n (%) [EAIR per 100 patient years] | 912 (45.9) [174] |
| Death, n | 3 |
| Non-fatal SAE, n (%) [EAIR per 100 patient years] | 81 (4.1) [10.6] |
| SAEs by system organ class, n (%) |                        |
| Infections and infestations | 22 (1.1) |
| Nervous system disorders | 8 (0.4) |
| Gastrointestinal disorders | 9 (0.5) |
| Cardiac disorders | 7 (0.4) |
| Vascular disorders | 6 (0.3) |
| Neoplasms | 6 (0.3) |
| Other | 23 (1.2) |
| Serious adverse events with suspected relationship to secukinumab | 22 (1.1) |

| AEs of special interest† n (%) [EAIR per 100 patient years] |                        |
| MACE | 5 (0.3) [0.7] |
| IBD | 4 (0.2) [0.5] |
| Candida infection | 42 (2.1) [5.7] |
| Malignancy | 10 (0.5) [1.3] |
| Hepatotoxicity | 2 (0.1) [0.3] |
| Injection site reactions | 11 (0.6) [1.5] |

| Discontinuation due to AE, n (%) | 137 (6.9) |
| Infection/infestation, n (%) [EAIR per 100 patient years] | 448 (22.5) [69.6] |

| Treatment emergent adverse events occurring in ≥1% subjects by preferred term, n (%) [EAIR per 100 patient years] |                        |
| Nasopharyngitis | 172 (8.7) [24.4] |
| Pruritus | 58 (2.9) [7.8] |
| Headache | 48 (2.4) [6.6] |
| Drug ineffective | 48 (2.4) [6.5] |
| Fatigue | 45 (2.3) [6.1] |
| Psoriasis | 46 (2.3) [6.2] |
| Diarrhoea | 43 (2.2) [5.9] |
| Arthralgia | 34 (1.7) [4.6] |
| Cough | 34 (1.7) [4.6] |
| Eczema | 31 (1.6) [4.2] |
| Oropharyngeal pain | 25 (1.3) [3.4] |
| Oral candidiasis | 25 (1.3) [3.4] |
| Nausea | 22 (1.1) [3.0] |
| Sinusitis | 20 (1.0) [2.7] |
| Pyrexia | 20 (1.0) [2.7] |
| Tonsillitis | 19 (1.0) [2.6] |

As assessed by investigator in routine treatment, AE, adverse event; EAIR, exposure adjusted incidence rate; IBD, inflammatory bowel disease; ISR, injection site reaction; MACE, major adverse cardiovascular event; SAE, serious adverse event.

†High-Level Terms: ‘Candida infection’; INMO1/inflammatory bowel disease’ (includes the three cases of Cronh’s Disease reported above); gNM1/MACE (MI, Stroke, Cardiovascular death’; hSMO/Malignant or unspecified tumours’; iSMO/Hypersensitivity’; jSMO/Drug-related hepatic disorder – severe events only’.

Despite this, a high level of effectiveness in terms of relative PASI improvement at week 24 was observed that was comparable to that observed in clinical trials.

The majority of PROSPECT subjects had received a wide range of prior recommended treatments for psoriasis, historically and in the year prior to starting secukinumab. The most common treatments in the year prior to starting secukinumab were conventional systemic agents, most frequently methotrexate or FAEs, or phototherapy. Transition periods between prior treatments and secukinumab in clinical practice were variable in length, but median times were longer that might be expected. There was some variation between transition periods associated with different types of prior treatment, with topical treatments having a much shorter median transition period overall than conventional systemic or biologic therapies. While transition times were frequently shorter in clinical practice than washout periods specified by clinical trials, these transition times were still longer than recommended by the consensus guidelines. The most common reasons for discontinuation of previous treatments were insufficient response and loss of efficacy.

Just under one half of subjects were receiving concomitant therapy at baseline. The most frequently used concomitant agents were topical steroids and vitamin D3 analogues. Methotrexate was used most frequently as concomitant systemic therapy, with phototherapy also frequently used.

The effectiveness of secukinumab in subjects who started secukinumab at baseline was comparable to that observed in Phase 3 trials. High levels of effectiveness were observed also in subjects who had received previous biologic therapies, although the response rates were numerically lower, as might be expected in a difficult to treat population. In addition, lower baseline PASI in patients with prior biologic treatment could also reduce the relative decrease in PASI observed over the course of the study.

Rapid and pronounced improvements in quality of life were seen with secukinumab treatment in PROSPECT. However, DLQI was documented in fewer than half of all subjects, demonstrating that despite guideline recommendations and being a standard disease assessment tool DLQI is still not a widely used in routine clinical practice in Germany. The safety profile of secukinumab in the clinical setting of PROSPECT and in conjunction with prior and concomitant treatment was similar to that observed in clinical trials. There were no new or unexpected safety signals.

Limitations of this study include the absence of a control group and the lack of consistent data availability. The duration of the study of 24 weeks is short for a real-world, long-term evaluation of effectiveness and safety. Due to the non-interventional nature of this study and the setting in routine clinical practice, some baseline characteristics were not fully documented; for example, there was high level of documentation for PASI but not for IGA or DLQI. Additionally, the patient
numbers at each visit varied since documentation of visits was not mandatory. Loss to follow-up, however, remained low. These interim data from PROSPECT confirm the effectiveness and safety of secukinumab in the routine clinical setting, in a large cohort of psoriasis patients with high disease severity. The results suggest no to minimal impact on safety and effectiveness of the shorter transition times and concomitant therapy common in the clinical setting, but absent from clinical trials. PROSPECT highlights points of divergence from expert recommendations, such as the application of the DLQI, and could therefore both guide dermatologists and improve patient care. The results of this study will help to inform clinical practice in the transition of patients with moderate-to-severe psoriasis to secukinumab treatment, with or without concomitant therapy.

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Data availability
Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

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Supporting information
Additional Supporting Information may be found in the online version of this article:

Table S1. Signs of higher disease severity (all subjects).
Table S2. Reasons for discontinuation of prior (a) conventional systemic treatment in subjects with no previous clinical trial experience (n = 1692); (b) biologic treatment.
Table S3. Duration of transitional period – (a) topical treatments; (b) conventional systemic treatments; (c) biologic treatments.
Table S4. Concomitant (a) topical treatments (all subjects); (b) conventional systemic treatments (all subjects).

Figure S1. PROSPECT Patient disposition at time of interim analysis.
Figure S2. Number of signs of higher disease severity (a) or psoriatic arthritis (b) (all subjects).
Figure S3. (a–b) Prior conventional systemic treatments in subjects with conventional systemic therapy/phototherapy as last prior psoriasis therapy (c–d) Prior biologic treatments in subjects with biologic treatment as last prior psoriasis therapy.