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PsoBest: Current status, profiles, impact for health care of the German National Registry on Psoriasis

CVderm
Competenzzentrum Versorgungsforschung
in der Dermatologie

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INTRODUCTION & OBJECTIVES

Patient registries are systematic, prospective, protocol-driven collections of patient data. The non-interventional German psoriasis registry PsoBest aims to gain long-term evidence on safety and effectiveness of systemic antipsoriatic drugs. Since 2008 this national project reaches a growing number of dermatologists and patients.

MATERIALS & METHODS

The PsoBest registry observes adult patients with moderate to severe psoriasis with or without psoriatic arthritis. CVderm was commissioned with the operation of the registry by the German Society of Dermatology and Professional Association of German Dermatologists. PsoBest is financially supported by almost all pharmaceutical companies having a licensed systemic antipsoriatic drug on the German market partly fulfilling pharmacovigilance requirements with PsoBest data.

Patients are registered at naïve systemic treatment start and are observed for 15 years in routine care. The registry data is collected using standardized case report forms (CRF) in dermatological practices and outpatient clinics. In harmonization with other European psoriasis registries, PsoBest targets on clinical parameters, e.g. the Psoriasis Area and Severity Index (PASI) and the Body Surface Area (BSA), as well as on patient reported outcomes like the Dermatology Life Quality Index (DLQI) and the Patient Benefit Index (PBI) and on treatment data. This also includes concomitant systemic and topical treatments. Drug safety data is collected on CRFs for adverse events and on a day to day form for serious adverse events.

Characteristics of the registry and inclusion rates are reported weekly on the website, reports on pharmacovigilance are prepared semiannually. Data analyses and publications are approved by a scientific advisory board and can be suggested also by participating dermatologists to meet research needs directly from routine care.

RESULTS

At present, 1,044 sites are registered in PsoBest – 79 outpatient clinics and 965 dermatology practices (see figure 1a). 601 of the registered centers (57.6 %) report patients and visits on a regular basis. A total of 14,177 patients were enrolled in the registry by September 2020. The majority was included by dermatology practices (83 %, see figure 1b).

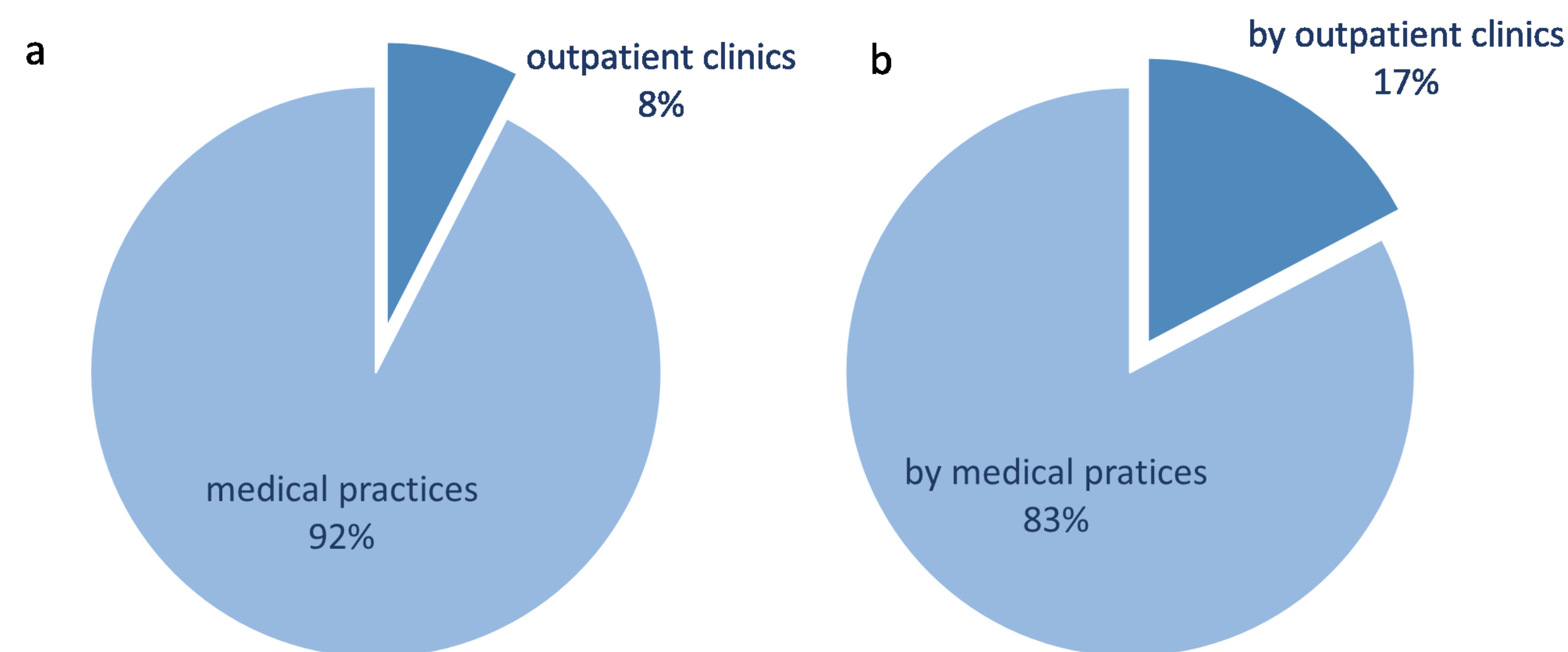


Figure 1. (a) Percentage of registered sites by type and (b) percentage of patients included by type of site. The majority of the patients is provided by registered dermatologists. (data cut: 01.10.2020)

RESULTS II

PsoBest patients were predominantly male (58.2 %) with a mean age of 47.7 years at baseline. The mean BMI was 28.6 kg/m², mean duration of psoriasis was 17.4 years. 28.8 % of the patients showed an involvement of joints and 47.5 % of fingernails at baseline. Mean BSA was 24.4 %, the mean PASI 15.0 and the mean DLQI 11.7. These numbers point to the high burden of the disease for these patients.

Patient characteristics by treatment group at baseline are shown in table 1.

Table 1. Patient baseline characteristics by treatment group (data cut: 31.12.2019)*

| | Non-biologics (n = 6,251) | | | Biologics (n = 3,889) | | | Biosimilars (n = 87) | | |
|---|------------------------------|------------|--------|--------------------------|------------|--------|-------------------------|------------|--------|
| | n | mean/ % | median | n | mean/ % | median | n | mean/ % | median |
| Age (years) | 6,251 | 47.6 | 48.0 | 3,888 | 47.7 | 48.0 | 87 | 47.8 | 49.0 |
| female gender (%) | 2,672 | 42.7 | NA | 1,502 | 38.6 | NA | 38 | 43.7 | NA |
| Body mass index (kg/m ²) | 6,188 | 28.4 | 27.5 | 3,837 | 29.0 | 28.1 | 87 | 31.5 | 31.2 |
| Waist-to-hip ratio | 5,821 | 0.9 | 0.9 | 3,549 | 0.9 | 0.9 | 81 | 0.9 | 0.9 |
| Duration of illness (full years) | 5,688 | 16.2 | 13.0 | 3,552 | 20.1 | 18.0 | 84 | 18.7 | 17.0 |
| Body surface area (% impairment) | 6,131 | 23.5 | 16.0 | 3,818 | 26.0 | 20.0 | 86 | 29.7 | 21.5 |
| Psoriasis Area and Severity Index (PASI); range 0 - 72 (highest severity) | 6,108 | 14.4 | 12.5 | 3,796 | 16.1 | 14.1 | 87 | 18.1 | 15.8 |
| Severity of Psoriasis; patient global assessment; VAS 0-10 (highest severity) | 5,900 | 6.5 | 7.0 | 3,660 | 6.7 | 7.0 | 86 | 6.6 | 7.0 |
| EQ 5-D VAS-health state; VAS 0-100 (best health state) | 5,819 | 57.5 | 60.0 | 3,630 | 54 | 55.0 | 85 | 50.5 | 50.0 |
| Dermatology Life Quality Index (DLQI); range 0-30 (highest impairment) | 5,957 | 11.2 | 11.0 | 3,704 | 12.4 | 12.0 | 86 | 13.2 | 11.5 |

*The different treatment groups are not additive at inclusion, because combinations of biologics/ biosimilars and non-biologics are possible.

The non-biologic group consists of Apremilast, Cyclosporine, Fumaric Acid Esters = FAE, Leflunomid, Methotrexate = MTX, Dimethylfumarate, Retinoids, Tofacitinib, UV and systemic PUVA = Psoralen plus UV-A. The biologics group consists of Abatacept, Adalimumab, Brodalumab, Certolizumab, Efalizumab, Etanercept, Golimumab, Guselkumab, Infliximab, Ixekizumab, Risankizumab, Secukinumab, Tildrakizumab and Ustekinumab. The biosimilar group includes all biosimilars licensed in Germany.

From 2008 until 2019 were 7,854 patient years (py) on biologic (mainly Adalimumab and Ustekinumab) and 9,147 py on non-biologic treatment (mainly FAE and MTX) observed. This is partly due to patients switching from one to another treatment and to combined treatments. Also biosimilars were observed (57 py). Figure 2 shows the amount of patients at baseline and patient years observed by antipsoriatic treatments, respectively.

In order to translate a better understanding of the genetic background of the psoriasis to phenotypes and real-world care, the project PsoBest Bioscience was started. A biobank will be set up in the registry and the genome of all patients participating will be analysed to gain knowledge on the disease and etiology, types of psoriasis and diagnosis, the course of disease and comorbidity, on treatment response and prevention. This knowledge would enable the industry to design personalized treatments and help dermatologists to shape treatment for each individual patient.

RESULTS III

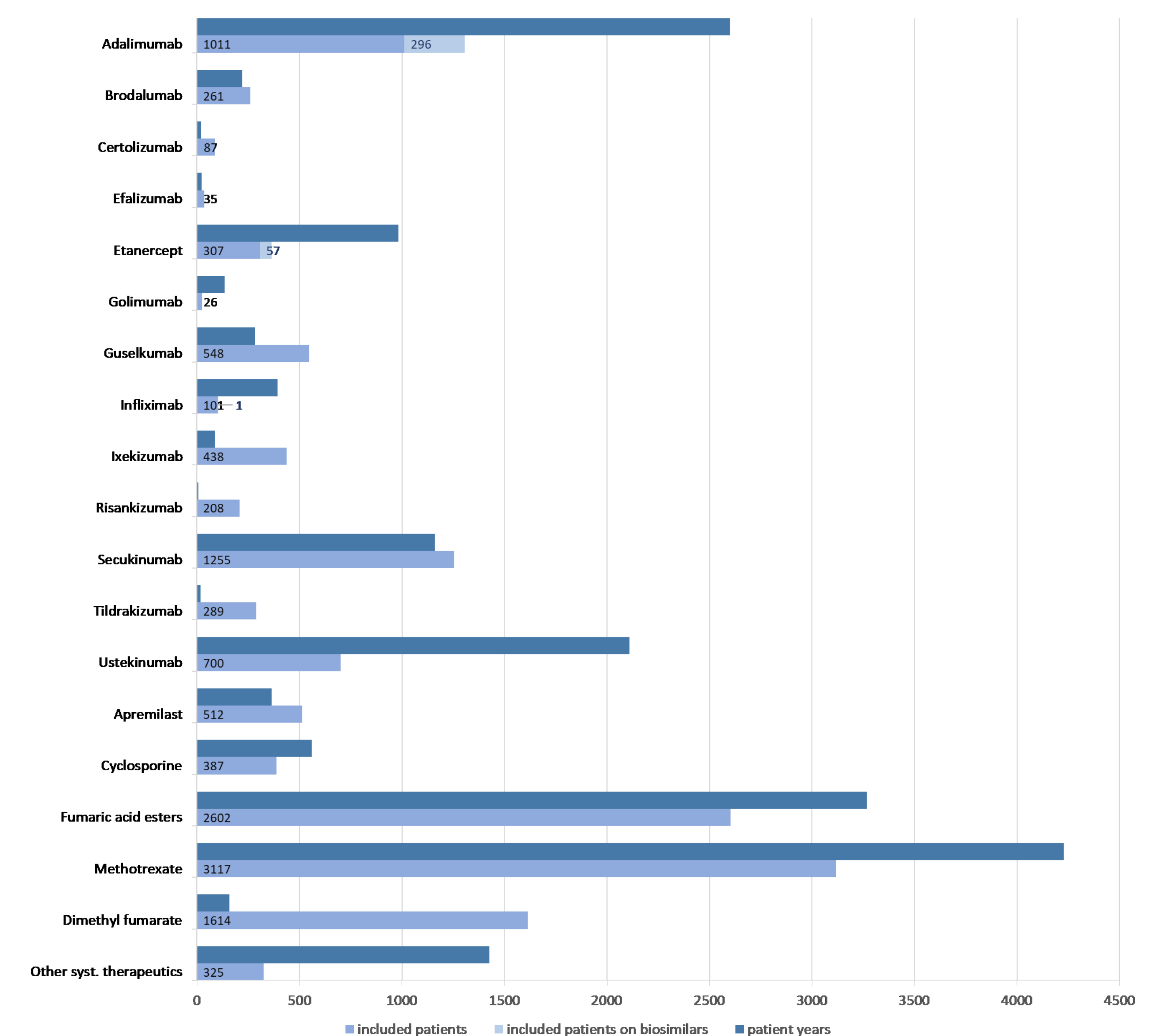


Figure 3. Number of patients per inclusion treatment and patient years observed (cumulative data from 13.12.2007 to 31.12.2019 for patient years, data cut for included patients: 01.10.2020).

CONCLUSIONS

In sum, the German psoriasis registry PsoBest was a pioneering step in 2008, taken towards long-term evidence on safety, effectiveness and patient benefit in routine health care. It is a still growing national project subsisting on the dedication of all participating dermatologists and patients. Today, PsoBest is the largest registry in German dermatology, data and evidence generated is well recognized beyond dermatology by all stakeholders of German health care. The next level of evidence will be reached through translational research from genes to real world health care.

Values and ranges

PASI: Psoriasis Area and Severity Index (0 – 72 = highest severity),

BSA: Body Surface Area (0 – 100 = maximum impairment),

DLQI: Dermatological Life Quality Index (0 – 30 = highest impairment),

EQ 5-D VAS (0 – 100 = best health state), Severity of Psoriasis (VAS 0 – 10 = highest severity)

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