

# Bimekizumab treatment in a real-world, prospective, non-interventional study in patients with moderate to severe hidradenitis suppurativa: Hi-LiGHT study design and baseline characteristics

P0039

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## Objective

Hi-LiGHT aims to evaluate clinical response, patient-reported outcomes, bimekizumab use and the care journey over 2 years in patients with moderate to severe hidradenitis suppurativa (HS) in routine practice. Here, the Hi-LiGHT study design is described and baseline, n (%) characteristics of patients enrolled in the first year of the study are reported.

## Introduction

- HS is a chronic, progressive, inflammatory disease characterised by painful and suppurating lesions, impaired work productivity and poor quality of life (QoL).<sup>1,2</sup>
- Bimekizumab (BKZ), a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,<sup>3</sup> received approval for HS treatment by the European Commission in April 2024.<sup>4</sup>
- Hi-LiGHT is a prospective non-interventional European study designed to provide insights into real-world outcomes in patients with moderate to severe HS treated with BKZ across multiple EU countries.

## Methods

- Hi-LiGHT is a prospective non-interventional European study with primary data collection currently ongoing across 110 sites in Austria, Denmark, France, Germany, Greece, Italy, the Netherlands and Spain (**Figure 1**).
- The aim is to enrol approximately 650 analysable patients with HS, whose physicians decided to prescribe BKZ independent from study participation, in routine clinical practice.
- Patients are enrolled in each country following local approval of BKZ for HS treatment and followed over 2 years (104 weeks), comprising 12 observational points (OPs) starting at BKZ initiation and continuing at Weeks 2, 4, 8 and 12, and approximately every 13 weeks thereafter (**Figure 2A**).
- The primary outcome is achievement of ≥55% reduction from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4-55) at Week 26 (OP 6). The secondary outcomes are shown in **Figure 2B**.
- Baseline characteristics are reported for patients who received ≥1 dose of BKZ enrolled in the first year of Hi-LiGHT.

## Results

- During the first year of Hi-LiGHT (data cut-off: 22nd October 2025), 180 were enrolled and received ≥1 dose of BKZ (safety set) across Germany (81.1%), Denmark (12.2%), France (5.0%) and Spain (1.7%).
- Half of the patients were female and the mean (standard deviation [SD]) age was 41.1 (11.0) years (**Table 1**).
- Approximately two thirds of patients were biologic-naïve.
  - Of the 60 biologic-experienced patients, 46 had received adalimumab and 33 had received secukinumab; the number of previous biologic agents received is reported in **Table 1**.
- Most patients presented with severe HS at study entry, with a mean (SD) IHS4 score of 23.2 (33.4); approximately half were classified as Hurley stage III and 62.2% presented with ≥1 draining tunnel.
- The mean (SD) time since diagnosis was 8.7 (8.8) years.
- Moreover, 18.3% of patients received ≥1 lesional intervention within the 6 months prior to enrolment and 56.7% had comorbidities associated with, or related to, HS, with hypertension, obesity and depression most commonly presented.
- Additional baseline characteristics are reported in **Table 1**.

## Conclusions

The patient population enrolled in the first year of Hi-LiGHT (predominantly in Germany) displayed a high disease burden profile with significant unmet needs, similar to that seen in pivotal bimekizumab clinical trials.<sup>5,6</sup>

Despite high disease severity and an average of ≥8 years since diagnosis, most enrolled patients in Hi-LiGHT to date were biologic-naïve. This treatment delay warrants further investigation into addressing barriers to earlier biologic therapy initiation.

## Summary

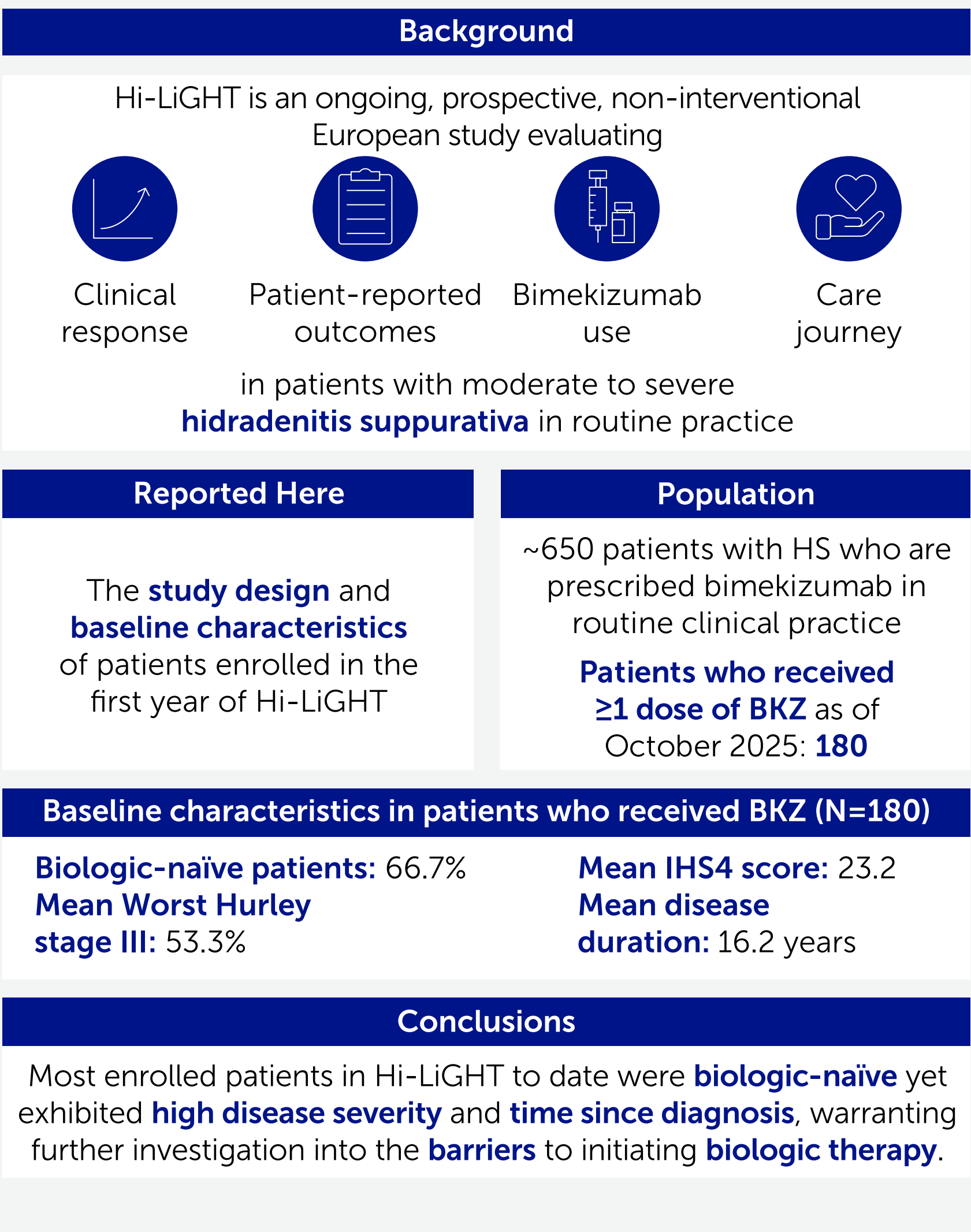


Figure 1 Hi-LiGHT study sites

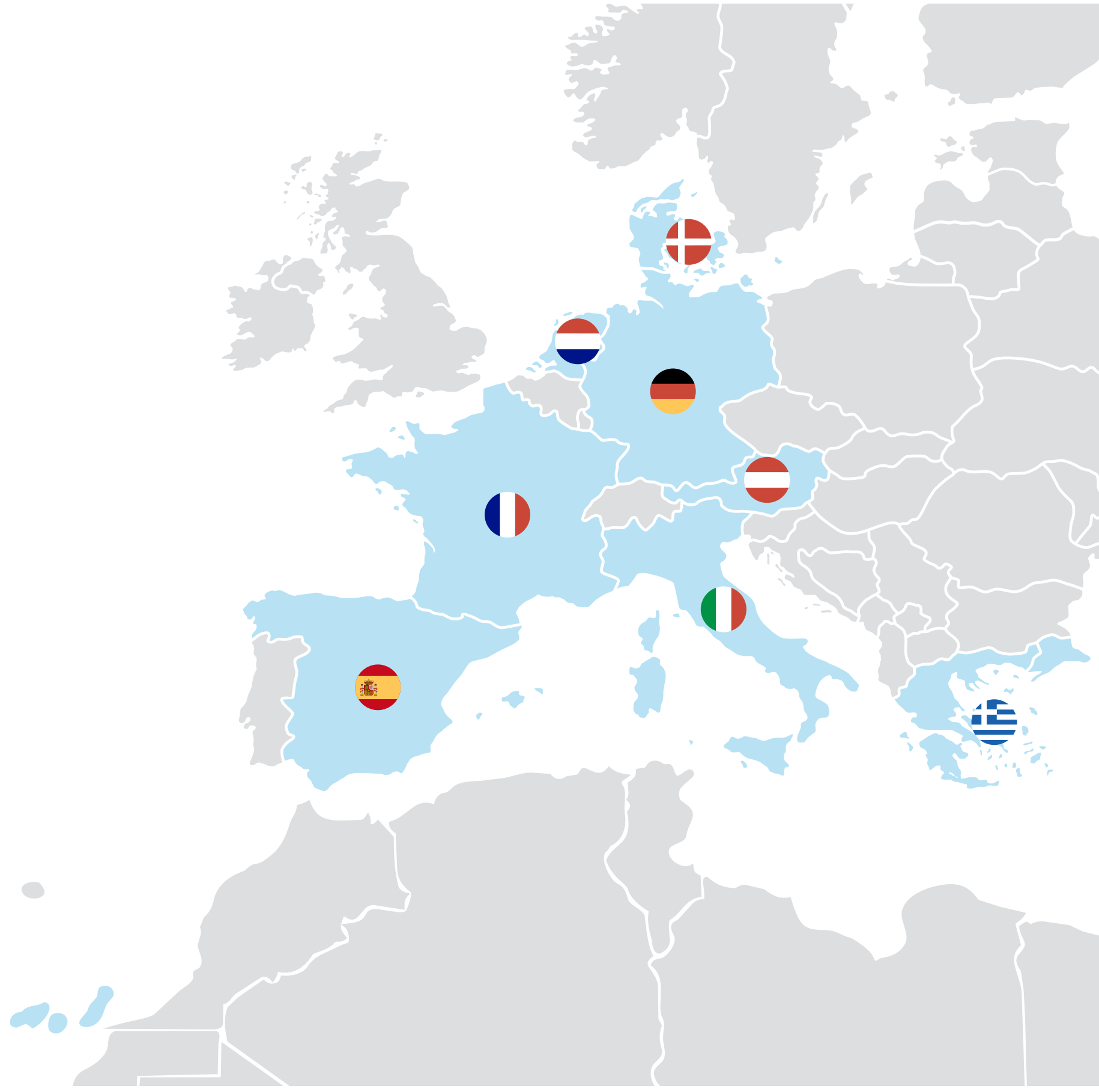
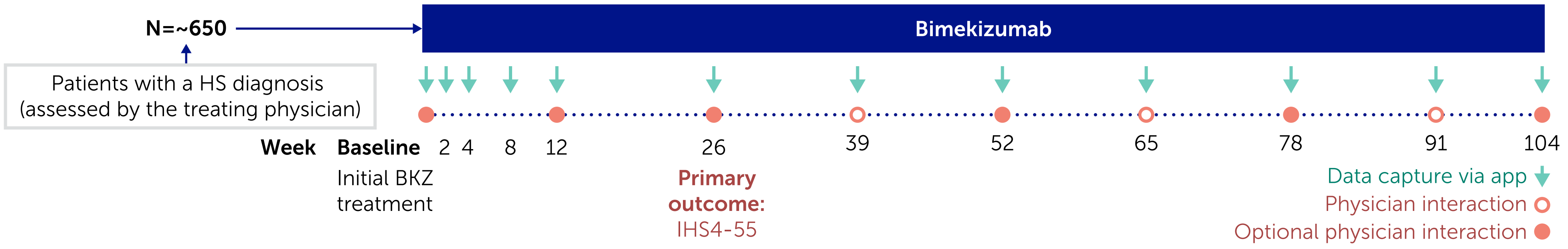


Figure 2 Hi-LiGHT design

### A) Study design



### B) Study collected outcomes

| Recorded at baseline                                                                            | Recorded from baseline to Week 104                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Patient characteristics</b></p> <p><b>Medical history</b></p> <p><b>Health status</b></p> | <p><b>Patient-reported outcomes</b></p> <p><b>Every observation point</b></p> <p>BKZ dosing, HS-related signs &amp; symptoms (e.g. flares &amp; wound care), HSSQ, IHS4-55/75/90/100, PGI-S-HS</p> <p><b>Selected observation points</b></p> <p>DLQI, HiSQOL, HISCR-50/75/90/100, PBI (PNQ at OP1; PBQ individual item scores and PBI-HS index thereafter) TSQM-9, WPAI-SHP</p> |
|                                                                                                 | <p><b>Physician-reported outcomes</b></p> <p><b>Physician interaction observation points</b></p> <ul style="list-style-type: none"><li>Lesion count</li><li>Hurley stage</li><li>Folliculitis presence</li><li>Lesional interventions</li><li>BKZ use (dose &amp; discontinuation)</li><li>HS care</li><li>Adverse events</li></ul>                                             |

Table 1

Baseline characteristics

|                                                                                       | First-year patients<br>N=180 |
|---------------------------------------------------------------------------------------|------------------------------|
| <b>Age</b> , years, mean (SD) [median]                                                | 41.1 (11.0) [41.0]           |
| <b>Age</b> , years, n (%)                                                             |                              |
| 18–45                                                                                 | 115 (63.9)                   |
| >45–65                                                                                | 63 (35.0)                    |
| >65                                                                                   | 2 (1.1)                      |
| <b>Sex</b> , female, n (%)                                                            | 90 (50.0)                    |
| <b>Country</b> , n (%)                                                                |                              |
| Denmark                                                                               | 22 (12.2)                    |
| France                                                                                | 9 (5.0)                      |
| Germany                                                                               | 146 (81.1)                   |
| Spain                                                                                 | 3 (1.7)                      |
| <b>Smoking status</b> , n (%)                                                         |                              |
| Current smoker                                                                        | 112 (62.2)                   |
| Former smoker                                                                         | 26 (14.4)                    |
| <b>Employment status</b> , n (%)                                                      |                              |
| Full-time                                                                             | 113 (62.8)                   |
| Part-time                                                                             | 25 (13.9)                    |
| Unemployed                                                                            | 36 (20.0)                    |
| Student <sup>a</sup>                                                                  | 2 (1.1)                      |
| <b>BMI</b> , kg/m <sup>2</sup> , mean (SD)                                            | 33.7 (7.4)                   |
| <b>BMI</b> , kg/m <sup>2</sup>                                                        |                              |
| <30                                                                                   | 63 (35.0)                    |
| ≥30                                                                                   | 113 (62.8)                   |
| Missing                                                                               | 4 (2.2)                      |
| <b>Weight</b> , kg                                                                    |                              |
| <100                                                                                  | 82 (45.6)                    |
| ≥100                                                                                  | 94 (52.2)                    |
| Missing                                                                               | 4 (2.2)                      |
| <b>Worst Hurley stage experienced</b> , n (%)                                         |                              |
| Stage I                                                                               | 7 (3.9)                      |
| Stage II                                                                              | 73 (40.6)                    |
| Stage III                                                                             | 96 (53.3)                    |
| Missing                                                                               | 4 (2.2)                      |
| <b>IHS4</b> , mean (SD) [median] N                                                    | 23.2 (33.4) [12.0] 174       |
| <b>IHS4 severity status</b> , n (%)                                                   |                              |
| Mild (<4)                                                                             | 23 (12.8)                    |
| Moderate (4–10)                                                                       | 56 (31.1)                    |
| Severe (11–30)                                                                        | 53 (29.4)                    |
| Very severe (≥31)                                                                     | 42 (23.3)                    |
| Missing                                                                               | 6 (3.3)                      |
| <b>PGI-S-HS response status</b> , n (%)                                               |                              |
| Mild                                                                                  | 24 (13.3)                    |
| Moderate                                                                              | 46 (25.6)                    |
| Severe                                                                                | 59 (32.8)                    |
| Very severe                                                                           | 26 (14.4)                    |
| Missing                                                                               | 24 (13.3)                    |
| None                                                                                  | 1 (0.6)                      |
| <b>≥1 draining tunnel</b> , n (%)                                                     | 112 (62.2)                   |
| <b>Prior biologic exposure</b> , n (%)                                                |                              |
| Biologic-naïve                                                                        | 120 (66.7)                   |
| Biologic-experienced                                                                  | 60 (33.3)                    |
| 1                                                                                     | 29 (16.1)                    |
| 2                                                                                     | 17 (9.4)                     |
| >2                                                                                    | 14 (7.8)                     |
| <b>Patients with any prior or ongoing HS-related medication<sup>b</sup></b> , n (%)   | 147 (81.7)                   |
| Adalimumab                                                                            | 46 (25.6)                    |
| Secukinumab                                                                           | 33 (18.3)                    |
| <b>Prior or concomitant HS-related interventions of interest</b> , n (%)              |                              |
| Antiseptic wash/cream                                                                 | 20 (11.1)                    |
| Systemic antibiotic                                                                   | 108 (60.0)                   |
| Anti-inflammatory and anti-rheumatic products <sup>c</sup>                            | 11 (6.1)                     |
| Other analgesics                                                                      | 11 (6.1)                     |
| <b>HS-related antibiotic medication received ≤3 months prior to enrolment</b> , n (%) | 71 (39.4)                    |
| <b>Lesional interventions received ≤6 months prior to enrolment</b> , n (%)           |                              |
| Yes                                                                                   | 33 (18.3)                    |
| Surgery                                                                               | 27 (15.0)                    |
| 1                                                                                     | 17 (9.4)                     |
| 2                                                                                     | 6 (3.3)                      |
| >2                                                                                    | 4 (2.2)                      |
| Other                                                                                 | 8 (4.4)                      |
| 1                                                                                     | 7 (3.9)                      |
| 2                                                                                     | 0                            |
| >2                                                                                    | 1 (0.6)                      |
| <b>Disease duration since onset of symptoms</b> , years, mean (SD) N                  | 16.2 (11.0) 178              |
| <b>Time since initial diagnosis</b> , years, mean (SD) N                              | 8.7 (8.8) 179                |
| <b>Any comorbidities relevant to HS<sup>d</sup></b> , yes, n (%)                      | 102 (56.7)                   |
| <b>Comorbidities commonly observed in patients with HS<sup>e</sup></b> , n (%)        |                              |
| Obesity                                                                               | 39 (21.7)                    |
| Hypertension                                                                          | 38 (21.1)                    |
| Depression                                                                            | 28 (15.6)                    |

Safety set (patients who received ≥1 dose of bimekizumab). **[a]** Students reported as a subset of part-time and/or unemployed subjects; **[b]** Any medications specifically prescribed to treat HS symptoms; **[c]** Only includes ibuprofen; **[d]** Comorbidities determined as being associated with, or related to, HS; **[e]** The three most common are reported.

BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; HiSQOL: HS Quality of Life; HISCR: Hidradenitis Suppurativa Clinical Response; **HISCR-50/75/90/100**: ≥50/75/90/100% reduction in total abscess and inflammatory nodule count from OP1 with no increase from baseline in abscess or draining tunnel count; **HS**: hidradenitis suppurativa; **HSSQ**: HS Symptom Questionnaire; **IHS4**: International Hidradenitis Suppurativa Severity Score System; **IHS4-55/75/90/100**: ≥55/75/90/100% reduction from baseline in the International Hidradenitis Suppurativa Severity Score System; **NSAID**: non-steroidal anti-inflammatory drug; **OP**: observational point; **PBI**: Patient Benefit Index; **PBQ**: Patient Benefit Questionnaire; **PGI-S-HS**: Patient Global Impression (PGI) of Hidradenitis Suppurativa Severity; **PBI**: Patient Benefit Index; **PBQ**: Patient Benefit Questionnaire; **SD**: standard deviation; **TSQM-9**: Treatment Satisfaction Questionnaire for Medication – 9 items; **WPAI-SHP**: World Productivity & Activity Impairment Questionnaire-Specific Health Problem.

**References:** <sup>1</sup>Kaur AP et al. Skin Health Dis 2023;3:e214; <sup>2</sup>Montero-Vilchez T et al. Int J Environ Res Public Health 2021;18:6709; <sup>3</sup>Adams R et al. Front Immunol 2020;11:1894; <sup>4</sup>BIMZELX® (bimekizumab) EU SmPC, April 2024; <sup>5</sup>Kimball AB et al. Lancet 2024;403:2504–19; <sup>6</sup>Sayed CJ et al. J Am Acad Dermatol 2026;94:867–78. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **SSB, LS, RH, FF, HBo, HBe, KS, Mo, GN, DT, SFT**; Drafting of the publication, or reviewing it critically for important intellectual content: **SSB, LS, RH, FF, HBo, HBe, KS, Mo, GN, DT, SFT**; Final approval of the publication: **SSB, LS, RH, FF, HBo, HBe, KS, Mo, GN, DT, SFT**; Received honoraria for participation in advisory boards, in clinical trials, and/or as speaker from AbbVie, Biogen, Boehringer Ingelheim, Hexal, MoonLake Immunotherapeutics, Novartis, Sanofi and UCB; **LS**: No relevant conflicts of interest to declare; **RH**: No relevant conflicts of interest to declare; **FF, HBo, HBe, KS, Mo**: Employees and shareholders of UCB; **GN**: Received honoraria and travel grants from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Novartis and UCB; former institution received honoraria from Molnlycke GmbH for his participation in advisory boards; **DT**: Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Celtrion, Eli Lilly and Company, Galderma, Incyte, Johnson and Johnson, Kyowa Kirin, LEO Pharma, L'Oréal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Stada, Sun Pharma, Takeda, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma and Novartis; **SFT**: Advisory boards: AbbVie, ALK Abelló, Almirall, Boehringer Ingelheim, CSL, Eli Lilly and Company, Galderma, Incyte, Janssen, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Sanofi, Servier, UCB, Union Therapeutics and Zealand Pharma; Speaker: AbbVie, Almirall, Dr. August Wolff, Eli Lilly and Company, Galderma, Johnson & Johnson, LEO Pharma, Novartis, Novo Nordisk, Pfizer, Sanofi, Symphogen and UCB; Research support: AbbVie, Almirall, Galderma, Janssen, LEO Pharma, Novartis, Novo Nordisk, Pfizer, Sanofi and UCB. **Acknowledgements:** This study was funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to this study. The authors also thank Susana Lobo Berastegui, MSc, of UCB, for editorial review during poster development and publication coordination, Lauren Carlberg, PhD, and Sarah Johnson, MSc, Costello Medical, Manchester, UK, for medical writing and editorial assistance and the Costello Medical Creative team for design support. All costs associated with development of this poster were funded by UCB.



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