

# Bimekizumab 2-year Impact on HS Symptoms by Baseline Draining Tunnel Count: Data from BE HEARD EXT

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# Disclosures & Acknowledgments

## Disclosures

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**RW:** Veramed statistical consultant for UCB.

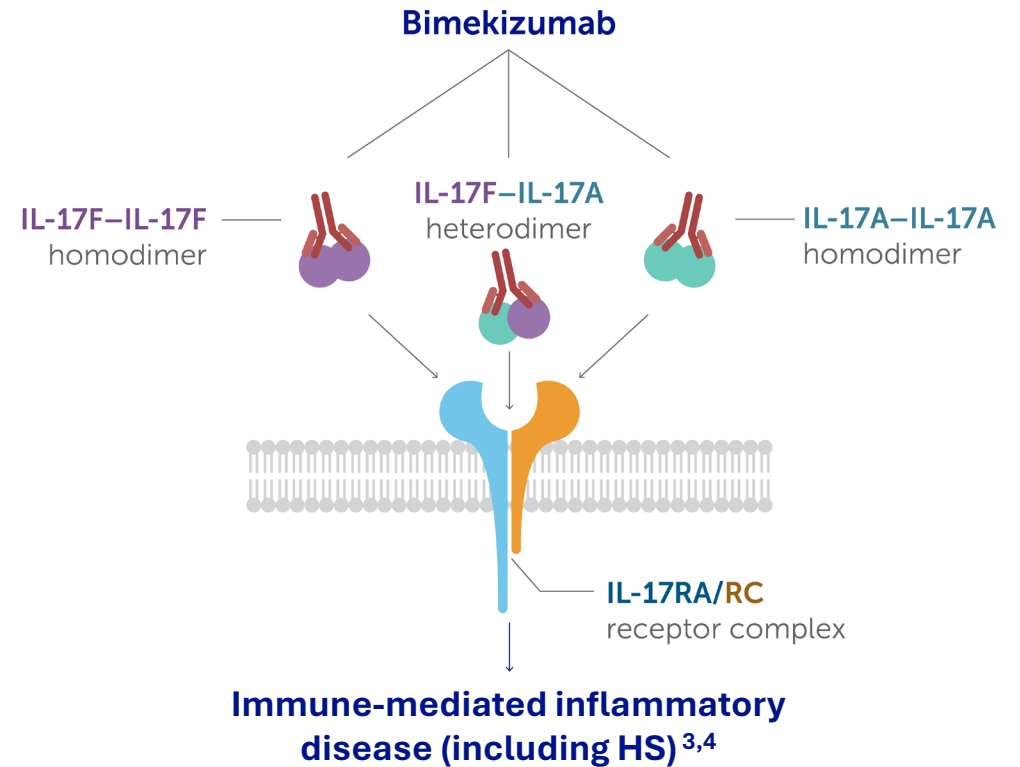
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# Background

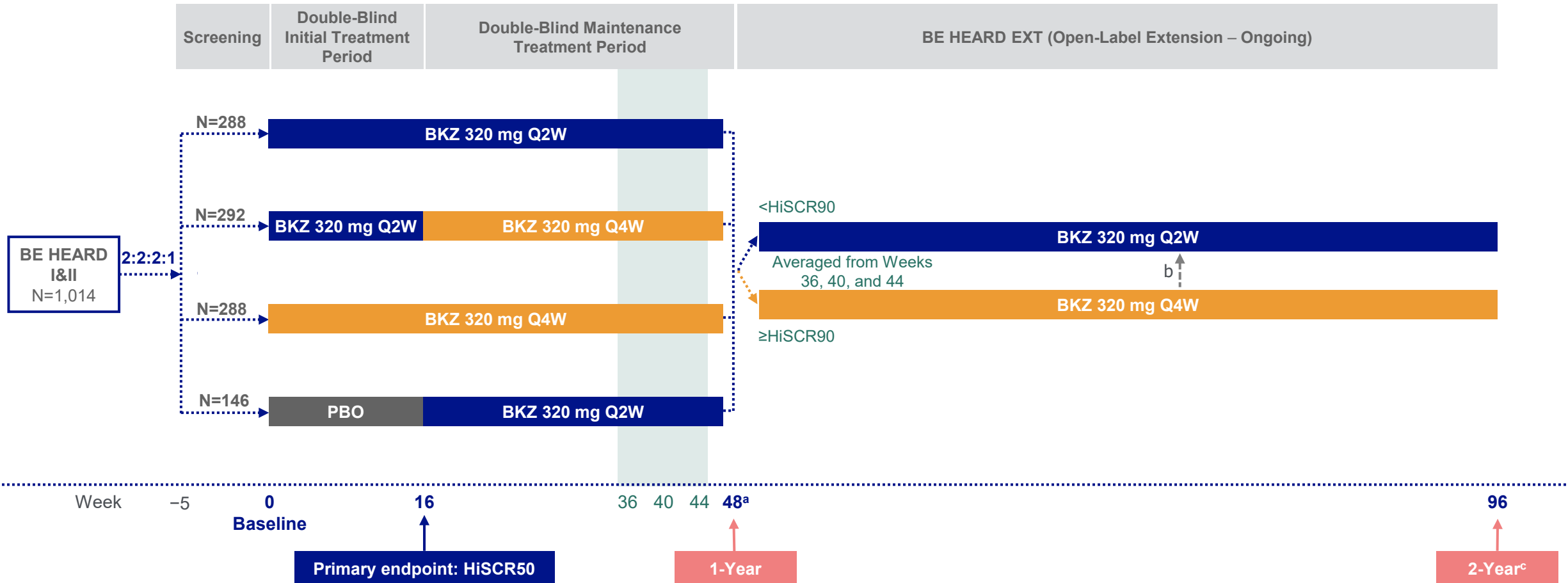
- **Hidradenitis suppurativa (HS)** is characterized by recurrent formation of lesions, including abscesses and **draining tunnels (DTs)** (fistulas/sinus tracts), that are often painful, pruriginous, and exude a malodorous discharge.<sup>1</sup>
- HS has a substantial negative effect on patients' **quality of life**.<sup>1</sup>
- **Bimekizumab (BKZ)**, is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.<sup>2</sup>



**OBJECTIVE:** We report how HS-specific patient-reported symptoms improve with BKZ treatment over time stratified by baseline DT count.

# Study Design

- The phase 3 BE HEARD I&II and BE HEARD EXT study designs:<sup>1,2</sup>



Among 657 BE HEARD I&II completers who entered BE HEARD EXT, 556 patients received BKZ from baseline. **[a]** Patients who completed Week 48 of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). **1.** Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **2.** BE HEARD EXT: <https://clinicaltrials.gov/study/NCT04901195>. **Abbreviations:** AN: abscess and inflammatory nodule; BKZ: bimekizumab; HiSCR50/90: ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; PBO: placebo; Q2W: every two weeks; Q4W: every four weeks.

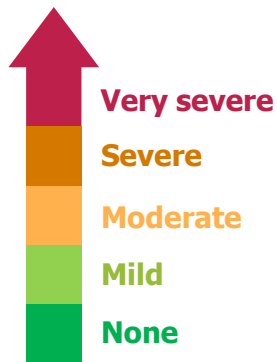
# Methods – Outcomes

- Pooled data are reported for all patients randomized to BKZ in **BE HEARD I&II** who enrolled in the open-label **BE HEARD EXT** (BKZ Total).<sup>1,2</sup>
- Number of baseline DTs were grouped as 0, 1–2, 3–5, or >5.

We report:

- Proportion of patients in severity categories ('none' to 'very severe') for each item in the **HS Symptom Questionnaire (HSSQ)** based on item scores over 2 years.
- Data are reported using **observed case (OC)**.

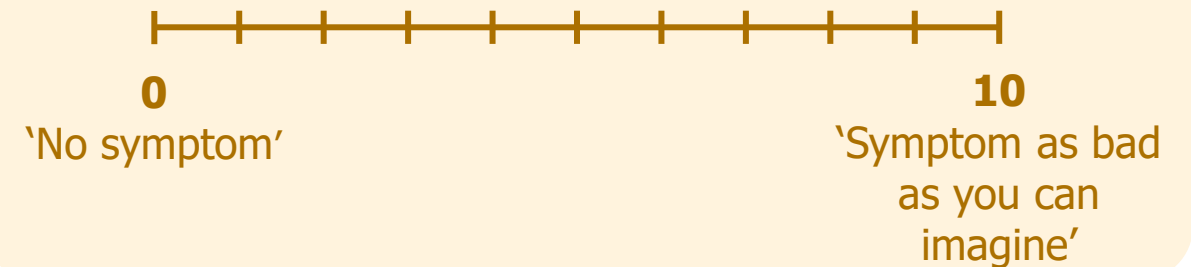
## HSSQ Symptom Item Severity Categories



## HSSQ (HS symptoms)

- Items individually capture patient-reported severity of **skin pain, smell/odor, drainage/oozing** and **itch**.
- Items scored on an 11-point numeric rating scale.

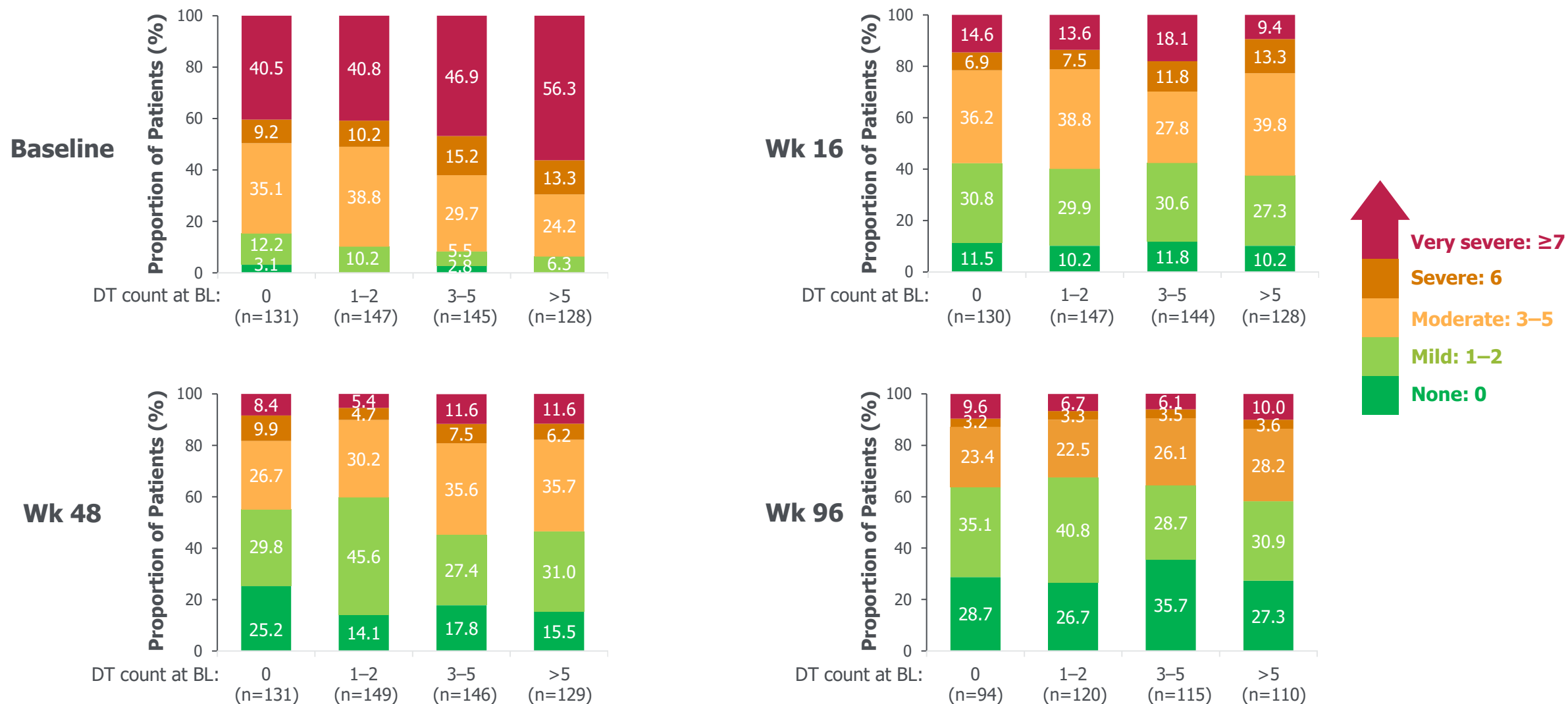
Please rate your [**symptom**] from your HS lesions in the past 7 days:



# Baseline Characteristics

	<b>BKZ Total</b> N=556
<b>Age (years)</b> , mean ± SD	36.3 ± 12.2
<b>Sex, female</b> , n (%)	299 (53.8)
<b>Racial group</b> , n (%)	
white	448 (80.6)
black or African American	55 (9.9)
<b>BMI (kg/m<sup>2</sup>)</b> mean ± SD	32.5 ± 7.8
<b>Smoking status, current</b> , n (%)	260 (46.8)
<b>Duration of HS (years)</b> , mean ± SD	7.4 ± 7.1
<b>AN count</b> , mean ± SD	16.9 ± 18.5
<b>DT count</b> , mean ± SD	3.8 ± 4.3
<b>Hurley stage</b> , n (%)	
<b>II</b>	303 (54.5)
<b>III</b>	253 (45.5)
<b>DLQI total score</b> , mean ± SD	11.0 ± 6.8
<b>HiSQOL total score</b> , mean ± SD	24.6 ± 12.8
<b>Prior biologic use<sup>a</sup></b> n (%)	112 (20.1)
<b>Baseline antibiotic use</b> , n (%)	54 (9.7)
<b>DT count at baseline</b> , n (%)	
0	131 (23.6)
1–2	149 (26.8)
3–5	147 (26.4)
>5	129 (23.2)

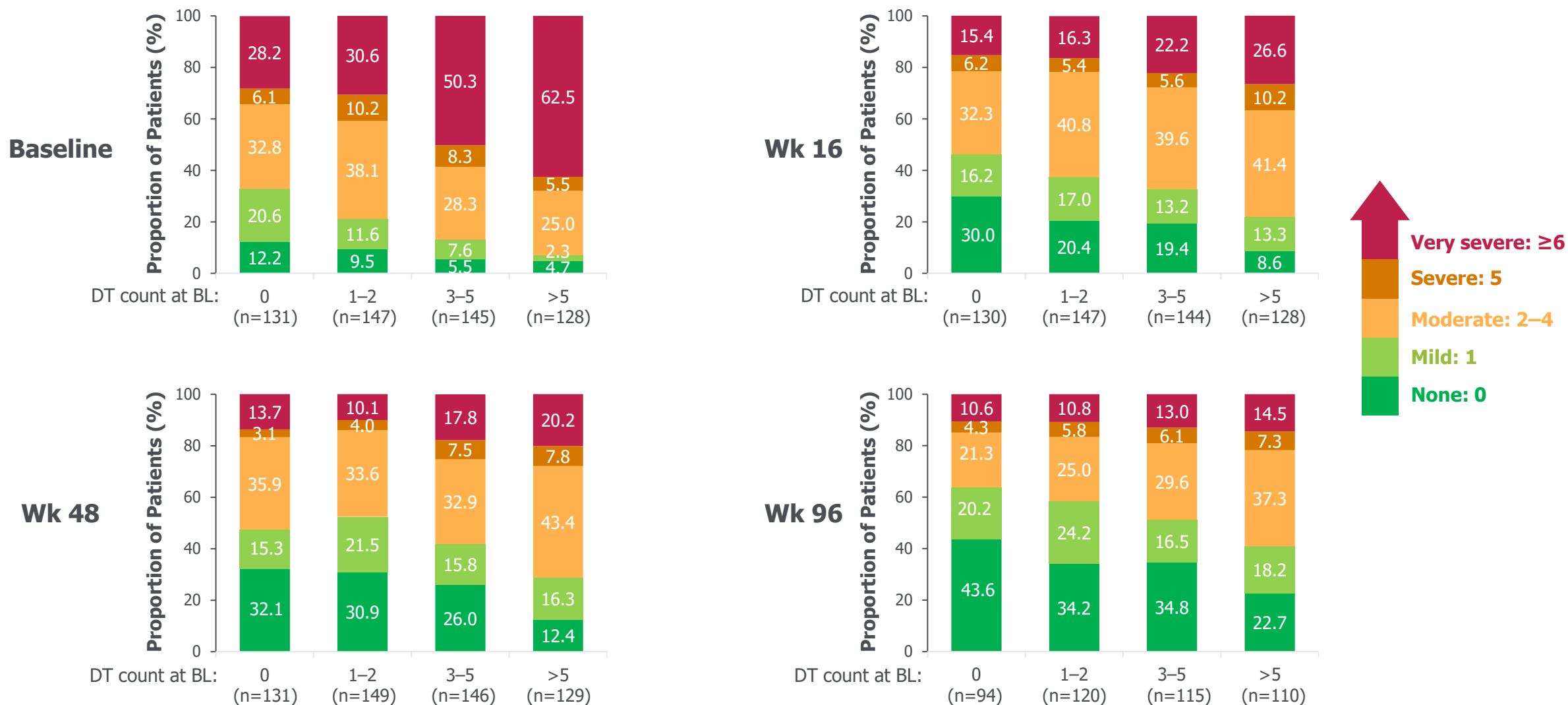
# HSSQ Skin Pain by DT Count at Baseline (OC)



With BKZ treatment, the proportion of patients with **none/mild skin pain** increased over 2 years, regardless of DT count at baseline.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ assesses patients' perception of symptoms over the past 7 days. HSSQ scores are reported for BKZ Total. DT count at baseline are categorized as follows: 0 (N=131), 1–2 (N=149), 3–5 (N=147), and >5 (N=129). **Abbreviations:** BKZ: bimekizumab; BL: baseline; DT: draining tunnel; HS: hidradenitis suppurativa; HSSQ: HS Symptom Questionnaire; OC: observed case; Wk: Week.

# HSSQ Smell/Odor by DT Count at Baseline (OC)

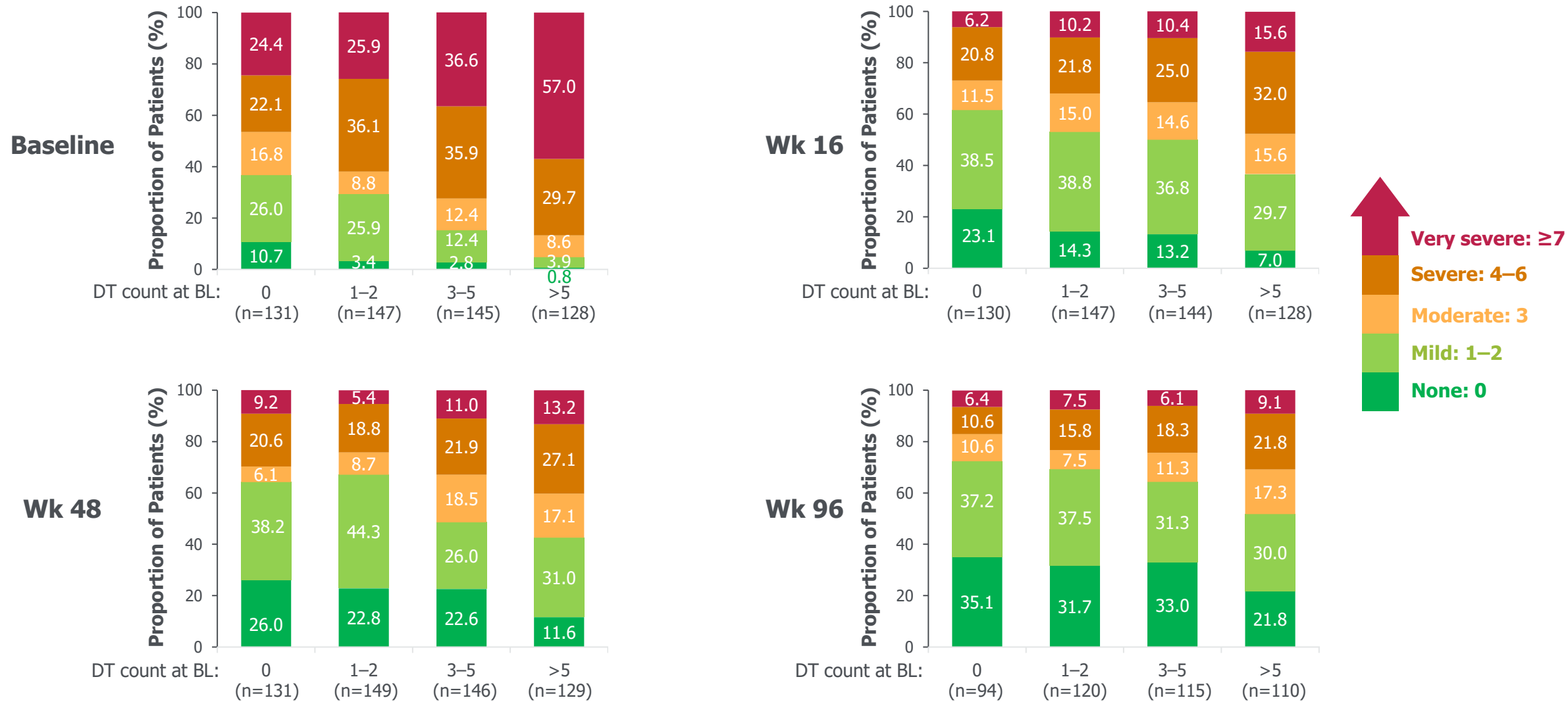


With BKZ treatment, the proportion of patients with **none or mild smell/odor** increased over 2 years, irrespective of DT count at baseline.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ assesses patients' perception of symptoms over the past 7 days. HSSQ scores are reported for BKZ Total. DT count at baseline are categorized as follows: 0 (N=131), 1-2 (N=149), 3-5 (N=147), and >5 (N=129). **Abbreviations:** BKZ: bimekizumab; BL: baseline; DT: draining tunnel; HS: hidradenitis suppurativa; HSSQ: HS Symptom Questionnaire; OC: observed case; Wk: Week.



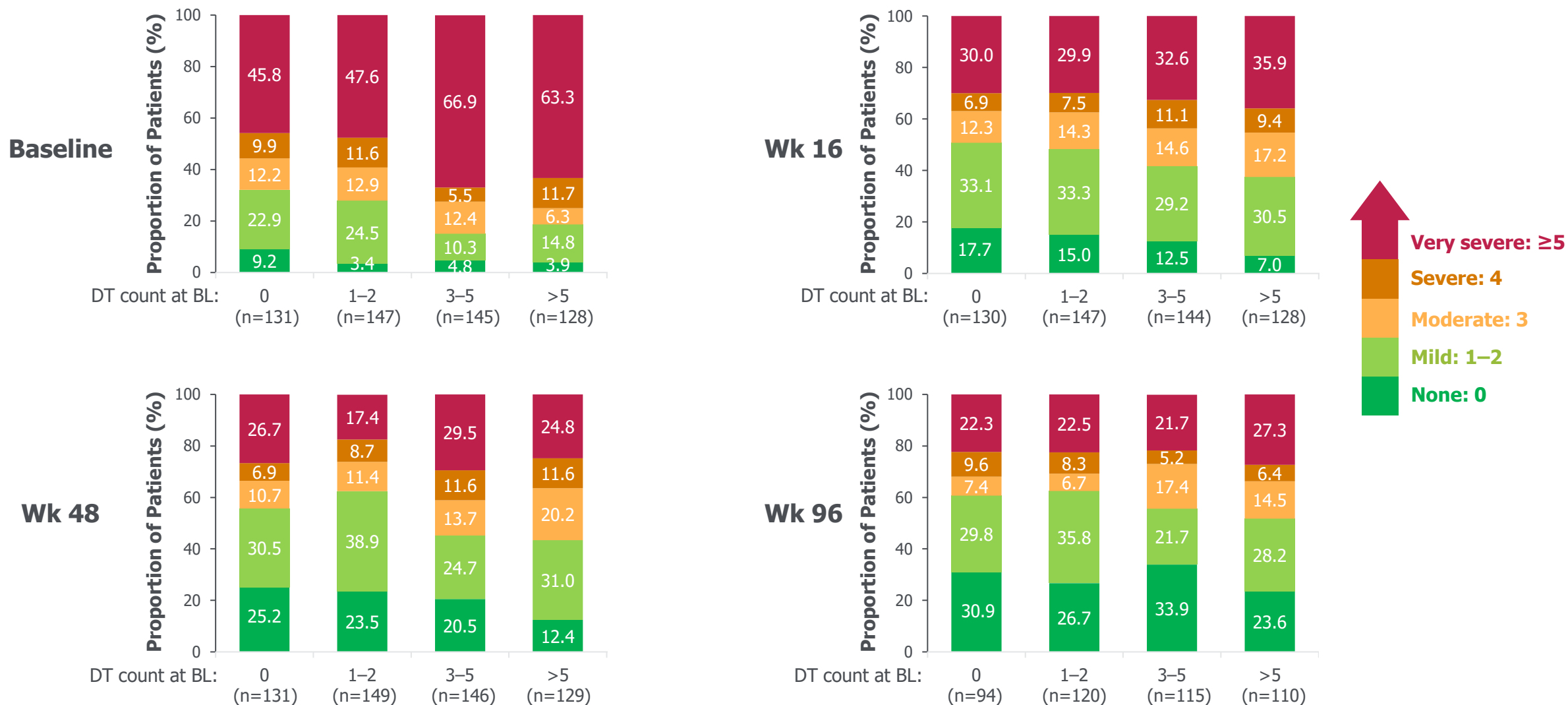
# HSSQ Drainage/Oozing by DT Count at Baseline (OC)



Over 2 years, the proportion of patients with **none/mild drainage/oozing** generally increased following BKZ treatment, irrespective of baseline DT count.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ assesses patients' perception of symptoms over the past 7 days. HSSQ scores are reported for BKZ Total. DT count at baseline are categorized as follows: 0 (N=131), 1-2 (N=149), 3-5 (N=147), and >5 (N=129). **Abbreviations:** BKZ: bimekizumab; BL: baseline; DT: draining tunnel; HS: hidradenitis suppurativa; HSSQ: HS Symptom Questionnaire; OC: observed case; Wk: Week.

# HSSQ Itch by DT Count at Baseline (OC)



Over 2 years, the proportion of patients reporting **none/mild itch** increased with BKZ treatment, irrespective of baseline DT count.

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ assesses patients' perception of symptoms over the past 7 days. HSSQ scores are reported for BKZ Total. DT count at baseline are categorized as follows: 0 (N=131), 1-2 (N=149), 3-5 (N=147), and >5 (N=129). **Abbreviations:** BKZ: bimekizumab; BL: baseline; DT: draining tunnel; HS: hidradenitis suppurativa; HSSQ: HS Symptom Questionnaire; OC: observed case; Wk: Week.

# Conclusions

- Patients with a **higher number of DTs at baseline** rated their individual symptoms (skin pain, draining/oozing, smell/odor and itch) as **more severe**.
- The proportion of patients achieving **no/mild** symptoms **increased** after 2 years of treatment with bimekizumab.
- With **bimekizumab treatment**, patient reported symptoms related to HS lesions **improved** over 2 years **regardless of baseline DT count**, with an increase in the proportion of patients achieving no/mild symptoms across each individual HS symptom after 2 years.

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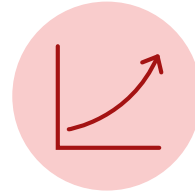


# Plain Language Summary



## Why was this study needed?

Hidradenitis suppurativa (HS) is a long-term skin disease. The sores, known as lesions, that patients have can smell, itch, drain pus, and cause pain. Patients can have many or few lesions. Studies were conducted to evaluate if the drug, bimekizumab, could help treat the symptoms of patients with moderate to severe HS.



## What did this study show?

Bimekizumab can help treat the symptoms caused by HS lesions, regardless of the number of lesions. Patients saw their pain, smell, pus, and itch symptoms get better.



## Why is this important?

It is important to make sure that new drugs for HS work well in treating the symptoms of HS.