Bimekizumab efficacy by disease duration in moderate to severe hidradenitis suppurativa: 2-year phase 3 results from BE HEARD EXT

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OBJECTIVE

- To report the impact of **disease duration**[a] since diagnosis on bimekizumab (BKZ) efficacy outcomes in patients with moderate to severe hidradenitis suppurativa (HS) over 2 years.

Background

- Patients with HS generally face **diagnosis delays**; therefore, **effective early treatment is crucial** to achieve better outcomes.[1,2]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[3]

Methods

- Data were pooled from the phase 3 trials BE HEARD I&II and their open-label extension, BE HEARD EXT.[4,5]
- We report the proportions of patients achieving ≥50/75/90/100% HS Clinical Response (**HiSCR50/75/90/100**) over 2 years, by **lowest** (**<2.38 years**) and **highest** (**≥10.74 years**) disease duration quartiles.
- Data are reported for patients randomized to BKZ 320 mg from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ (**BKZ Total**).[4,5]
- Data are reported as observed case (OC).

1. Saunte DM. et al. Br J Dermatol 2015;173:1546–9; **2.** Kokolakis G. et al. Dermatol 2020;236:421–30; **3.** Adams R. et al. Front Immunol 2020;11:1894; **4.** Kimball AB. et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **5.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195.

[a] Disease duration is calculated from date of diagnosis of hidradenitis suppurativa. BKZ: bimekizumab; HiSCR50/75/90/100: ≥50/75/90/100% HS Clinical Response; HS: hidradenitis suppurativa; Ig: immunoglobulin; IL: interleukin; OC: observed case.

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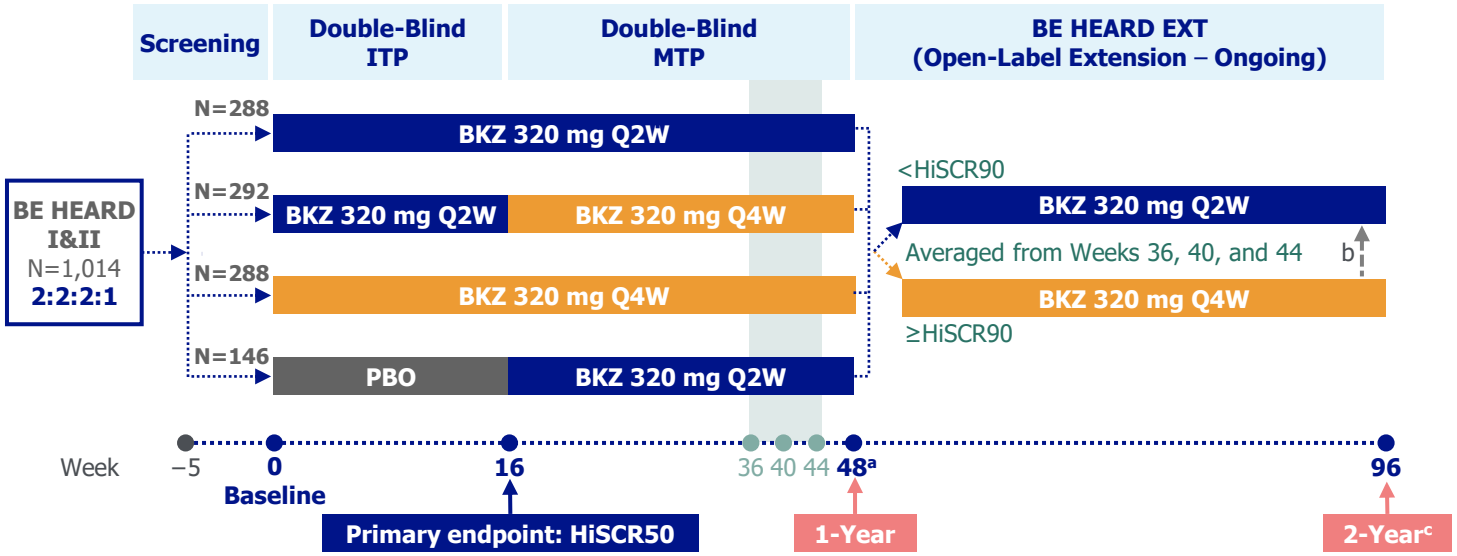
Study Design



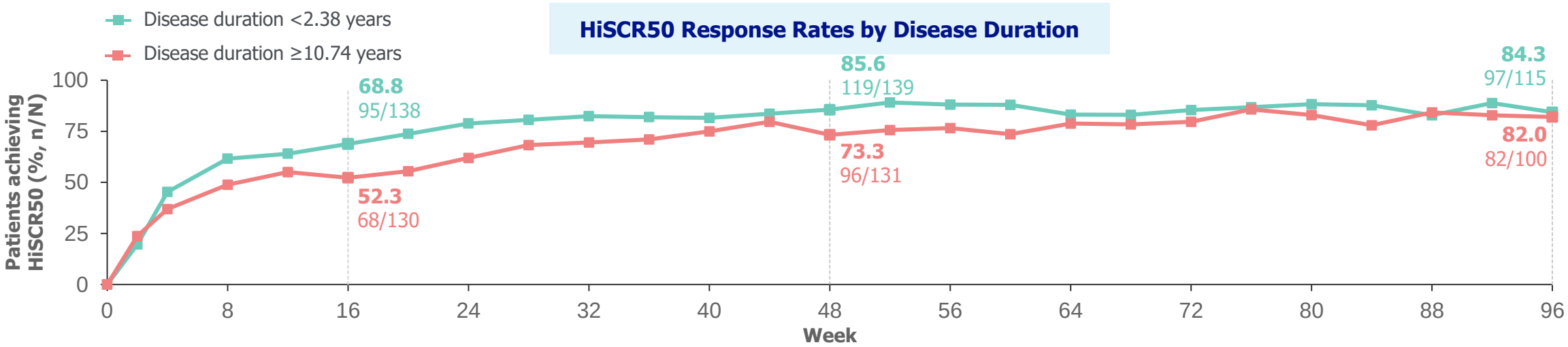
- Patients completing the 48-week BE HEARD I&II studies could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or Q4W based on HiSCR90 response averaged from Weeks 36, 40, and 44.[1,2]
- Baseline characteristics varied between the subgroups. The **highest** disease duration quartile had more older patients, females, smokers, and prior biologic users.

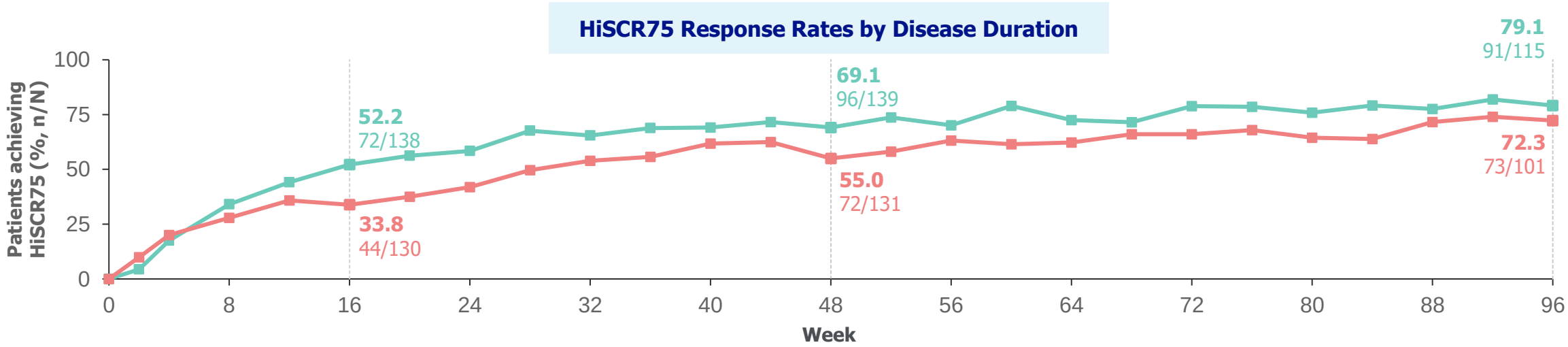
Baseline Characteristics

	Disease duration <2.38 years	Disease duration ≥10.74 years
	BKZ 320 mg Total N=139	BKZ 320 mg Total N=131
Age (years), mean (SD)	34.8 (13.5)	41.8 (10.3)
Sex, female, n (%)	63 (45.3)	84 (64.1)
Racial group, n (%)		
White	111 (79.9)	109 (83.2)
Black	6 (4.3)	13 (9.9)
BMI (kg/m²), mean (SD)	31.2 (7.4)	33.3 (7.8)
Smoking status, current, n (%)	57 (41.0)	66 (50.4)
Duration of HS (years), mean (SD)	1.3 (0.6)	17.8 (6.9)
AN count, mean (SD)	16.1 (14.6)	19.4 (25.9)
DT count, mean (SD)	3.3 (3.3)	3.9 (4.6)
Hurley stage, n (%)		
II	82 (59.0)	75 (57.3)
III	57 (41.0)	56 (42.7)
DLQI total score, mean (SD)	10.0 (6.5)	12.3 (6.9)
Prior biologic use,[d] n (%)	11 (7.9)	29 (22.1)
Baseline antibiotic use, n (%)	13 (9.4)	15 (11.5)

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. **[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); **[d]** Patients received prior biologic therapy for any indication. **1.** Kimball AB. et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); **2.** BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HiSCR50/90: ≥50%/90% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; ITP: initial treatment period; MTP: maintenance treatment period; OLE: open-label extension; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SD: standard deviation.

HiSCR50/75 Rates by Lowest and Highest Disease Duration Quartiles to Week 96 (OC)

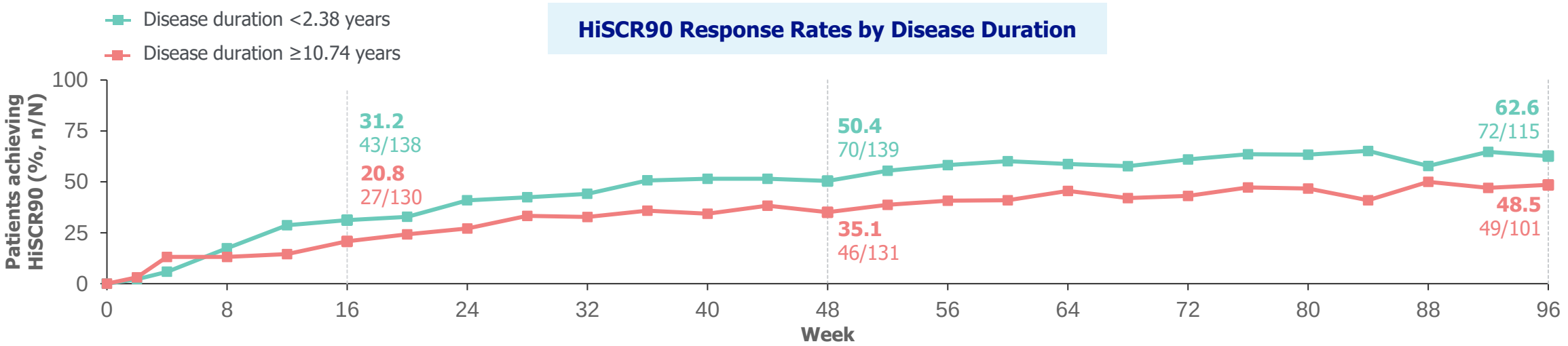


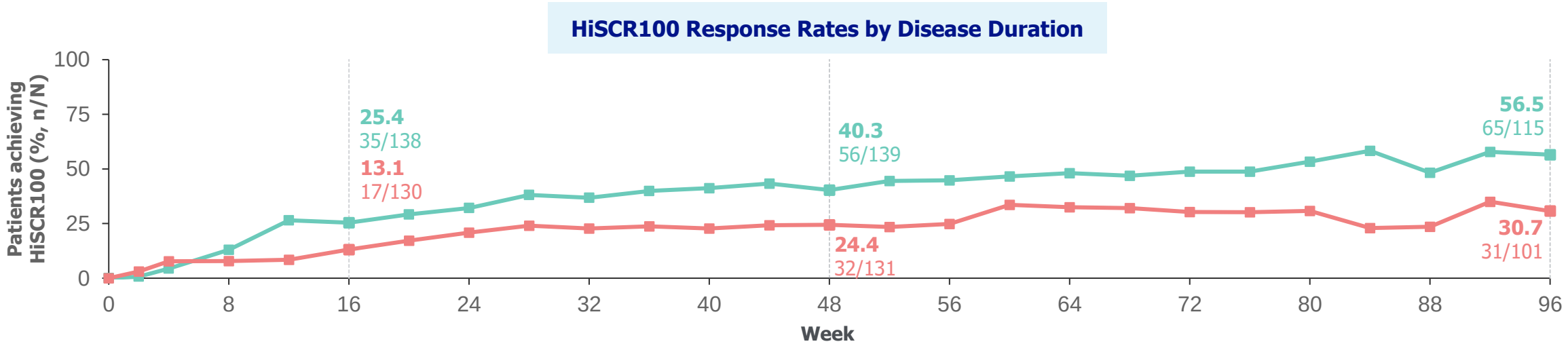


- Most patients achieved HiSCR50/75 by Week 96 in both the **lowest** and **highest** disease duration quartiles.

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. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. Data are stratified by lowest and highest disease duration quartiles; disease duration is calculated from date of diagnosis of HS. BKZ: bimekizumab; HiSCR: HS Clinical Response; HiSCR50/75: ≥50/75% reduction in the total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; OC: observed case; OLE: open-label extension.

HiSCR90/100 Rates by Lowest and Highest Disease Duration Quartiles to Week 96 (OC)





- Achievement of HiSCR90/100 generally increased over time in both the **lowest** and **highest** disease duration quartiles.

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CONCLUSIONS:

Patients treated with bimekizumab demonstrated efficacy at **high HiSCR thresholds,** in the highest and lowest disease duration quartiles, over 2 years.

More patients in the **lowest** disease duration quartile achieved the stringent HiSCR90 and HiSCR100 thresholds, than in the **highest** disease duration quartile.

Patients with shorter disease duration had better outcomes, emphasizing the importance of **early treatment** for patients with moderate to severe hidradenitis suppurativa.

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