Bimekizumab efficacy and safety through 4 years in moderate to severe plaque psoriasis: Long-term results from the BE SURE trial and BE BRIGHT open-label extension

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OBJECTIVE:

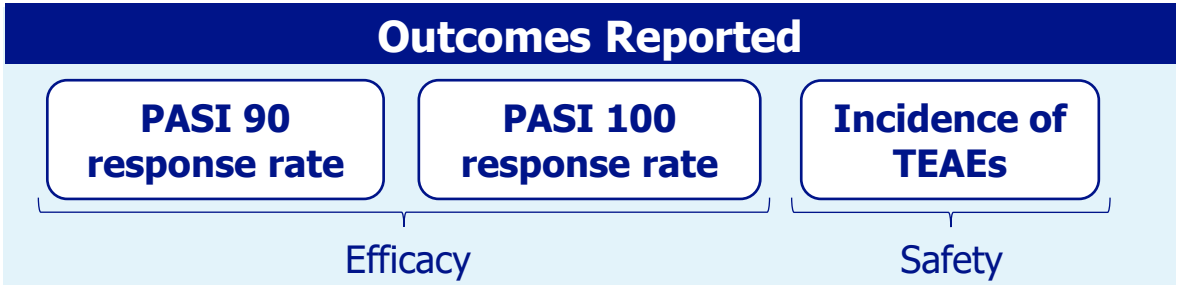
- To evaluate the efficacy, as measured by complete/near-complete skin clearance using the Psoriasis Area and Severity Index (PASI), and long-term safety of bimekizumab (BKZ) in patients with moderate to severe plaque psoriasis through 4 years of treatment.

Background:

- BKZ is a monoclonal IgG1 antibody which selectively inhibits interleukin (IL)-17F in addition to IL-17A.[1]
- Clinical improvements over 3 years, with no unexpected safety findings, were previously reported with BKZ in the BE SURE phase 3 trial and BE BRIGHT open-label extension.[2,3]

Methods:

- Patients who completed the 56-week BE SURE phase 3 trial could enroll in BE BRIGHT open-label extension.
- **Efficacy data are reported through Week 200** by initial randomization treatment groups. Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data (modified non-responder imputation; mNRI).
- **Treatment-emergent adverse events** (TEAEs) occurring whilst receiving BKZ (incidence/100 patient-years [PY]) are reported through Weeks 0–200.



1. Adams R et al. Front Immunol 2020;11:1894; **2.** Thaçi D et al. Br J Dermatol 2023;188:22–31, NCT03412747, NCT03598790; **3.** Thaçi D et al. Presented at EADV 2022, P1572. BKZ: bimekizumab; IL: interleukin; mNRI: modified non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90/100% improvement from baseline in PASI; PY: patient-years; TEAEs: treatment-emergent adverse events.

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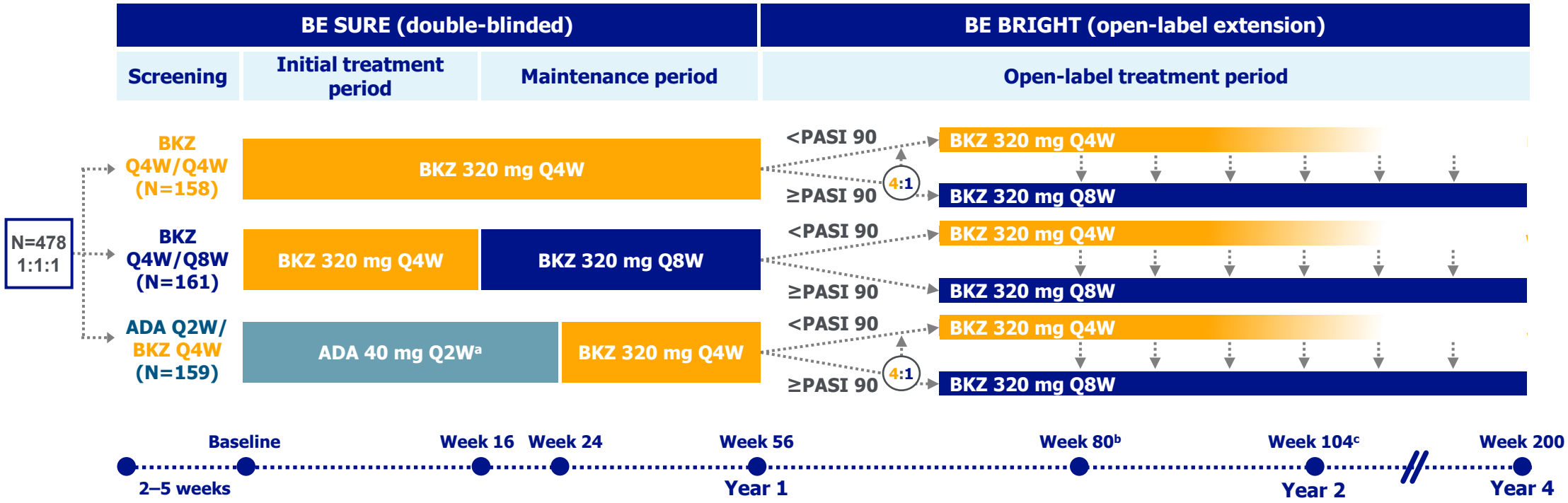
BE SURE and BE BRIGHT Study Design



Patients Included in this Analysis

Safety Analyses

Patients receiving **≥1 dose** of BKZ (**BKZ Total**) and the subset receiving **BKZ Q4W/Q8W/Q8W** (dose approved for most patients)

Efficacy Analyses

Patients randomized to **BKZ Q4W/Q4W, BKZ Q4W/Q8W,** or **ADA Q2W/BKZ Q4W[d]**

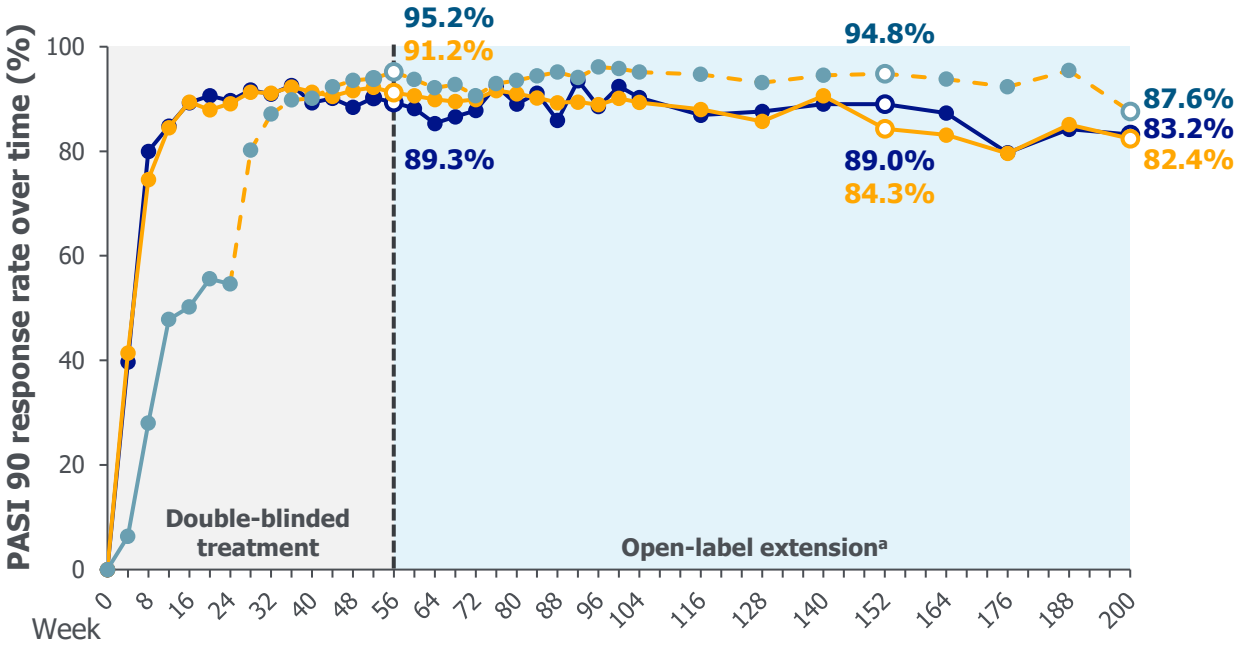
Baseline characteristics have been reported previously and were similar between the groups examined[1]

[a] ADA was dosed 80 mg at Week 0 and 40 mg at Week 1, then every 2 weeks until Week 24, at which point patients were switched to BKZ 320 mg Q4W; **[b]** At Week 80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; **[c]** All patients were switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 104 visit (OLE Week 48) following protocol amendment; **[d]** Patients could have received BKZ Q4W or Q8W on entry to the OLE. **1.** Thaçi D et al. Br J Dermatol 2023;188:22–31, NCT03412747, NCT03598790. ADA: adalimumab; BKZ: bimekizumab; OLE: open-label extension; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity index; Q2W: every 2 weeks; Q4W: every 4 weeks; Q8W: every 8 weeks.

Efficacy: PASI 90 and PASI 100 Response Rate Through Week 200

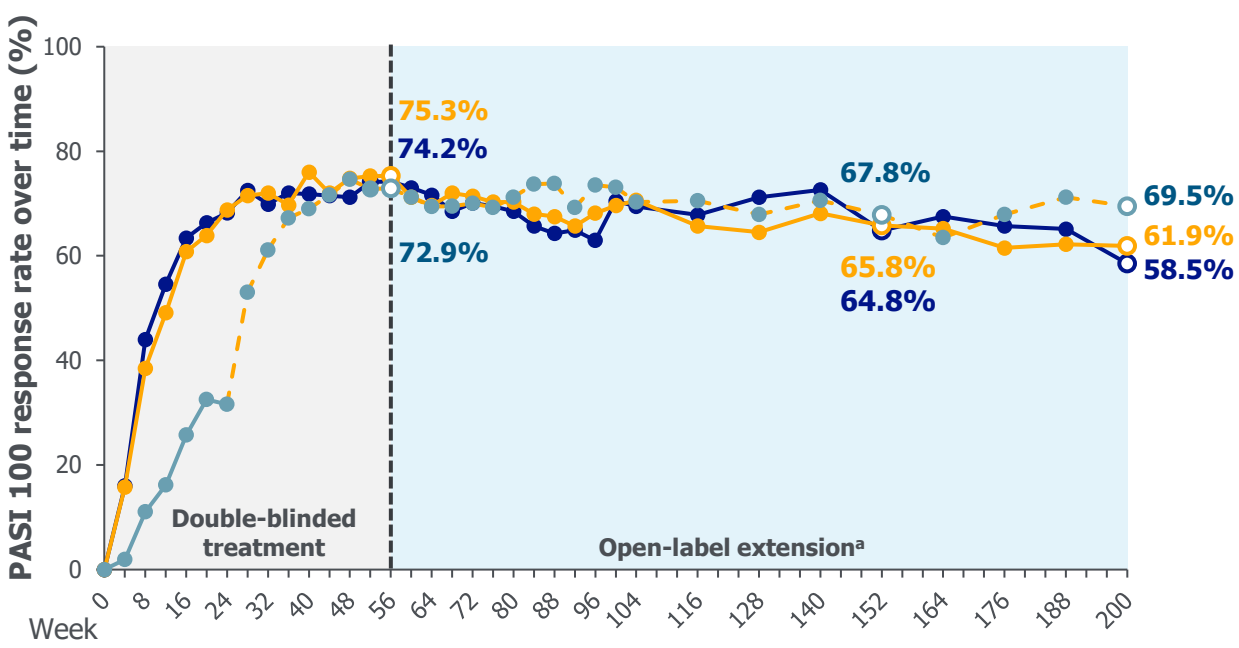
BKZ Q4W/Q4W (N=158) — BKZ Q4W/Q8W (N=161) — ADA/BKZ Q4W (N=159)

PASI 90 (mNRI)



	Year 1	Year 2	Year 3	Year 4
Week	56	104	152	200
BKZ Q4W/Q4W (OC), n/N (%)	134/140 (95.7)	121/129 (93.8)	113/123 (91.9)	107/117 (91.5)
BKZ Q4W/Q8W (OC), n/N (%)	133/143 (93.0)	119/126 (94.4)	111/116 (95.7)	98/109 (89.9)
ADA/BKZ Q4W (OC), n/N (%)	130/133 (97.7)	121/123 (98.4)	113/115 (98.3)	98/104 (94.2)

PASI 100 (mNRI)



	Year 1	Year 2	Year 3	Year 4
Week	56	104	152	200
BKZ Q4W/Q4W (OC), n/N (%)	114/140 (81.4)	102/129 (79.1)	95/123 (77.2)	84/117 (71.8)
BKZ Q4W/Q8W (OC), n/N (%)	113/143 (79.0)	101/126 (80.2)	90/116 (77.6)	78/109 (71.6)
ADA/BKZ Q4W (OC), n/N (%)	106/133 (79.7)	98/123 (79.7)	92/115 (80.0)	84/104 (80.8)

Data presented for all patients initially randomized to receive treatment, by initial randomization group. **[a]** All patients were switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 104 visit (OLE Week 48) following protocol amendment. ADA: adalimumab; BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

Safety: Incidence Rates of TEAEs Through Week 200

Overview of TEAEs[a] EAIR/100 PY (95% CI)	BKZ Total N=468 1,509 PY	BKZ 320 mg Q4W/Q8W/Q8W N=106 392 PY
TEAE Summary		
Any TEAE	139.1 (126.4, 152.6)	149.7 (122.1, 181.8)
Serious TEAEs	4.9 (3.8, 6.2)	4.1 (2.3, 6.7)
Discontinuation due to TEAEs	3.0 (2.2, 4.0)	2.0 (0.9, 4.0)
Drug-related TEAEs	22.9 (20.0, 26.1)	25.8 (19.6, 33.4)
Severe TEAEs	4.6 (3.5, 5.8)	3.7 (2.0, 6.3)
TEAEs leading to death	0.3 (0.1, 0.8)	0.3 (0.0, 1.4)
Most Common TEAEs		
Nasopharyngitis	12.3 (10.3, 14.5)	11.1 (7.6, 15.6)
Oral candidiasis	8.3 (6.8, 10.1)	9.6 (6.4, 13.7)
Upper respiratory tract infection	6.0 (4.8, 7.5)	5.9 (3.6, 9.1)

Safety Topics of Interest EAIR/100 PY (95% CI)	BKZ Total N=468 1,509 PY	BKZ 320 mg Q4W/Q8W/Q8W N=106 392 PY
Infections and infestations	71.9 (64.8, 79.5)	81.6 (65.8, 100.1)
Serious infections	1.2 (0.7, 1.9)	0.8 (0.2, 2.3)
Active tuberculosis	0	0
Fungal infections	14.2 (12.1, 16.6)	13.6 (9.6, 18.6)
Candida infections	9.3 (7.7, 11.2)	10.4 (7.0, 14.7)
Oral candidiasis	8.3 (6.8, 10.1)	9.6 (6.4, 13.7)
Definite or probable adjudicated IBD	0.2 (0.0, 0.6)	0.3 (0.0, 1.4)
Adjudicated suicidal ideation and behavior	0	0
Adjudicated major adverse cardiac event	0.5 (0.2, 1.0)	0.5 (0.1, 1.8)
Malignancies	1.0 (0.6, 1.7)	1.9 (0.7, 3.8)
Any malignancies (excluding NMSC)	0.7 (0.4, 1.3)	1.0 (0.3, 2.6)
Serious hypersensitivity reactions	0.1 (0.0, 0.4)	0
Injection site reactions	1.5 (0.9, 2.3)	2.4 (1.1, 4.6)
Hepatic events	3.4 (2.5, 4.5)	1.6 (0.6, 3.4)
ALT or AST >3x ULN	2.2 (1.5, 3.1)	0.8 (0.2, 2.3)
ALT or AST >5x ULN[b]	0.6 (0.3, 1.1)	0.3 (0.0, 1.4)

Most oral candidiasis events (**99.2%**) were mild or moderate; no cases of oral candidiasis led to discontinuation.

Data cut-off: November 14, 2022. Data were pooled for all patients who randomized ≥1 dose of BKZ throughout the study (BKZ Total). Data are also presented for the subset of these patients who received BKZ Q4W during the initial treatment period, BKZ Q8W during the maintenance treatment period and BKZ Q8W during the OLE period (BKZ Q4W/Q8W/Q8W). **[a]** TEAEs occurring whilst receiving BKZ are reported; **[b]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; NMSC: non-melanoma skin cancer; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

CONCLUSIONS:

- Clinical improvements achieved after one year of bimekizumab treatment were maintained through 4 years.
- Efficacy outcomes improved in adalimumab-treated patients who switched to bimekizumab at Week 24 and high responses were durable to Week 200.
- Bimekizumab was well-tolerated through Week 200 and no new safety signals were identified with longer exposure, including in the subset of patients who received the bimekizumab dosing regimen approved for most patients (Q4W/Q8W/Q8W).

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **DT**, **LP**, **JFM**, **DJ**, **AC**, **MW**, **DD**, **JMLP**, **ML**; Drafting of the publication, or reviewing it critically for important intellectual content: **DT**, **LP**, **JFM**, **DJ**, **AC**, **MW**, **DD**, **JMLP**, **ML**; Final approval of the publication: **DT**, **LP**, **JFM**, **DJ**, **AC**, **MW**, **DD**, **JMLP**, **ML**. **Disclosures: DT:** Served as an investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galapagos, Galderma, Janssen, Kyowa Kirin, LEO Pharma, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, Target-Solution, and UCB Pharma; received grants from AbbVie, LEO Pharma, and Novartis. **LP:** Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Baxalta, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Gebro, Janssen, JS BIOCAD, LEO Pharma, Merck Serono, MSD, Mylan, Novartis, Pfizer, Regeneron, Roche, Samsung Bioepis, Sandoz, Sanofi-Genzyme, and UCB Pharma. **JFM:** Consultant and/or investigator for AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Pfizer, Novartis, Regeneron, Sanofi, Sun Pharma, and UCB Pharma. **DJ:** Served as a board member and/or consultant for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Fresenius Kabi, Janssen, LEO Pharma, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB Pharma; received payment for development of educational presentations including service on speakers' bureaus from AbbVie, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, MEDAC, Novartis, Pfizer; and travel/accommodations expenses covered or reimbursed by AbbVie, Amgen, Biogen, Celgene, Eli Lilly and Company, Fresenius Kabi, Janssen, LEO Pharma, MEDAC, MSD, Novartis, Pfizer, Sanofi, and UCB Pharma. **AC:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sandoz, Sanofi, and UCB Pharma. **MW, DD, JMLP:** Employees and shareholders of UCB Pharma. **ML:** Employee of Mount Sinai and receives research funds from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Incyte, Inozyme, Janssen, LLC, Ortho Dermatologics, Sanofi-Regeneron, and UCB Pharma; consultant for Almirall, AltruBio Inc., AnaptysBio, Arcutis, AstraZeneca, Avotres, Boehringer Ingelheim, Brickell Biotech, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, EPI, Evommune Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, Strata, Trevi, and Verrica.

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Q4W: every 4 weeks; Q8W: every 8 weeks.