Slides for public – Part 1 [redacted]

Committee presentation

Risankizumab for treating moderate to severe plaque psoriasis

1st Appraisal Committee meeting - Fast track appraisal (FTA)

Committee B

Chair: Sanjeev Patel

NICE technical team: Iordanis Sidiropoulos, Eleanor Donegan

ERG: Aberdeen Health Technology Assessment (HTA) Group

30 May 2019

[redacted]

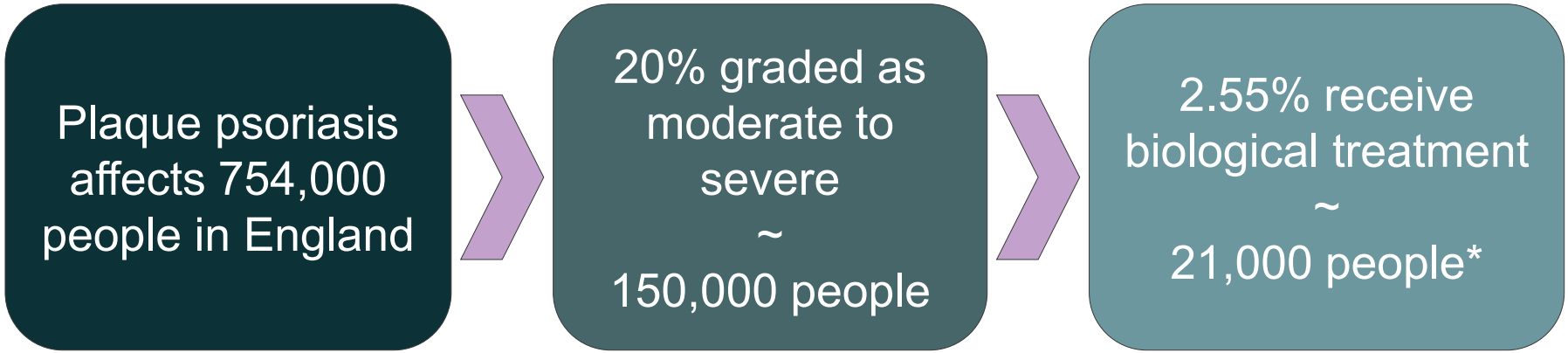
Key issues

- **Company has proposed this appraisal follow the fast track appraisal (FTA) process (cost comparison) based on risankizumab having similar health benefits to guselkumab (technology appraisal guidance 521 - TA521).**
- Is guselkumab a relevant comparator?
- Are the health benefits and safety of risankizumab and guselkumab similar?
- Does risankizumab have similar resource requirements to guselkumab?
- Is it reasonable to recommend risankizumab in the same way as guselkumab?

[redacted]

Plaque psoriasis - disease background

- Chronic inflammatory condition characterised by flaky, scaly, itchy and red plaques on skin
- Varies in severity and distribution ranging from small patches on the elbows and knees to almost complete body coverage
- Unpredictable, relapsing and remitting course
- Associated with comorbidities such as depression, anxiety, arthritis, cardiovascular disease
- Graded as mild, moderate or severe (based on location, area affected, severity of lesions and impact on individual)
- Population:



*NICE Clinical guideline [CG153]

Patient and clinical perspective

Distressing and debilitating, need for a range of highly effective convenient treatments with minimal adverse reactions and impact on lifestyle

Impact of psoriasis

psoriasis is a relapsing/remitting life-long disease that often starts in teenage years and can last well into old age

itch is an under-treated / reported aspect of psoriasis that causes great distress to patients

People would like

consideration of high-impact and difficult-to-treat sites such as palms, soles, flexures, genitals

consideration to people who have received all biological therapies and then had treatment failure

Risankizumab

p19 inhibitors have a new mechanism of action and may offer improved effectiveness (particularly clearance which is very important to patients) and prolonged action

Patient, professional organisation and expert submissions

- Guselkumab is one of the first line biological treatment options for eligible patients with plaque psoriasis without psoriatic arthritis and therefore a relevant comparator
- The choice of subsequent drug treatments in patients who have discontinued risankizumab is **not** expected to differ substantially compared with patients who have discontinued guselkumab
- Risankizumab's dosage frequency during maintenance (once every 12 weeks) is **not** expected to have a significant impact on patients' compliance compared to guselkumab (once every 8 weeks)
- Majority of biological treatments administered at home
- The psoriasis area and severity index (PASI) may underestimate disease severity in people with darker skin (type IV-VI) as redness may be less evident (a key component of the PASI).

[redacted]

Company's positioning of risankizumab

1st

Topical therapy
corticosteroid, vitamin D, vitamin D analogues, coal tar

2nd

Phototherapy

3rd

Systemic non-biological therapy
methotrexate, ciclosporin, acitretin

4th

Systemic biological therapy
Severe (PASI ≥10 & DLQI >10)
adalimumab (TA146)
etanercept (TA103)
ixekizumab (TA442)
secukinumab (TA350)
ustekinumab (TA180)
brodalumab (TA511)
tildrakizumab (TA575)
certolizumab pegol (TA574)
guselkumab (TA521)
Very severe (PASI ≥20 & DLQI >18)
infliximab (TA134)

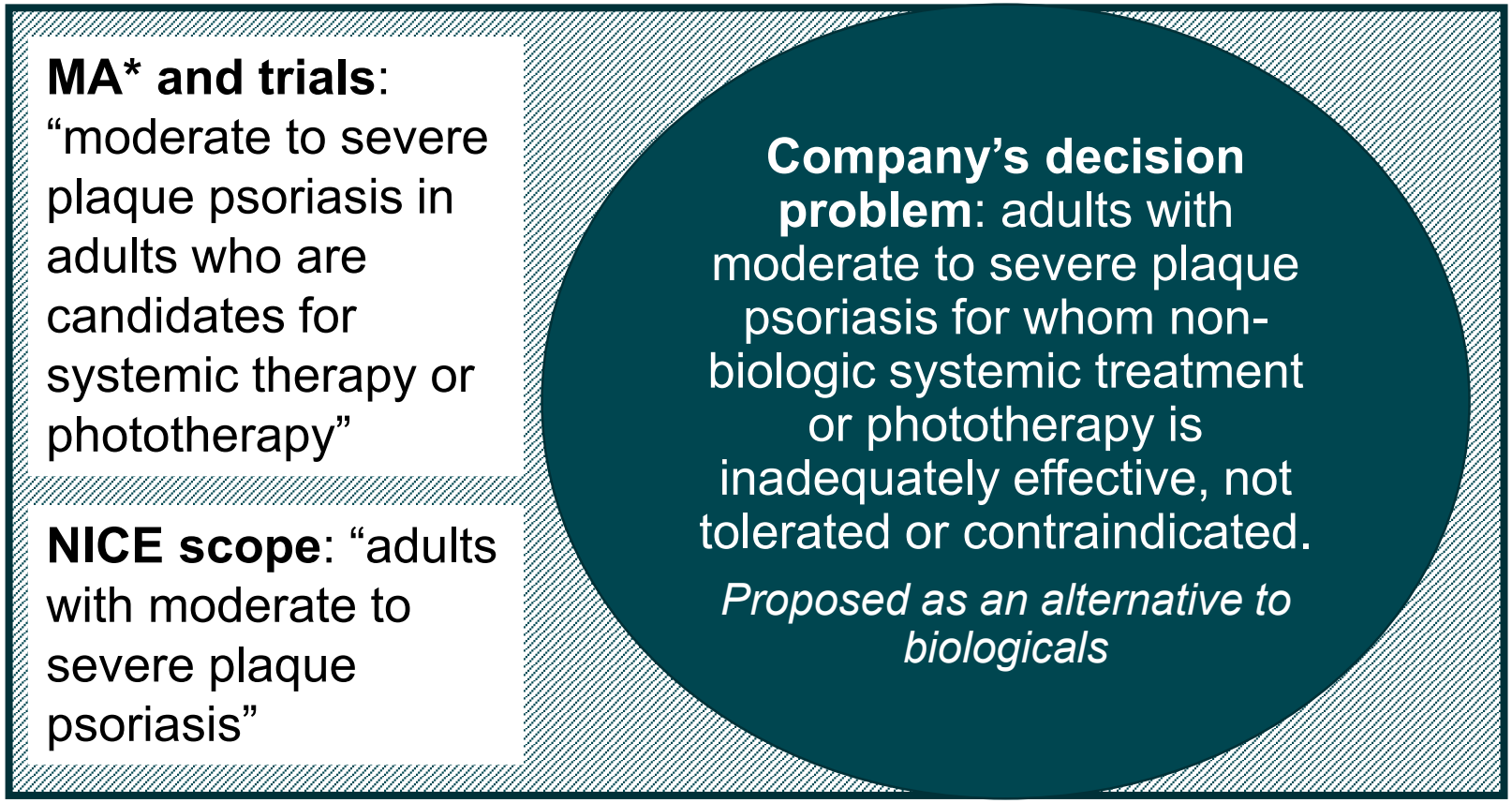
Risankizumab
Proposed as an alternative to systemic biologicals

Severe (PASI ≥10 & DLQI >10)
apremilast (TA419)
dimethyl fumarate (TA475)

BSC

Best supportive care

Decision problem – population



- **The population in the submission is narrower than the population in the scope, the MA and the risankizumab trials and in line with previous NICE appraisals including TA521**

*MA: Marketing authorization

The technologies

	Risankizumab	Guselkumab
Mechanism of action	Immunoglobulin G1 monoclonal antibody binding to the p19 subunit of interleukin-23	
Marketing authorisation	…indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy	
Posology and method of administration	• 150 mg (two 75 mg injections) administered by subcutaneous injection at weeks 0, 4 and every 12 weeks onwards • A treatment-specific stopping rule is applied in patients who have shown no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.	• 100mg administered by subcutaneous injection at weeks 0,4 and every 8 weeks onwards • 'Consideration should be given to discontinuing treatment in patients who have shown no response after **16 weeks** of treatment.'
Monitoring	• Tuberculosis (TB) monitoring (pre-treatment evaluation and monitoring for active TB during and after treatment) • Monitoring of psoriasis response to treatment	

[redacted]

Choice of comparator for cost comparison

- **Guselkumab received a positive recommendation for severe plaque psoriasis (TA521) based on a cost-comparison with ixekizumab and secukinumab**.
  - (PASI ≥10 & DLQI >10) in people not responsive to systemic therapy
  - Assessment at 16 weeks. Treatment continued if PASI 75 OR PASI 50 and 5 point reduction in DLQI
- Network meta-analysis (TA521): Guselkumab is comparable to NICE-recommended treatments for severe plaque psoriasis. Comparable PASI75, PASI90 and PASI100 to ixekizumab and PASI 100 to secukinumab. Better responses than other biologics.
- Costs of guselkumab similar/lower than to secukinumab and ixekizumab in TA521.
- Market share of guselkumab is likely to be low (recent launch 09/2018)
- Clinical expert statement confirms that it is part of established practice and notes that costs and effectiveness are similar to other biological treatments.
- ERG considers the company's rationale for choosing guselkumab to be acceptable.
- ERG agrees that because guselkumab was approved on the basis of a cost-comparison with ixekizumab and secukinumab, a further cost comparison between risankizumab, ixekizumab and secukinumab is not required in the current appraisal

Abbreviations: PASI: Psoriasis area and severity index; DLQI: Dermatology Life Quality Index, ERG: Evidence Review Group

Clinical effectiveness

- Clinical evidence was presented comparing risankizumab:
  - Head-to-head vs ustekinumab and adalimumab:
    - UltIMMa1, UltIMMa2 (risankizumab vs placebo and ustekinumab)
    - IMMvent (risankizumab vs adalimumab)
    - IMMhance (risankizumab vs placebo)
  - Naïve direct comparison of the risankizumab and guselkumab trials
  - Adjusted indirect comparisons vs all biologics including guselkumab
- Risankizumab and guselkumab have not been studied in head-to-head randomised controlled trials.

[redacted]

Risankizumab trials (vs placebo and ustekinumab)

UltIMMa-1 and UltIMMa-2

Design: 52-week, multi-centre, multi-national, double-blind, double dummy, with patients randomised in a ratio of 3:1:1 to risankizumab, ustekinumab, and placebo.

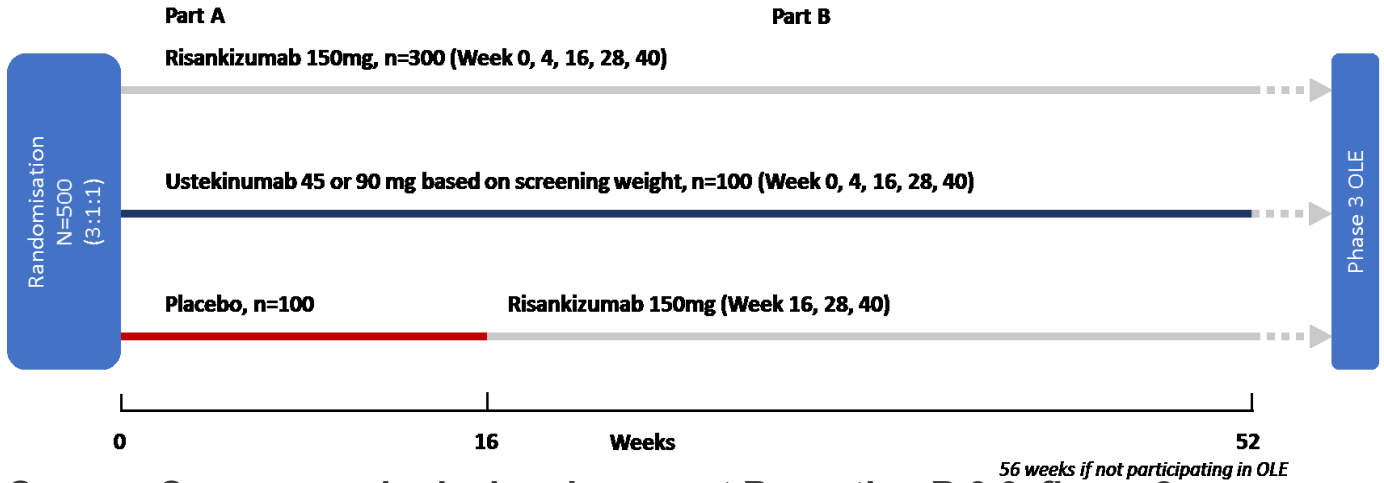
Population: 997 patients aged ≥18 years with stable moderate-to-severe (body surface area (BSA) ≥10%, a PASI ≥12 and sPGA ≥3) plaque psoriasis of ≥ 6 months duration who were candidates for systemic therapy or phototherapy.

Intervention: Risankizumab 150mg SC at weeks 0, 4 and then every 12 weeks

Comparators: Ustekinumab at week 0, 4 and then every 12 weeks, Placebo at week 0 and 4 followed by risankizumab 150mg SC at week 16, 28 and 40

Primary outcomes: PASI90 at week 16 vs placebo and sPGA0/1 at week 16 vs placebo
Secondary outcomes: Other PASI responses including PASI75, sPGA scores, DLQI

Abbreviations: PASI: Psoriasis area and severity index; SC: Subcutaneous; sPGA: static Physician's Global Assessment, DLQI: Dermatology Life Quality Index



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Source: Company submission document B, section B.3.3, figure 2

Risankizumab trial results: UltIMMa-1 and UltIMMa-2

- Both trials achieved both co-primary endpoints (PASI 90 and sPGA 0/1) at week 16 vs placebo and all ranked secondary endpoints (PASI 75, PASI 100, sPGA 0, DLQI 0/1) at 16 and 52 weeks (p<0.001 for all endpoints).

	UltIMMa-1						**UltIMMa-2**					
	Week 16			**Week 52**			**Week 16**			**Week 52**		
	PBO N=102	UST N=100	RZB N=304	PBO→ RZB N=97	UST N=100	RZB N=304	PBO N=98	UST N=99	RZB N=294	PBO→ RZB N=94	UST N=99	RZB N=294
PASI 75, n (%)	* 10 (9.8)	* 70 (70.0)	* 264 (86.8)	90 (92.8)	70 (70.0)	279 (91.8)	* 8 (8.2)	* 69 (69.7)	* 261 (88.8)	87 (92.6)	76 (76.8)	269 (91.5)
PASI 90, n (%)	**5 (4.9)**	**42 (42.0)**	**229 (75.3)**	76 (78.4)	44 (44.0)	249 (81.9)	**2 (2.0)**	**47 (47.5)**	**220 (74.8)**	80 (85.1)	50 (50.5)	237 (80.6)
PASI 100, n (%)	0 (0.0)	12 (12.0)	109 (35.9)	53 (54.6)	21 (21.0)	171 (56.3)	2 (2.0)	24 (24.2)	149 (50.7)	63 (67.0)	30 (30.3)	175 (59.5)
sPGA score 0/1, n (%)	**8 (7.8)**	**63 (63.0)**	**267 (87.8)**	88 (90.7)	54 (54.0)	262 (86.2)	**5 (5.1)**	**61 (61.6)**	**246 (83.7)**	82 (87.2)	54 (54.5)	245 (83.3)
sPGA score 0, n (%)	2 (2.0)	14 (14.0)	112 (36.8)	53 (54.6)	21 (21.0)	175 (57.6)	3 (3.1)	25 (25.3)	150 (51.0)	63 (67.0)	30 (30.3)	175 (59.5)
DLQI score 0/1, n (%)	8 (7.8)	43 (43.0)	200 (65.8)	60 (61.9)	47 (47.0)	229 (75.3)	4 (4.1)	46 (46.5)	196 (66.7)	64 (68.1)	44 (44.4)	208 (70.7)

***PASI 75 ranked secondary endpoint was measured at week 12, In bold the co-primary endpoints**
Source: Company submission document B, section B.3.6, table 8, pp 60
Abbreviations: PBO: placebo, UST: ustekinumab, RZB: risankizumab, PASI: Psoriasis area and severity index; SC: Subcutaneous; sPGA: static Physician's Global Assessment, DLQI: Dermatology Life Quality Index, AE: adverse event

Risankizumab trials (vs placebo and adalimumab)

IMMvent	IMMhance
Design: 44-week, multi-centre, double-blind, double-dummy study with patients randomised in a ratio of 1:1 to risankizumab or adalimumab. At week 16 patients on adalimumab continued or switched treatment based on response: <PASI 50 switched to risankizumab, PASI 50 to <PASI 90 were re-randomised, PASI 90 continued to receive adalimumab **Population***: N=605 patients **Intervention/Comparators:** risankizumab, adalimumab **Primary outcomes**: PASI90 at week 16, sPGA0/1 at week 16, PASI 90 at week 44 on the re-randomized cohort **Secondary outcomes:** Other PASI responses including PASI75, sPGA scores, DLQI	**Design:** 104-week, multi-centre, double-blind, study with patients randomised in a ratio of 4:1 to risankizumab or placebo. Patients originally on placebo switched to risankizumab at week 16. Patients originally on risankizumab and with a sPGA response of clear or almost clear at week 28 were re-randomised to continue risankizumab or to receive placebo. **Population***: N=507 patients **Intervention/Control:** risankizumab, placebo **Primary outcomes**: PASI90 at week 16, sPGA0/1 at week 16, sPGA0/1 at week 52 on the re-randomized cohort **Secondary outcomes:** Other PASI responses including PASI75, sPGA scores, DLQI

***Eligibility criteria as in UltIMMa trials.**

Abbreviations: PASI: Psoriasis area and severity index; sPGA: static Physician's Global Assessment, DLQI: Dermatology Life Quality Index, AE: adverse event

Risankizumab trial results: IMMvent

Risankizumab (RZB) demonstrated superior response rates (p<0.001) in PASI 75, PASI 90, PASI 100, sPGA 0/1, sPGA 0 and DLQI 0/1 at week 16 compared to adalimumab (ADA)

IMMvent	Week 16	
	ADA N=304	RZB N=301
PASI 75, n/N (%)	218 (71.7)	273 (90.7)
PASI 90, n/N (%)	**144 (47.4)**	**218 (72.4)**
PASI 100, n/N (%)	70 (23.0)	120 (39.9)
sPGA score 0/1, n (%)	**183 (60.2)**	**252 (83.7)**
sPGA score 0, n (%)	71 (23.4)	124 (41.2)
DLQI 0/1, n (%)	148 (48.7)	198 (65.8)

*in bold the co-primary endpoints, Source: Company submission document B, section B.3.6, table 9, pp71

[redacted]

IMMvent	Week 44
PASI 75, n/N (%)	[redacted]
PASI 90, n/N (%)	
PASI 100, n/N (%)	
sPGA score 0/1, n (%)	
sPGA score 0, n (%)	
DLQI 0/1, n (%)	

Source: Company submission document B, section B.3.6, table 9, pp71

Risankizumab trial results: IMMhance

- Risankizumab achieved all primary endpoints. It demonstrated superior response rates in PASI 75, PASI 90, PASI 100, sPGA 0/1, sPGA 0 and DLQI 0/1 at week 16 compared to placebo (p<0.001 for all endpoints).
- Following re-randomization at week 28, 87.4% of patients continuing risankizumab achieved sPGA 0/1 (87.4%) at week 52 compared to 61.3% of those re-randomised to placebo (p<0.001).

IMMHANCE	Week 16		Week 52
	PBO N=100	RZB N=407	
PASI 75, n/N (%)	8 (8.0)	361 (88.7)	
PASI 90, n/N (%)	**2 (2.0)**	**298 (73.2)**	
PASI 100, n/N (%)	1 (1.0)	192 (47.2)	
sPGA score 0/1, n (%)	**7 (7.0)**	**340 (83.5)**	
sPGA score 0, n (%)	1 (1.0)	189 (46.4)	
DLQI score 0/1, n (%)	3 (3.0)	266 (65.4)	

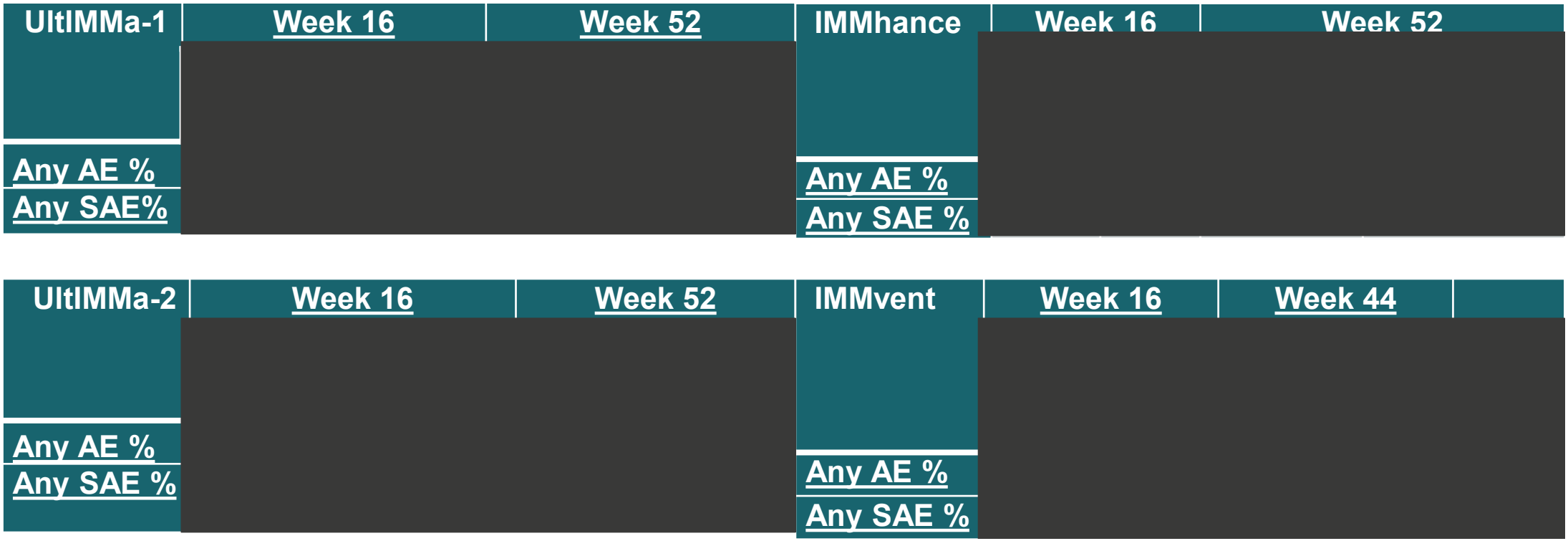
Source: Company submission document B, section B.3.6, table 10, pp 75

*In bold the co-primary endpoints

Abbreviations: DLQI: Dermatology Life Quality Index; NA: Not Available; PASI: Psoriasis Area and Severity Index; sPGA: static Physician Global Assessment; PBO: Placebo; RZB: Risankizumab

Risankizumab: safety profile

- Clinical trial data suggest that risankizumab has a comparable safety profile to controls.
- ERG is of the opinion that the overall incidence and types of adverse events for risankizumab were within expected ranges.



Sources: Company submission, Document B, table 16-19, Company clarification responses.

Abbreviations: PASI: Psoriasis area and severity index, sPGA: static Physician's Global Assessment, DLQI: Dermatology Life Quality Index, AE: adverse event, AE: adverse event, SAE: serious adverse event, WDAE: Withdrawal due to adverse events, ADA: Adalimumab, RZB: Risankizumab, PBO: placebo, UST: ustekinumab

Critique of risankizumab trials

External validity: The population in the risankizumab trials consists of around XXX of participants naïve to prior systemic non-biologic treatment or prior phototherapy (i.e. outside the population as defined in the decision problem).

- The company argues that baseline characteristics of the patients in the risankizumab trials are broadly similar to those initiated on adalimumab in the BADBIR registry in terms of PASI, DLQI, BSA involvement, demographics.
- Similarly, in the guselkumab trials (VOYAGE 1 and 2) approximately 40% had not had prior phototherapy or non-biologic systemic agents.
- Subgroup analyses by prior treatment are consistent with the intention to treat analysis results in the risankizumab trials.
- **The ERG accepts that the trial results are generalisable to NHS eligible population**

Internal validity: The ERG expresses no concerns regarding the internal validity of the risankizumab trials.

Abbreviations: PASI: Psoriasis area and severity index, DLQI: Dermatology Life Quality Index, BSA: body surface area, ITT: intention to treat, BADBIR: British Association of Dermatologists Biologics and Immunomodulators Register, ERG: Evidence Review Group

Company naïve comparison: risankizumab vs guselkumab

- Common comparator (adalimumab) in risankizumab (IMMvent) and guselkumab (VOYAGE-1 and VOYAGE-2) trials.
- Baseline characteristics in IMMvent, VOYAGE-1 and VOYAGE-2 comparable.
- Unadjusted week 16 PASI and sPGA adalimumab response rates comparable.
- Unadjusted week 16 PASI and sPGA risankizumab and guselkumab response rates comparable.

	Week 16					
	IMMvent		VOYAGE-1		VOYAGE-2*	
	ADA N=304	RZB N=301	ADA N=329	GUS N=334	ADA N=248	GUS N=496
PASI 75 (%)	71.7	90.7	73.1	91.2	68.5	86.3
PASI 90 (%)	47.4	72.4	49.7	73.3	46.8	70.0
PASI 100 (%)	23.0	39.9	17.1	37.4	20.6	34.1
sPGA 0/1 (%)	60.2	83.7	65.9	85.1	67.7	84.1
sPGA 0 (%)	23.4	41.2	26.3	47.7	28.6	43.3

Source: Company submission document B, section B.3.6, table 10

Abbreviations: PASI: Psoriasis area and severity index, sPGA: static Physician's Global Assessment

[redacted]

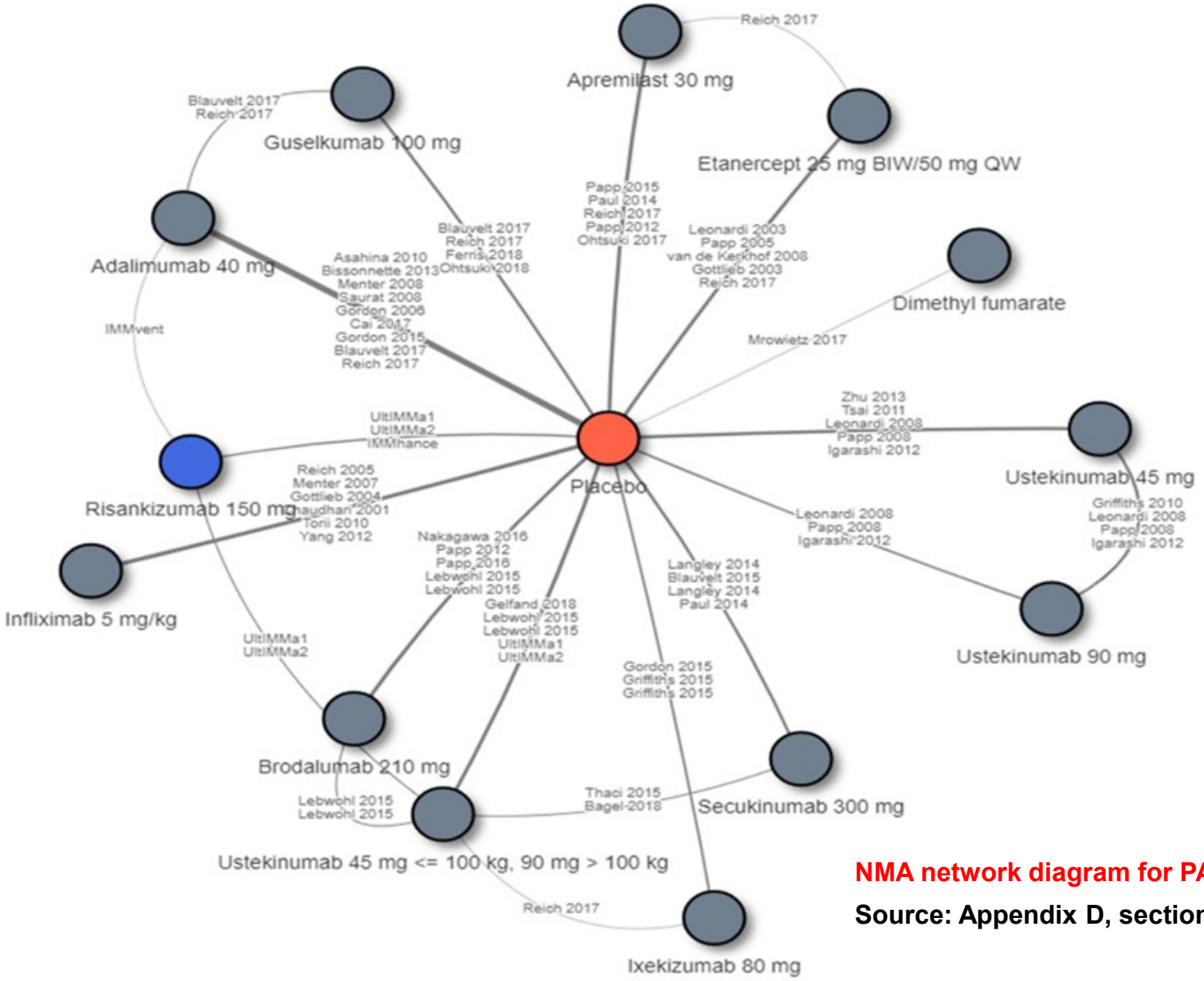
Company's network meta-analysis (NMA)

- A series of NMAs were performed for the following outcomes:
  - PASI (PASI 50, 75, 90, 100),
  - safety (AEs, SAEs, WDAEs)
  - health related quality of life (DLQI) outcomes.
- 53 trials included in the week 16 PASI response NMA
- Low heterogeneity between studies
- Fixed and random effect models were compared
- Random effects model was considered more appropriate as it fitted the data better than the fixed effects model

- ERG considers that overall the search strategy and the methodological quality of the RCTs included in the NMA is acceptable
- ERG agrees with the use of a random effects model and accepts that heterogeneity across studies is low.
- ERG is overall satisfied with the methods used for NMA and the interpretation of its results

Abbreviations: PASI: Psoriasis area and severity index, DLQI: Dermatology Life Quality Index, ERG: Evidence Review Group, AE: adverse event, AE: adverse event, SAE: serious adverse event, WDAE: Withdrawal due to adverse events

Company's network meta-analysis (NMA)



NMA network diagram for PASI response at 16 weeks

Source: Appendix D, section D.1.1.10 , figure 3

Company NMA results: risankizumab vs guselkumab

- Company reported probabilities of all biologics used in the NHS reaching each endpoint
- Risankizumab appears to be consistently similar to guselkumab across PASI endpoints with overlapping credible intervals.
- Risankizumab consistently offers comparable or greater clinical efficacy in terms of PASI response versus alternative biologics used in NHS practice.

Week 10-16	PASI 50		PASI 75		PASI 90		PASI 100	
Treatment	Median	(95% CrI)	Median	(95% CrI)	Median	(95% CrI)	Median	(95% CrI)
Guselkumab 100 mg								
Risankizumab 150 mg								

Source: Company submission document B, section B.3.9.8, table 15, pp88

ERG concludes that risankizumab is superior to several of the other biological treatments and comparable in terms of clinical effectiveness to guselkumab.

Abbreviations: PASI: Psoriasis area and severity index, ERG: Evidence Review Group

Company NMA results for all biological agents

Week 10-16	PASI 50	PASI 75	PASI 90	PASI 100
Etanercept				
Adalimumab				
Ustekinumab				
Infliximab				
Secukinumab				
Ixekizumab				
Brodalumab				
Guselkumab				
Risankizumab				

Source: Company submission document B, section B.3.9.8, table 15, pp88

Company NMA results: risankizumab vs guselkumab

DLQI and safety outcomes

- Risankizumab offers comparable improvement in DLQI 0/1 outcome at week 10-16 compared to guselkumab and comparable safety outcomes (AE, SAE, WDAE).
- Risankizumab is similarly effective at inducing a DLQI 0/1 when compared to most biologics, including guselkumab
- Risankizumab has a similar or slightly improved safety profile compared to other biologics

Week 10-16	DLQI 0/1		Any AE		Any SAE		WDAE	
Treatment	Median	(95% CrI)	Median	(95% CrI)	Median	(95% CrI)	Median	(95% CrI)
Guselkumab 100 mg								
Risankizumab 150 mg								

Source: Company submission appendices, Appendix D.1.1.16.2, tables 20-28

ERG concludes that risankizumab is likely to offer similar benefits to guselkumab with a similar safety profile.

Abbreviations: PASI: Psoriasis area and severity index, AE: adverse event, SAE: serious AE, WDAE: withdrawal due to adverse events, ERG: Evidence Review Group, DLQI: Dermatology Life Quality Index

Long term results: risankizumab vs guselkumab

- Long term (weeks 44 – 60) PASI responses were also similar.

Week 44-60	PASI 50		PASI 75		PASI 90		PASI 100	
Treatment	Response rate	(95% CI)	Response rate	(95% CI)	Response rate	(95% CI)	Response rate	(95% CI)
Guselkumab 100mg								
Risankizumab 150mg								

Source: Company submission appendices, Appendix D. 1.1.16.1, tables 20-28, table 18

ERG concludes that risankizumab is superior to several of the other biological treatments and comparable in terms of clinical effectiveness to guselkumab.

Abbreviations: PASI: Psoriasis area and severity index, Evidence Review Group

Resource use assumptions

Company resource use assumptions

- Healthcare resource costs assumed to be similar to guselkumab and excluded from the cost comparison (only acquisition costs considered).
  - Similar posology and method of administration
    - **But different dosage frequency. Risankizumab once every 12 weeks, guselkumab once every 8 weeks.**
  - Similar monitoring
  - Comparable safety profile
- Home self administration after suitable training (same as guselkumab guidance)

- ERG expresses no major concerns about company's resource use assumptions.

Company cost-comparison model

- Costs are estimated over a ten-year time horizon
- Model includes a 16 week induction phase
- Those who achieve PASI 75 at week 16 are assumed to go on to a maintenance phase
- Those who do not achieve the response stop treatment and no further costs are incurred for these patients in the model
- The 16-week response rate is based on the16-week PASI 75 response rate for risankizumab from the NMA ([redacted]) for both risankizumab and guselkumab in the base case (i.e. equal efficacy at week 16 assumed)
- Equal probability (20% per year in the base case) of long term discontinuation assumed

Abbreviations: PASI: Psoriasis area and severity index, NMA: network meta-analysis

Discontinuation rates

- Same discontinuation rate during maintenance (20% in base case) was assumed for both risankizumab and guselkumab in line with previous appraisals (TA521). But:
  - NMA for withdrawal due to AEs is [redacted]
  - Discontinuation rates with risankizumab may be lower than guselkumab because of improved adherence arising from differences in administration (12 weekly vs. 8 weekly respectively). Clinical expert notes that this is not likely.
- Patients in clinical practice discontinuing either drug would likely switch to another one. ERG and clinical expert note that there is no reason to expect the choice of subsequent drug treatments to differ substantially between risankizumab and guselkumab.

Abbreviations: AE: adverse event, ERG: Evidence Review Group, NMA: network meta-analysis

Company submission: cost comparison

Technologies	Acquisition costs (£)	Resource costs (£)	Adverse event costs (£)	Other costs (£)	TOTAL COSTS (£)
Risankizumab (list price)	£58,868	N/A	N/A	N/A	£58,868
Guselkumab (list price)	£58,048	N/A	N/A	N/A	£58,048
Difference	£820	N/A	N/A	N/A	£820
Time horizon: 10 years					

Both risankizumab and guselkumab have patients access schemes. The cost comparison based on PAS prices will be considered in a closed session.

[redacted]

Innovation

Consultee comments:

- **Company**: The dosing schedule is convenient compared to comparators (every 12 weeks vs 8 weeks for guselkumab for example)
- **British Association of Dermatologists**: p19 inhibitors are considered to be a 'step change' in terms of mechanism of action, specificity, effectiveness (particularly clearance which is very important to patients) and prolonged action
- **Psoriasis and Psoriatic Arthritis Alliance**: there are other similar targeted therapies now

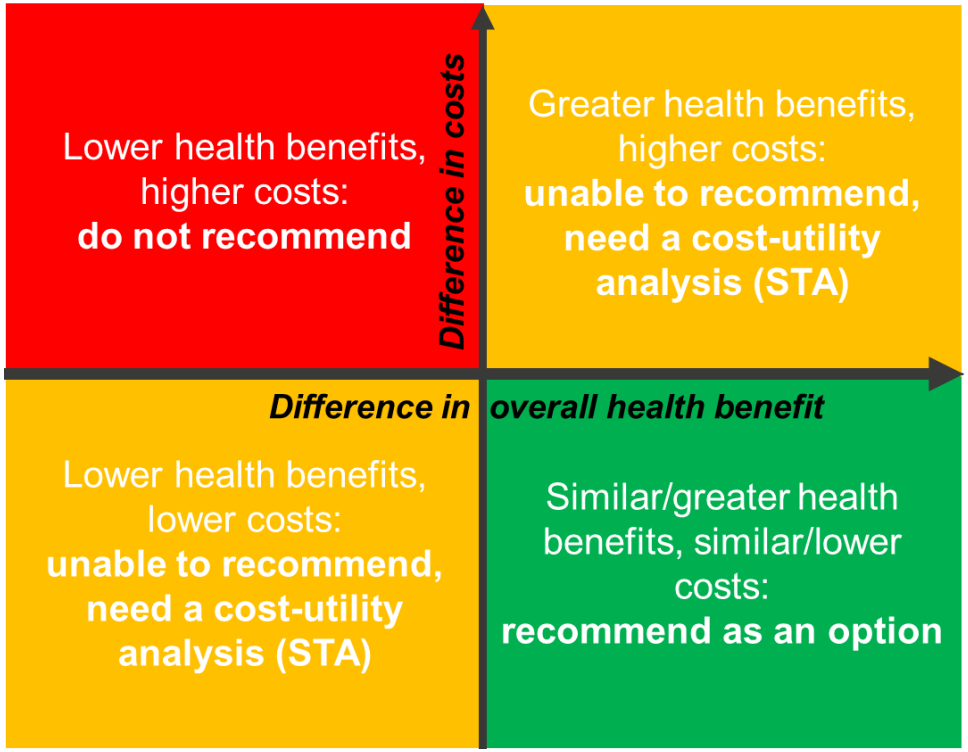
Equality

Consultee comments:

- PASI may underestimate disease severity in people with darker skin as redness may be less evident (a component of PASI)
- DLQI will underestimate impact in people who are not sexually active, or older (retired) or socially isolated; it does not capture anxiety and depression

Abbreviations: PASI: Psoriasis area and severity index, DLQI: Dermatology Life Quality Index

Potential recommendations: cost comparison



What is the committee view on:

- the choice of comparator
- the similarity of health benefits and safety of risankizumab and guselkumab
- discontinuation rates during maintenance for the cost calculation
- the exclusion of administration and adverse events costs

Is it reasonable to recommend risankizumab in the same way as guselkumab?

[redacted]

End of Part 1