Galápagos

Darwin2

DARWIN 2
Final filgotinib monotherapy results

11 August 2015

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Galapagos at a glance

5 key aspects

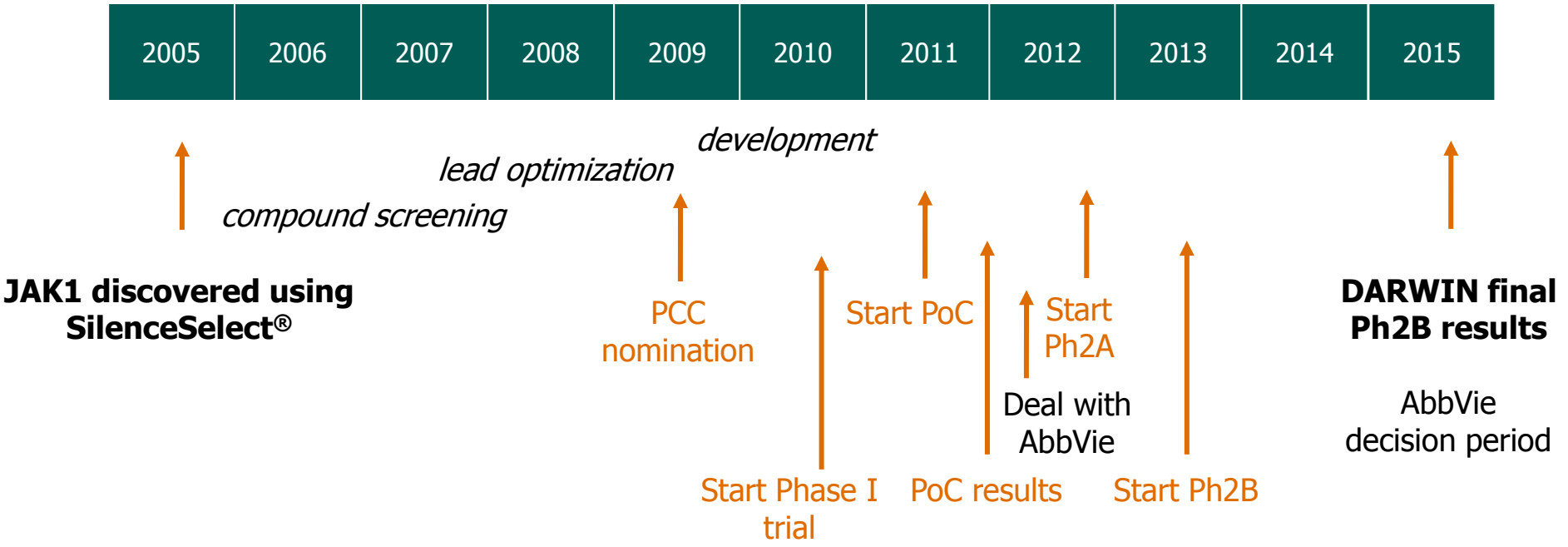
1. Filgotinib: first-in-class oral in RA
2. Transformational CF therapies
3. Fully-owned Ph2 programs in IBD/IPF
4. Platform to fill pipeline
5. Strong financials & partnerships

What are patients looking for in RA treatment?

- Oral administration
- Highly efficacious on patient relevant parameters (ACR50, ACR70, DAS28 remission)
- Rapid onset of action
- Safe & well tolerated

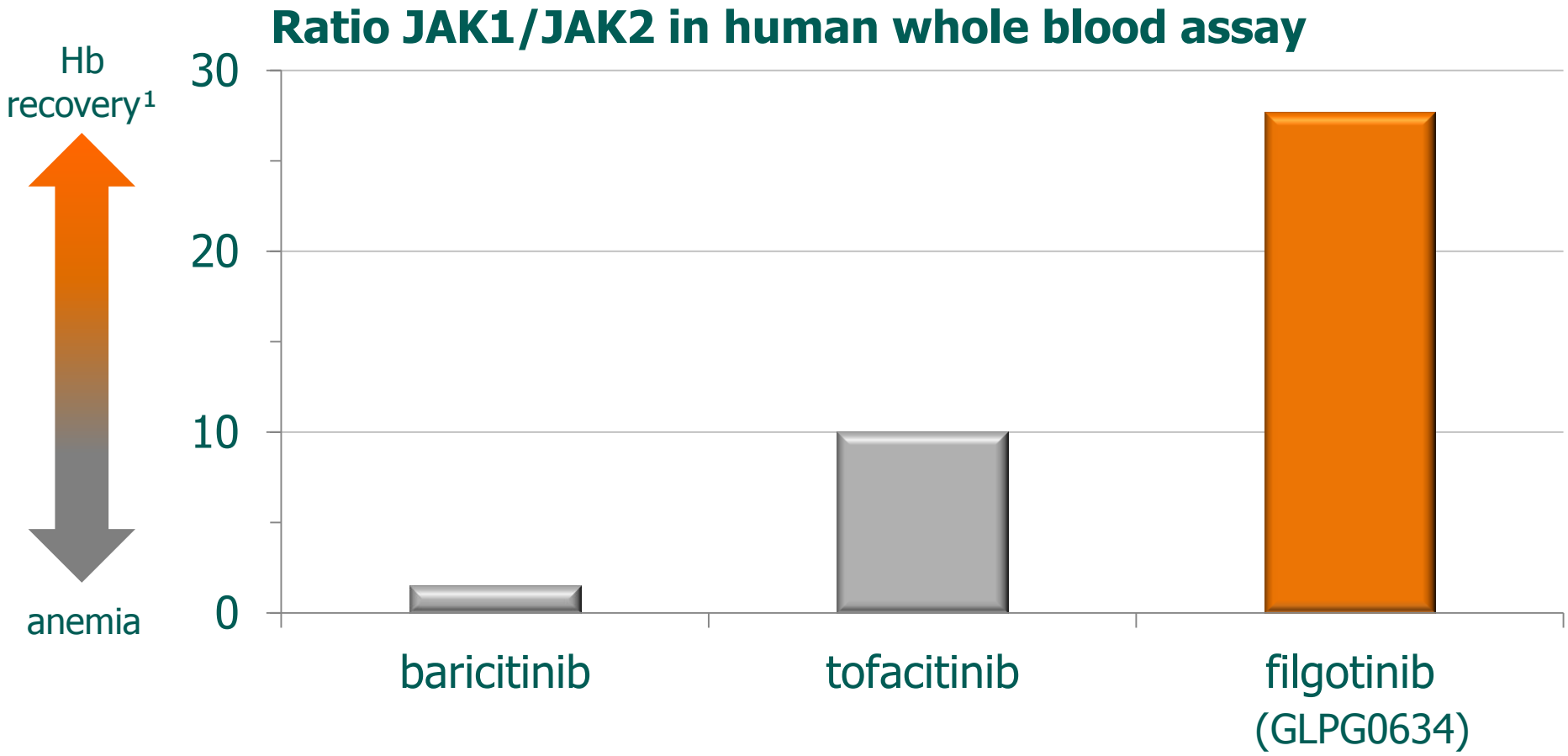
Filgotinib, a new mode of action

JAK1 discovered by us as target for bone & joint disease



Selectivity matters

Filgotinib is the selective JAK1 inhibitor



[1]A Pardanani, et al, Leukemia (2013) 27, 1322–1327

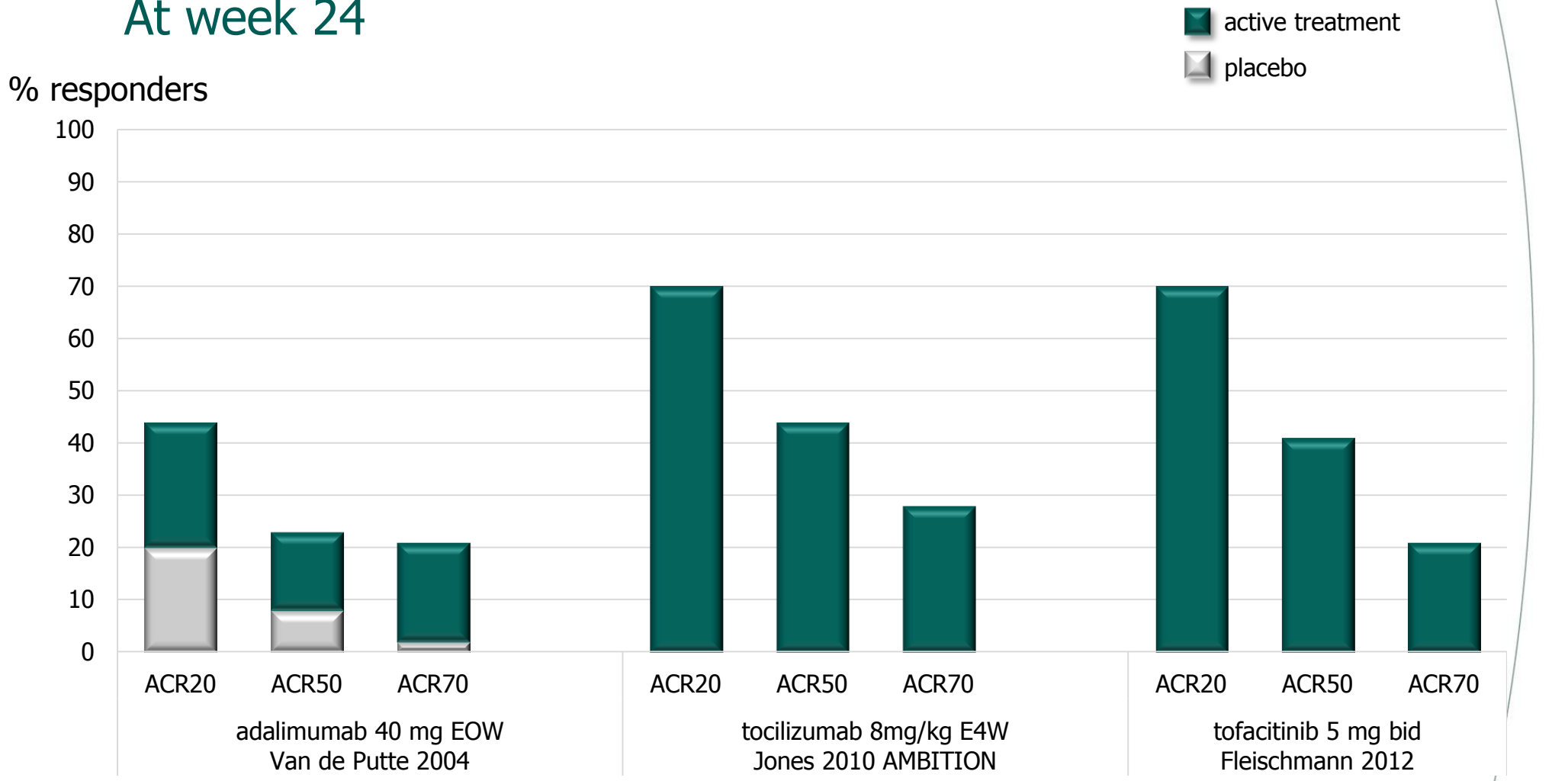
Conclusions DARWIN 2

After 12 weeks of treatment

- Primary and key efficacy endpoints achieved
- High ACR and DAS28(CRP) responses
- Fast onset within one week
- Safety profile consistent across all filgotinib RA studies

Competitor monotherapy data

At week 24



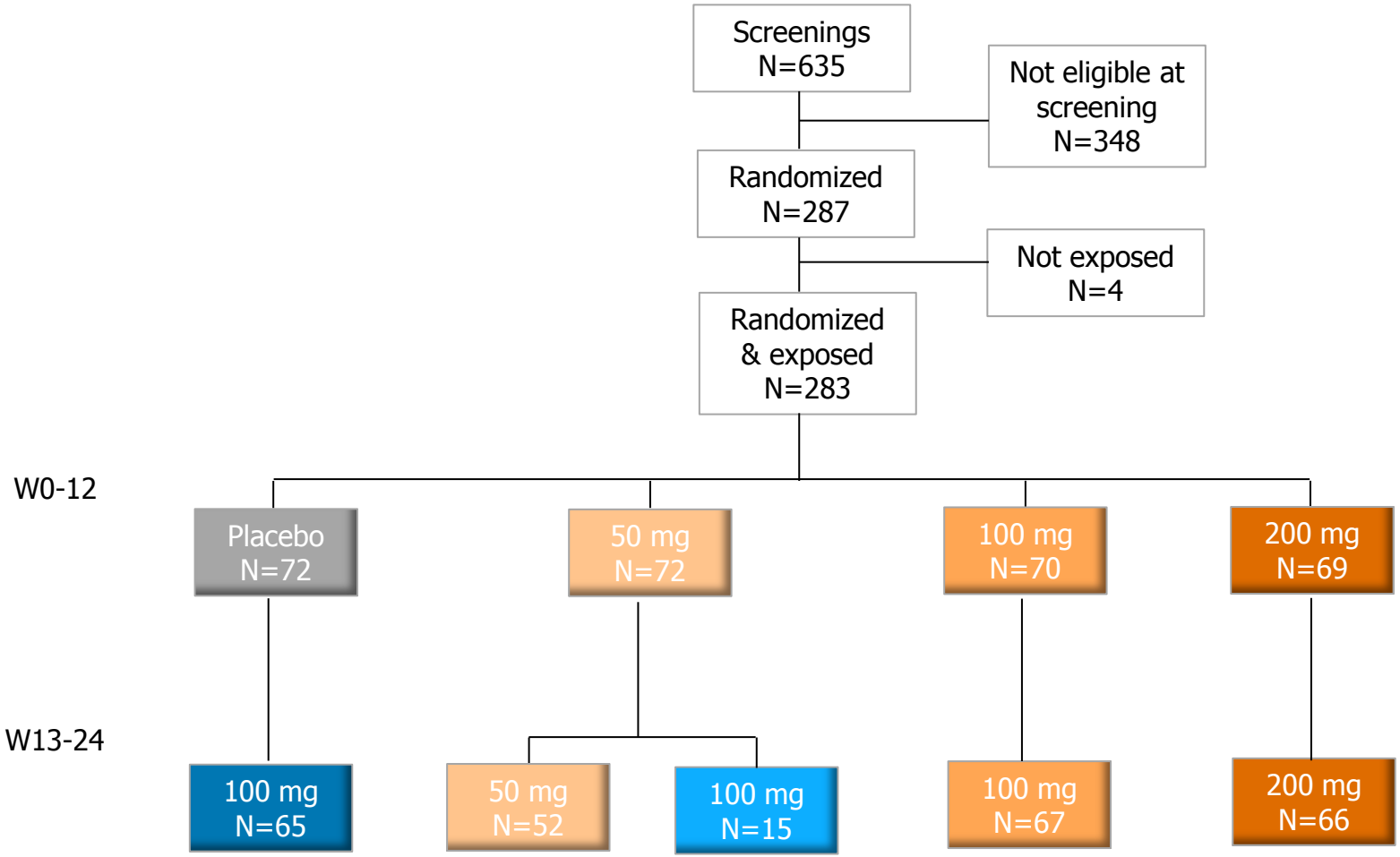
Note: data reported in listed publications, not resulting from head-to-head studies.

Key eligibility criteria

- Inclusion:
  - diagnosis of RA for at least 6 months (2010 ACR/EULAR criteria of RA and ACR functional class I-III)
  - ≥6 SJC (66 joint count) and ≥8 TJC (68 joint count)
  - screening serum CRP ≥0.7 x ULN*
  - inadequate response to MTX, MTX wash-out at least 4 weeks prior to enrolment
- Exclusion:
  - current therapy with any conventional DMARD, except anti-malarials
  - current or previous RA treatment with a biologic DMARD

* ULN = 9 mg/L

Patient disposition



Baseline demographics

Even distribution over dose groups

	Placebo	50 mg	100 mg	200 mg	Total
Age, mean, years	52	52	53	52	52
Female	78%	86%	76%	87%	82%
Duration of RA, mean, years	9	9	9	9	9
DAS28(CRP), mean	6.2	6.0	6.2	6.1	6.1
CRP, mean, mg/L	35	25	26	23	27
TJC68, mean	25	25	27	26	26
SJC66, mean	16	17	18	16	17

Early discontinuations

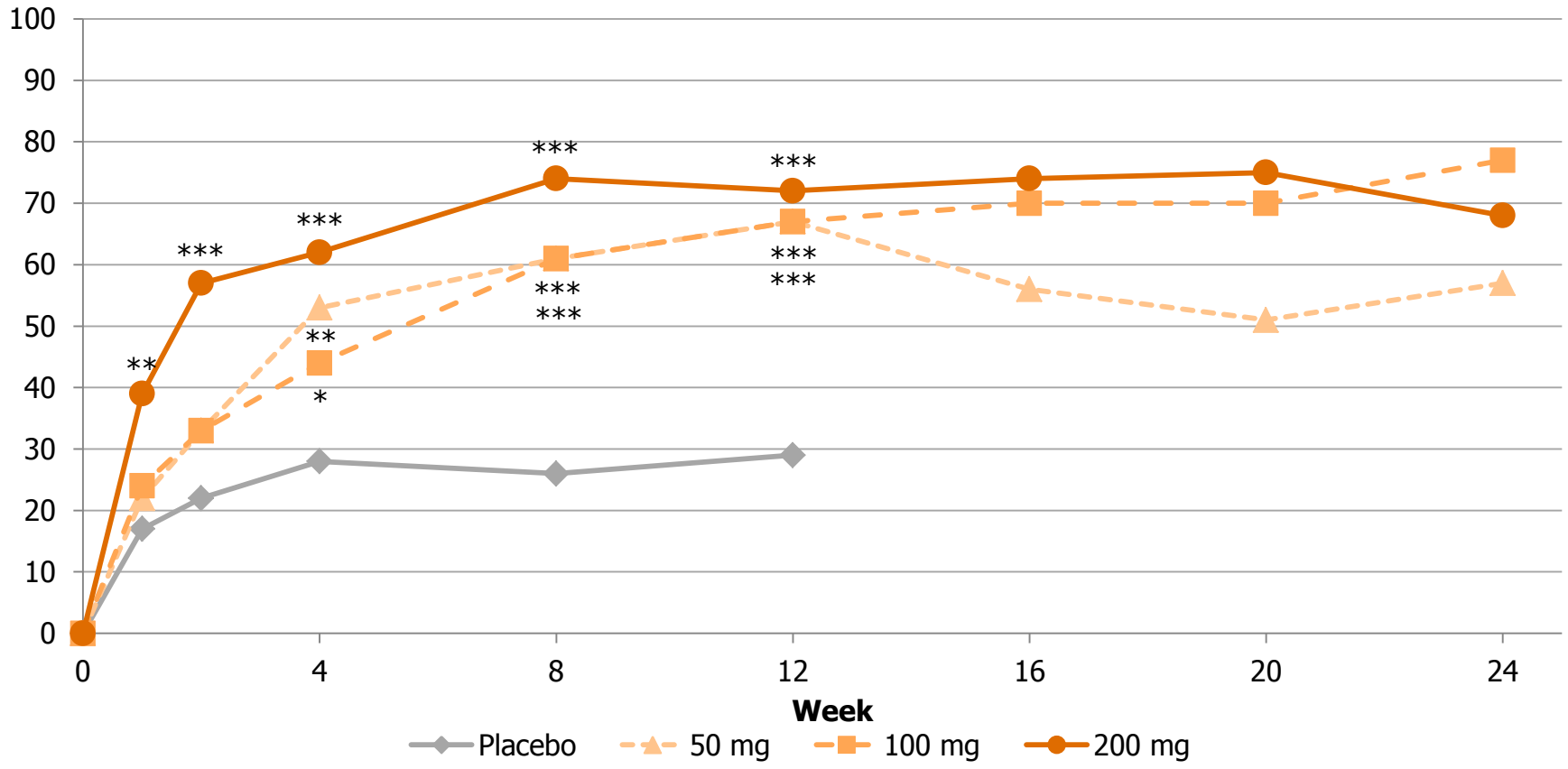
Week 0-24, number of patients

W0-12	Placebo (N=72)	50 mg (N=72)	100 mg (N=70)	200 mg (N=69)
Total	7	5	3	3
Safety	4	0	0	1
W13-24	**Placebo to 100 mg (N=65)**	**50 mg responders only (N=52)**	**100 mg (N=67)**	**200 mg (N=66)**
Total	2	2	3	1
Safety	1	2	2	1

ACR20

ITT-NRI

% responders

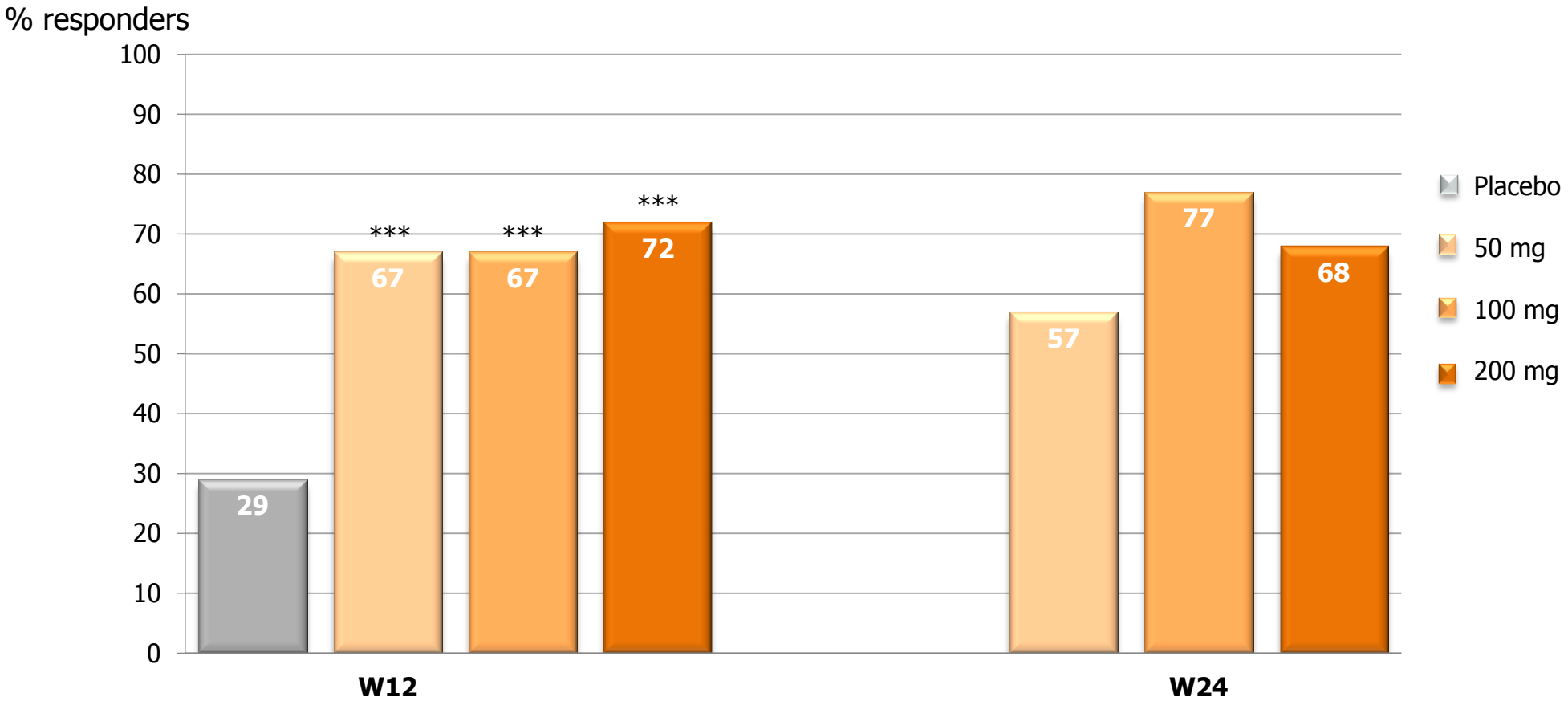


*: p<0.05; **: p<0.01; ***: p<0.001 (up to week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

ACR20

ITT-NRI



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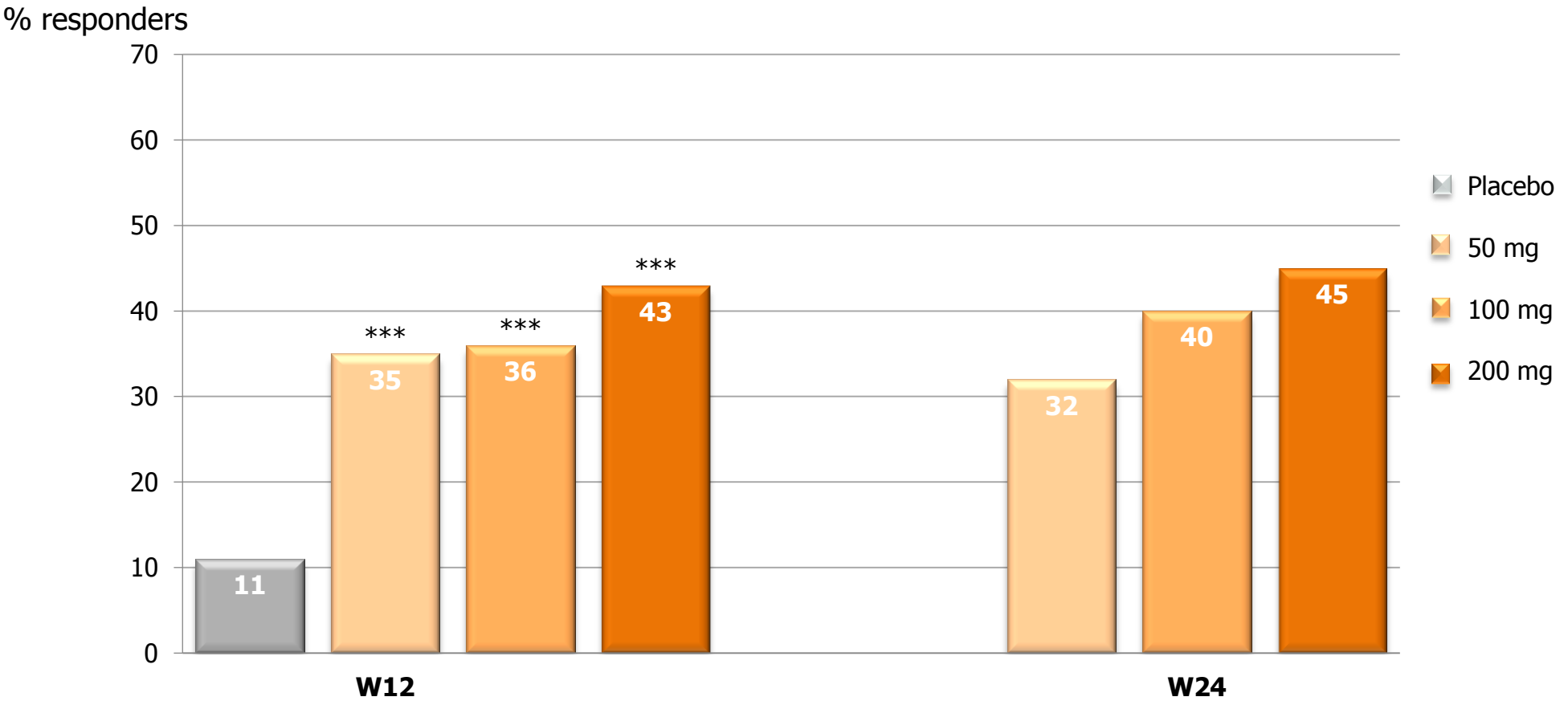
Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

ACR50
ITT-NRI



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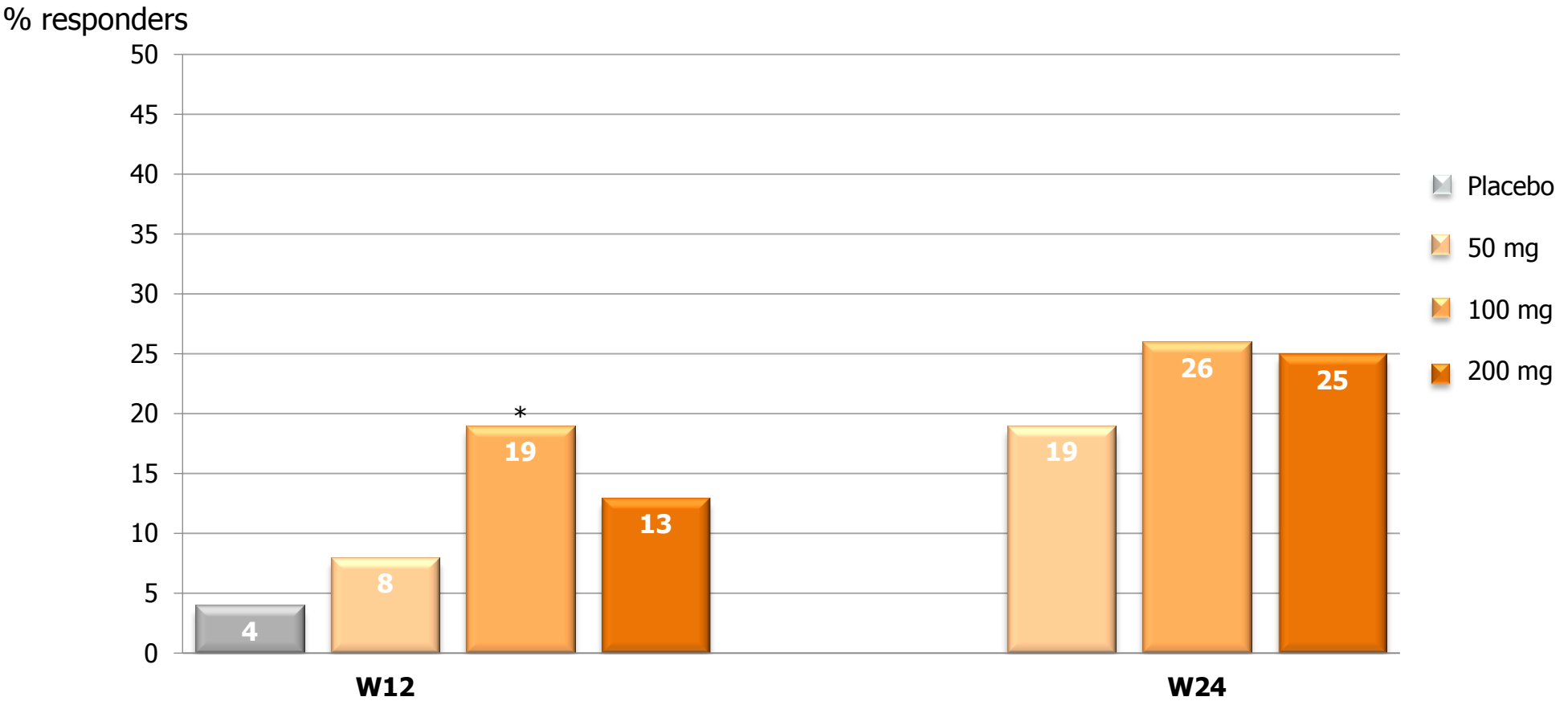
Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

ACR70

ITT-NRI



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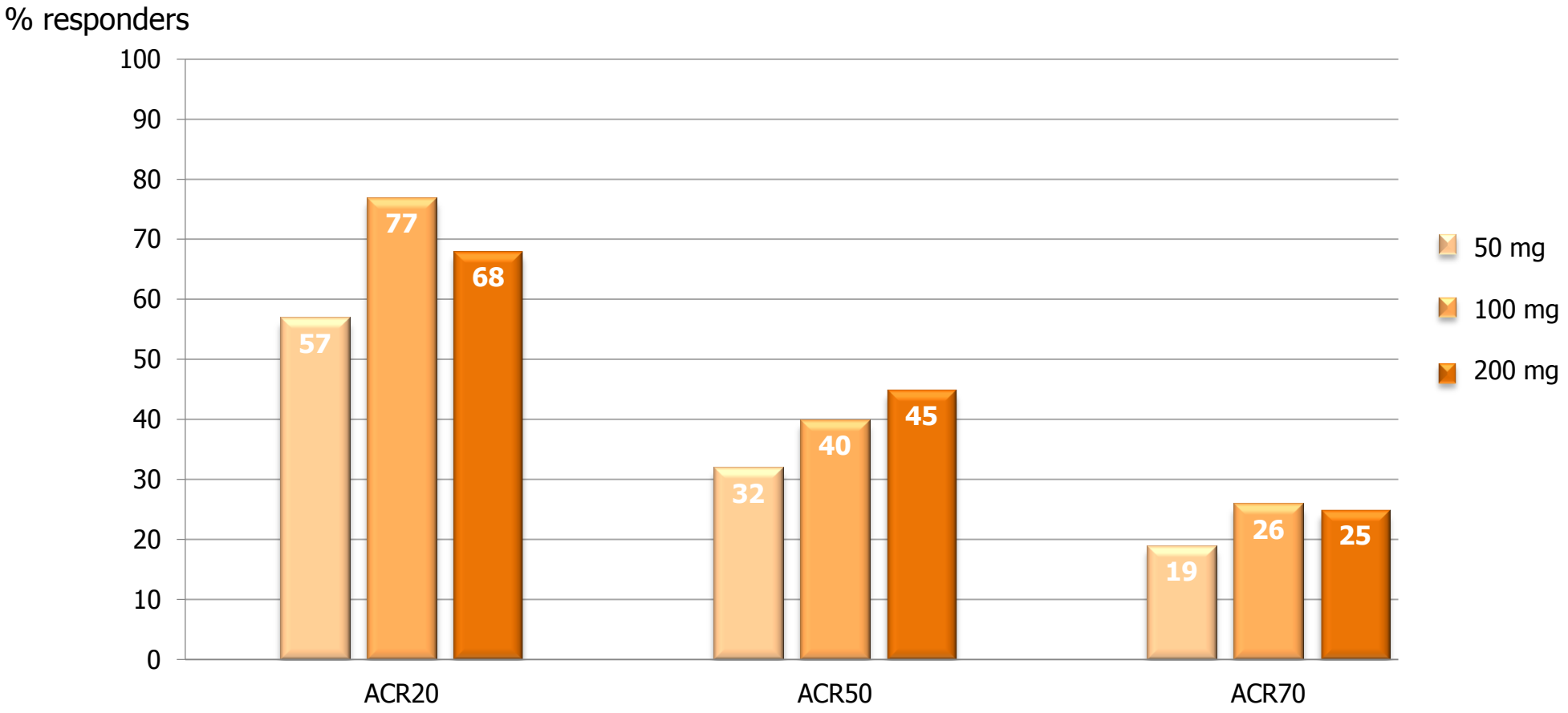
Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

ACR responses

ITT-NRI, at week 24

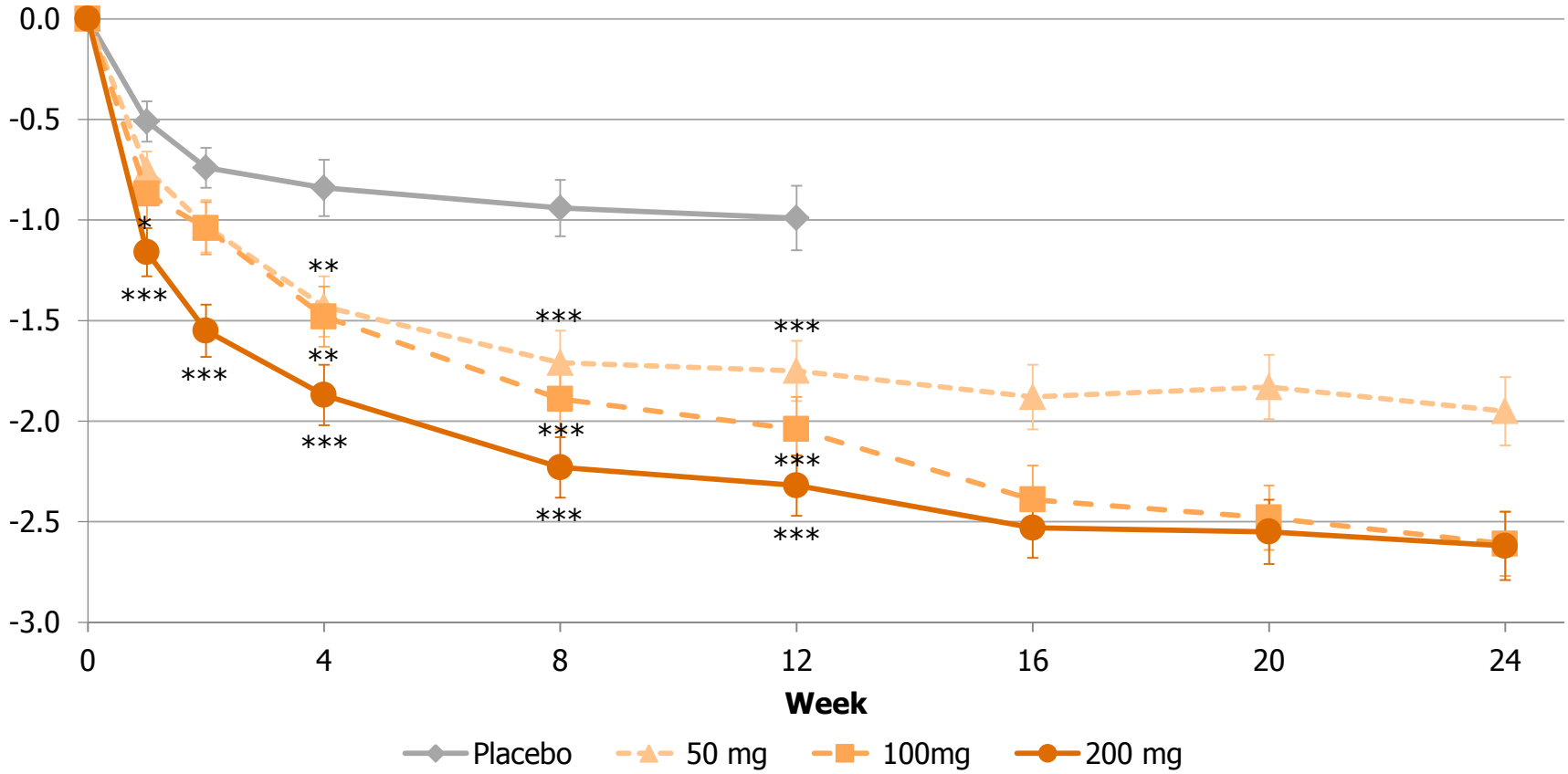


Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

DAS28(CRP)

ITT-LOCF

mean CFB

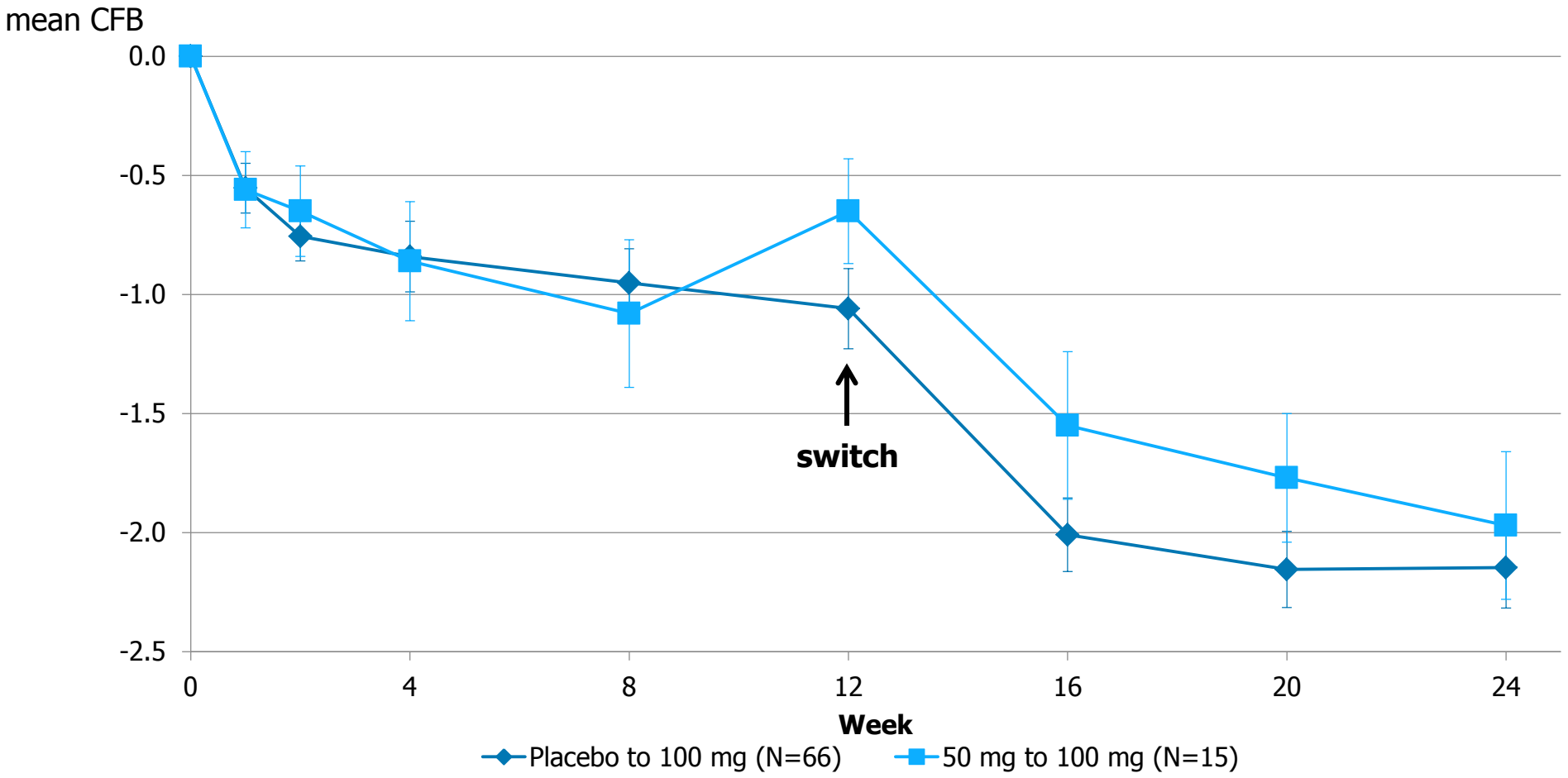


*: p<0.05; **: p<0.01; ***: p<0.001 (up to week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

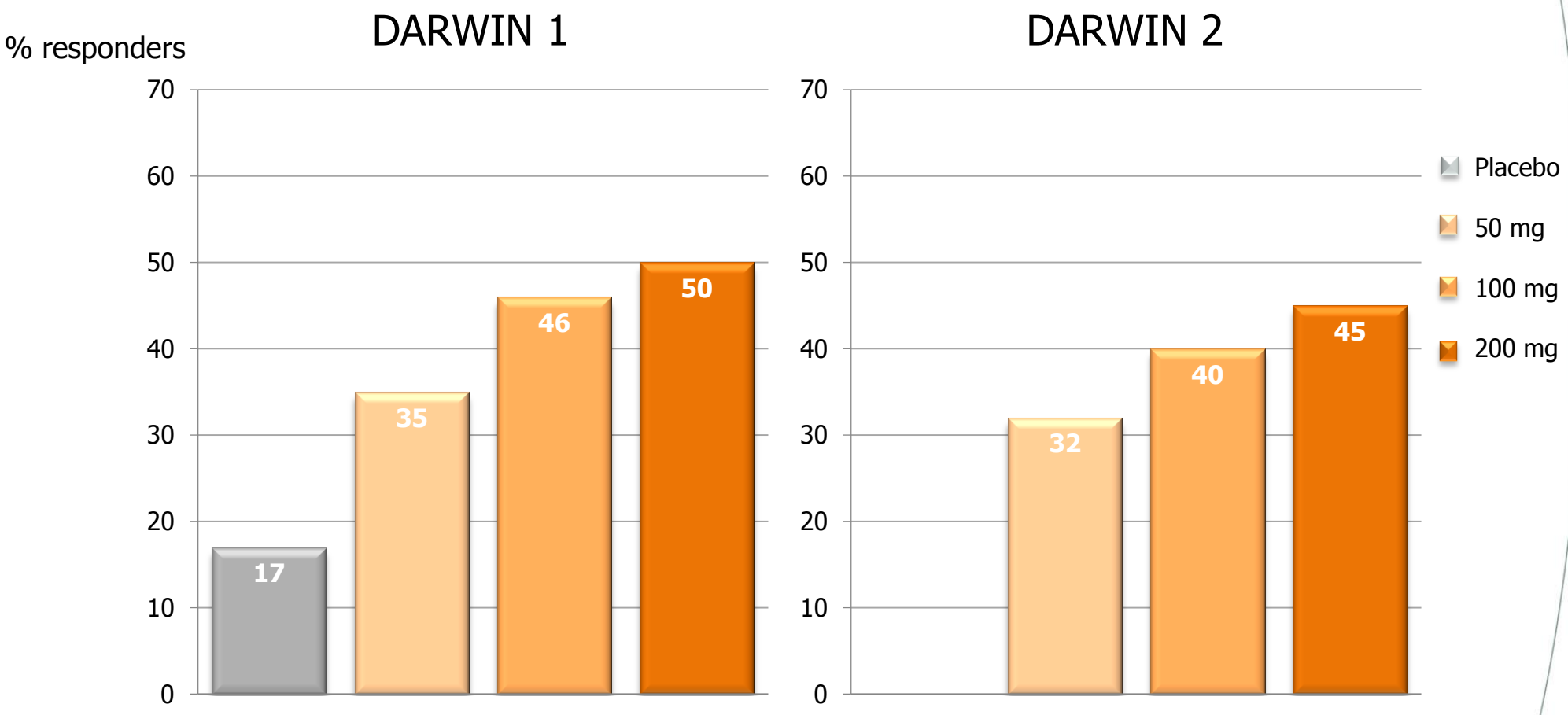
DAS28(CRP)

Patients switching to 100 mg/day



High efficacy rates in DARWIN 1 & 2

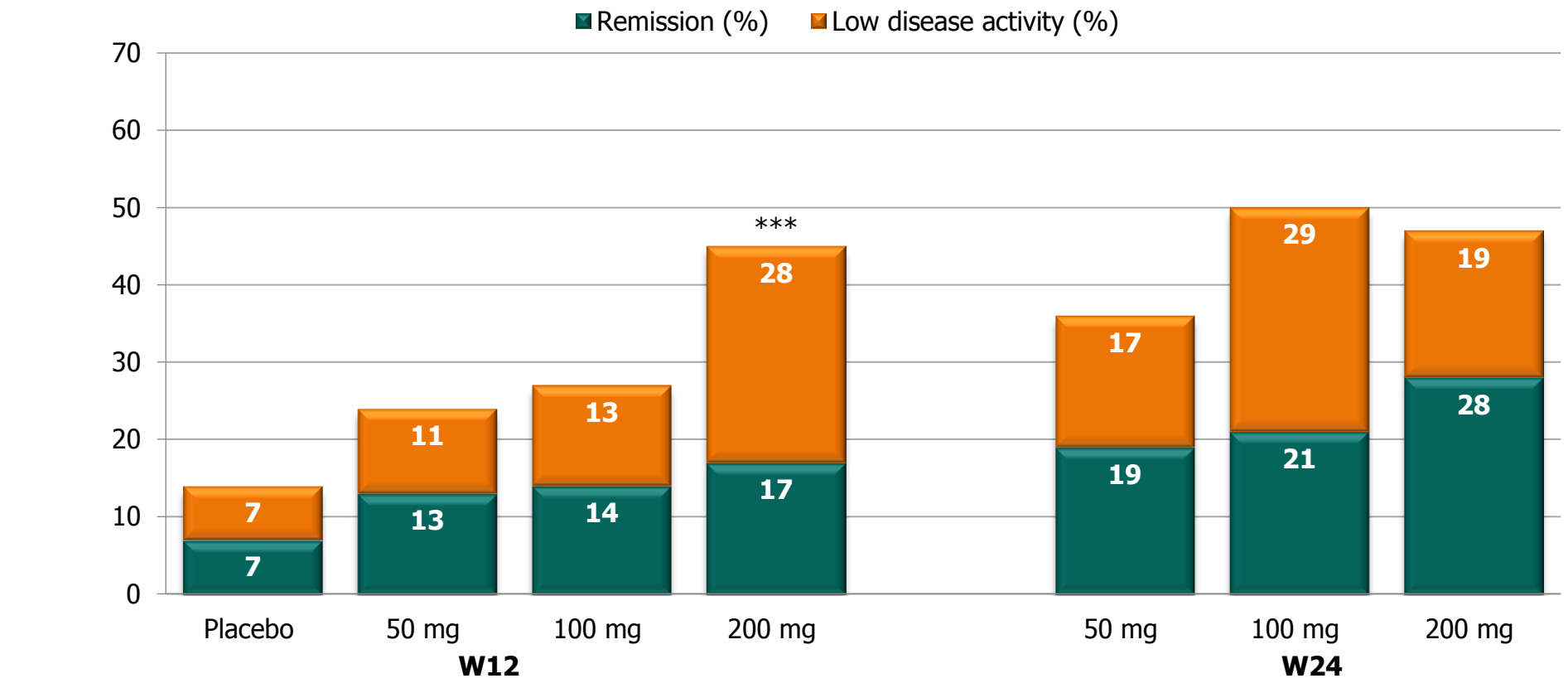
ACR50, QD groups, ITT-NRI, at week 24



Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

DAS28(CRP)

ITT-LOCF: remission rate & low disease activity



*: p<0.05; **: p<0.01; ***: p<0.001 (at week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12

Overview safety endpoints

Week 0-24, number of patients

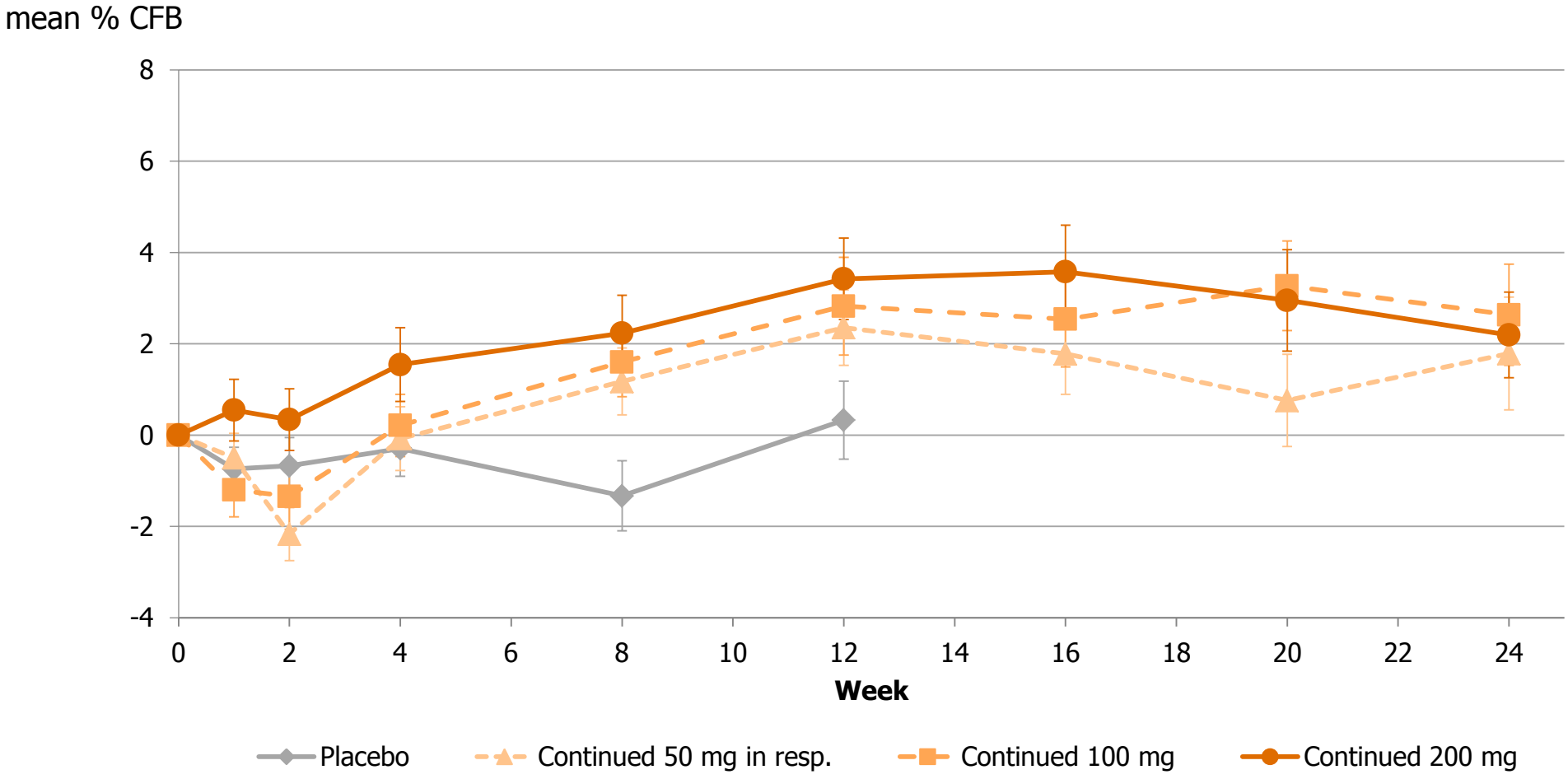
W0-12	Placebo (N=72)	50 mg (N=72)	100 mg (N=70)	200 mg (N=69)
TE AE	28	29	23	30
Serious TE AE	1	1	0	3
Serious TE infection	0	1	0	1
W13-24	**Placebo to 100 mg (N=65)**	**50 mg responders only (N=52)**	**100 mg (N=67)**	**200 mg (N=66)**
TE AE	10	16	21	19
Serious TE AE	1	1	2	0
Serious TE infection	1	0	1	0

TEAEs of special interest
Week 0-24

- No cases of MACE
- All infections – no dose response
  - filgotinib (16%) versus PBO (10%) at week 12
    - mainly urinary tract infections & upper respiratory tract infections
  - 1 pneumonia (200 mg)
  - 1 herpes zoster (50 mg)
- No opportunistic infections, no tuberculosis
- No malignancies, no lymphoma
- No death

Hemoglobin

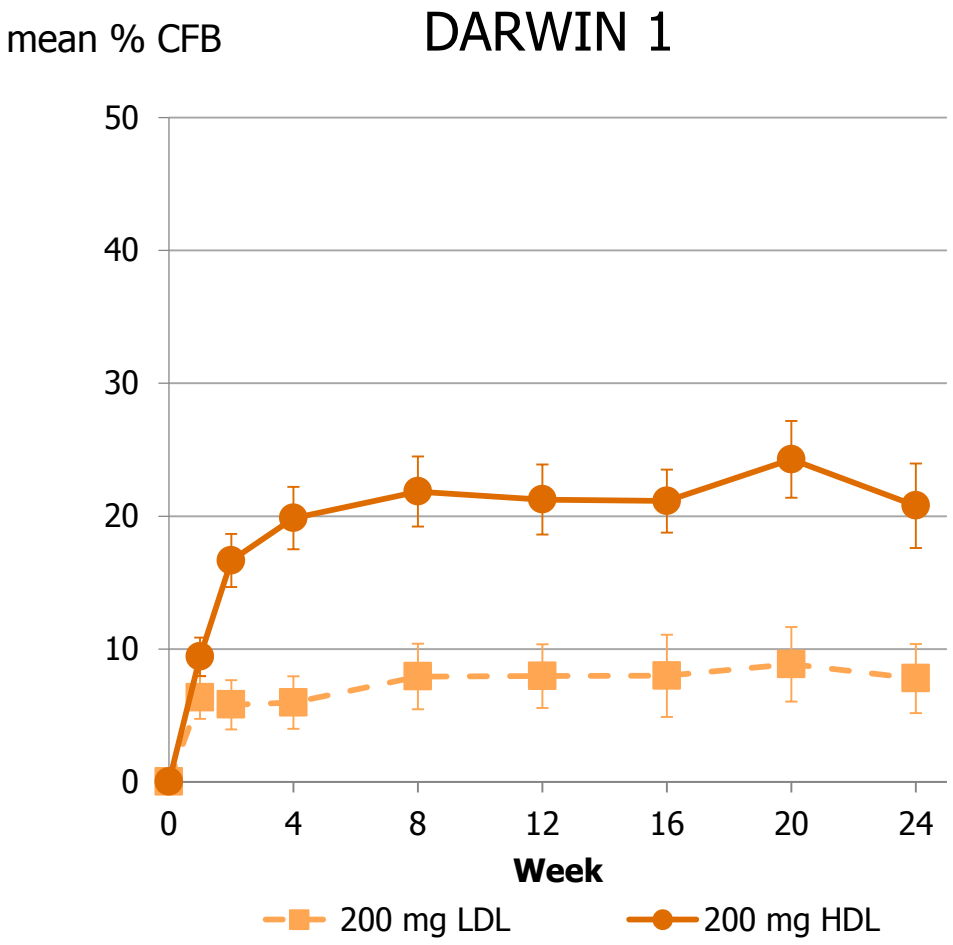
Data up to W24

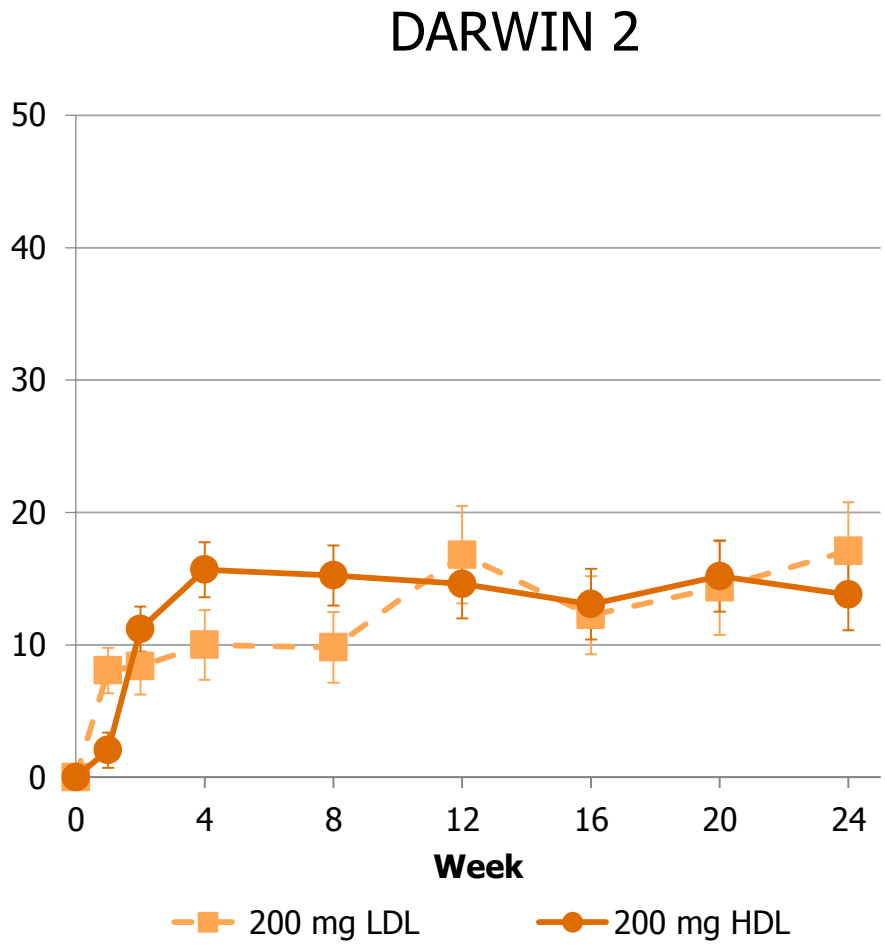


Responder: at least 20% drop in TJC68 and SJC66 versus baseline

LDL & HDL in DARWIN 1 & 2

200 mg QD





Safety – DARWIN 1 & 2

Week 0-24, change versus baseline

Parameter	Measure
Hemoglobin	increase up to 4%
Platelets	decrease towards mid normal value
Lymphocytes	no drop
Neutrophils	decrease towards mid normal value
Creatinine	increase up to 13%
ALT	no CTCAE gr 3-4 on treatment
Lipids	increase of HDL (up to 24%) & LDL (up to 17%)
Male hormones	no clinically meaningful changes

Conclusions – efficacy
Week 0-24

- Fast onset of action
- Dose response
- Sustained high level of ACR20 and ACR50 response
- Further increase in efficacy over 24 weeks
  - ACR70 response
  - DAS28 CRP remission
  - DAS28 CRP low disease activity

Conclusions – safety
Week 0-24

- Safety profile consistent with previous data
- Low drop out, SAE and serious infection rates
- Similar incidence in TEAEs and SAEs between filgotinib and placebo
- Higher incidence in infections on filgotinib, no dose dependency
- Stabilization of initial decrease in neutrophils and initial increase in creatinine, HDL & LDL
- Confirmation of differentiated safety profile in RA:
  - increase in hemoglobin, no drop in lymphocytes
  - no increase in liver function tests

Filgotinib in coming months

- AbbVie licensing decision coming up
- DARWIN 3 long term extension study in RA continues
- Start Phase 3 in RA in 2016
- FITZROY Phase 2 study in Crohn's disease
  - 10 week primary endpoint results expected before year end 2015
  - 20 week final results expected in Q1 2016

Thank you

- Patients
- Investigators
- Team
- AbbVie