UEG Week 2021
Vedolizumab Selection

Takeda Pharma GesmbH

20. Oktober 2021

GASTROENTEROLOGY

VV-MEDMAT-55395

GASTROENTEROLOGY

Real world experience of switching intravenous to subcutaneous vedolizumab as maintenance treatment for inflammatory bowel disease

A. Volkers[1], A. Sales[1], A. Levran[1], K. Gecse[1], C. Ponsioen[1], M. Duijvestein[1], J. Grootjans[1], J. Hanzel[1], M. de Jong[1], S. Stolte[1], J. Zwager[1], M. Löwenberg[1], G. D'Haens[1]

[1]Amsterdam UMC, Location AMC, University of Amsterdam, Gastroenterology & Hepatology, Amsterdam, Netherlands

Real world experience of switching intravenous to subcutaneous vedolizumab as maintenance treatment for inflammatory bowel disease (1/3)

Aim

- To assess the efficacy, safety, and PK profiles of patients with IBD who switched from IV to SC VDZ maintenance treatment

Methods

- An ongoing open-label, real life, prospective single centre cohort study with up to one year of follow-up
- All adult CD and UC patients receiving IV VDZ maintenance for >4 months (at different dose intervals) are offered to switch treatment to SC VDZ, 108 mg Q2W
- **Primary endpoint**: Proportion of patients discontinuing SC VDZ
- Secondary endpoints: Change in clinical disease activity (HBI for CD and SCCAI for UC), inflammatory biomarkers (CRP and FCP) and VDZ serum concentrations
- QoL questionnaires were also collected

CD, Crohn's disease; CRP, C-reactive protein; FCP, faecal calprotectin; HBI, Harvey–Bradshaw Index; IBD, inflammatory bowel diseases; IV, intravenous; PK, pharmacokinetic; Q2W, every 2 weeks; QoL, quality of life; SC, subcutaneous; SCCAI, Simple Clinical Colitis Activity Index; UC, ulcerative colitis; VDZ, vedolizumab.

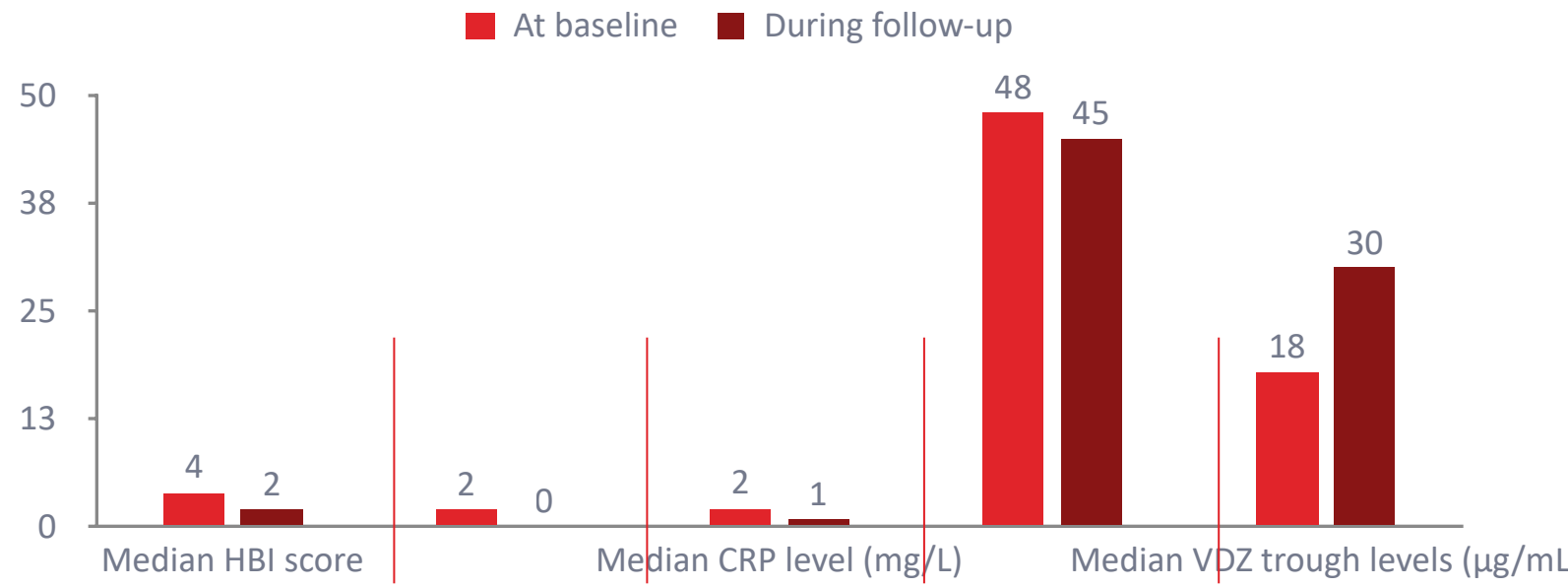
Volkers A, et al. *United European Gastroenterol J*. 2021;9(8):517–518.

Real world experience of switching intravenous to subcutaneous vedolizumab as maintenance treatment for inflammatory bowel disease (2/3)

Results

- N=106 patients have been invited to participate in the study
- **58 patients** with a median age of 54 years (IQR=30.5-64 years) and a median IV VDZ treatment duration of 24.5 months (IQR=12-46.5) have **been switched to SC VDZ up to date**
  - IV VDZ dose interval was every 6, 7 and 8 weeks for 5 (8.6%), 2 (3.4%) and 51 (87.9%) patients, respectively
- 29 patients preferred not to switch to VDZ SC

Change in clinical disease activity, inflammatory biomarkers and VDZ concentrations



Baseline; IQR	2-7	0-3.75	1.1-3.8	17-178	11-23
During follow-up*; IQR	0.75-4.75	0	0.5-2.4	20-294	23-46
n	6	4	11	10	10
p-value	0.04	0.32	0.76	0.53	0.08

CRP, C-reactive protein; FCP, faecal calprotectin; HBI, Harvey–Bradshaw Index; IQR, interquartile range; IV, intravenous; SC, subcutaneous; SCCAI, Simple Clinical Colitis Activity Index; VDZ, vedolizumab.

Volkers A, et al. *United European Gastroenterol J*. 2021;9(8):517–518.

Real world experience of switching intravenous to subcutaneous vedolizumab as maintenance treatment for inflammatory bowel disease (3/3)

Results: Safety

- 2 patients (3.5%) were switched back to IV, after 5 and 6 weeks, respectively, due to injection site reactions and an increased defecation frequency with abdominal pain (n=1) and fear for needles (n=1)
- **Reported AEs included:**
  - (worsening of) arthralgia (n=3),
  - injection site reactions (n=2),
  - (increase of) skin lesions (n=2),
  - fatigue (n=2), vomiting (n=1),
  - loose stools (n=1).

Conclusion

- This study reports the first experience of switching IV to SC VDZ maintenance treatment in IBD patients
- During the first follow-up time point, HBI scores were lower and VDZ concentrations were significantly higher following switch
- Further follow-up data still are being collected prospectively but at present switch from IV to SC VDZ appears a safe and effective intervention

AE, adverse event; HBI, Harvey–Bradshaw Index; IBD, inflammatory bowel diseases; IV, intravenous; SC, subcutaneous; VDZ, vedolizumab.

Volkers A, et al. *United European Gastroenterol J*. 2021;9(8):517–518.

GASTROENTEROLOGY

Long-term treatment with subcutaneous vedolizumab in Crohn's disease: Interim results from the visible open-label extension study

S. Danese[1], S. Vermeire[2], K. Kisfalvi[3], W. Zhang[3], S. Adsul[4], S. Bhatia[3], W. Sandborn[5]

[1]Humanitas Research Hospital and Humanitas University, IBD Center, Milan, Italy; [2]University Hospital Leuven, Dept. of Gastroenterology, Leuven, Belgium; [3]Takeda, Cambridge, United States; [4]Takeda, Zurich, Switzerland; [5]University of California San Diego, Division of Gastroenterology, La Jolla, United States

VV-MEDMAT-55395

Long-term treatment with subcutaneous vedolizumab in Crohn's disease: Interim results from the VISIBLE open-label extension study (1/3)

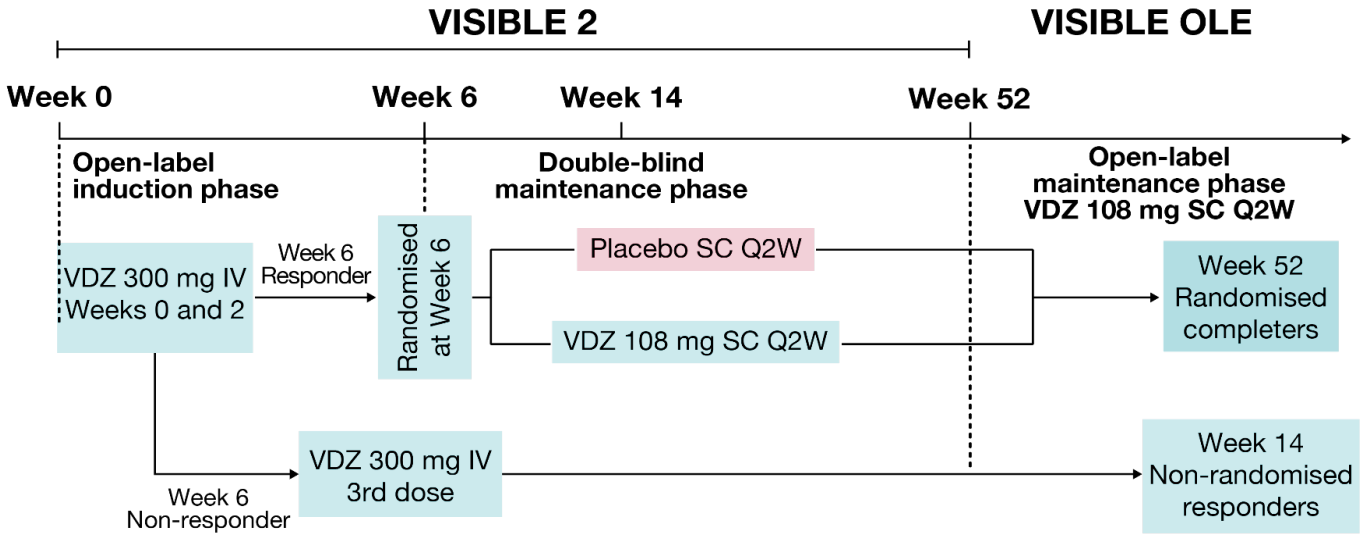
Aim

- To evaluate long-term safety and efficacy of vedolizumab SC in patients with CD from the ongoing OLE study, with data cutoff dates of June 2020 (safety) and May 2019 (efficacy)

Methods

- Patients who did not have a clinical response at Week 6 but responded at Week 14 in VISIBLE 2 received VDZ SC 108 mg Q2W in the OLE
- Safety and efficacy results during the OLE study are summarized by prior treatment groups in VISIBLE 2 for Week 52 randomized completers and Week 14 non-randomized responders

VISIBLE 2 OLE Study design



CD, Crohn's disease; IV, intravenous; OLE, open-label extension; Q2W, every 2 weeks; SC, subcutaneous; VDZ, vedolizumab.

Danese S, et al. *United European Gastroenterol J*. 2021;9(8):200–201.

Long-term treatment with subcutaneous vedolizumab in Crohn's disease: Interim results from the visible open-label extension study (2/3)

Results

- 458 patients with CD were enrolled in the OLE, of whom 53.3% (244/458) were male, with median (range) age of 36.5 (18-77) years, and median (range) duration of CD of 7.7 (0.6-52.0) years
- Most common SAEs were GI disorders, which were observed among randomized completers in 12.3% and 8.8% of placebo and VDZ SC 108 mg groups, and 11.0% of non-randomized non-responders

Summary of observed safety data from CD patients in VISIBLE OLE

	Week 52 Randomised Completers (Prior Placebo) (n=114)	Week 52 Randomised Completers (Prior VDZ SC 108 mg) (n=226)	Week 14 Non-Randomised Responders (n=118)
AEs, n (%)	91 (**79.8**)	180 (**79.6**)	99 (**83.9**)
SAEs, n (%)	22 (19.3)	38 (16.8)	27 (22.9)
Injection site AEs, n (%)	3 (2.6)	5 (2.2)	6 (5.1)
Discontinuations due to AEs, n (%)	7 (6.1)	9 (4.0)	8 (6.8)
Discontinuations due to SAEs, n (%)	0	3 (1.3)	3 (2.5)
Most frequent drug-related AEs by preferred term, n (%)[a]			
Crohn's disease	3 (2.6)	10 (4.4)	6 (5.1)
Upper respiratory tract infection	0	4 (1.8)	3 (2.5)
Arthralgia	2 (1.8)	6 (2.7)	1 (0.8)
Headache	0	1 (0.4)	3 (2.5)

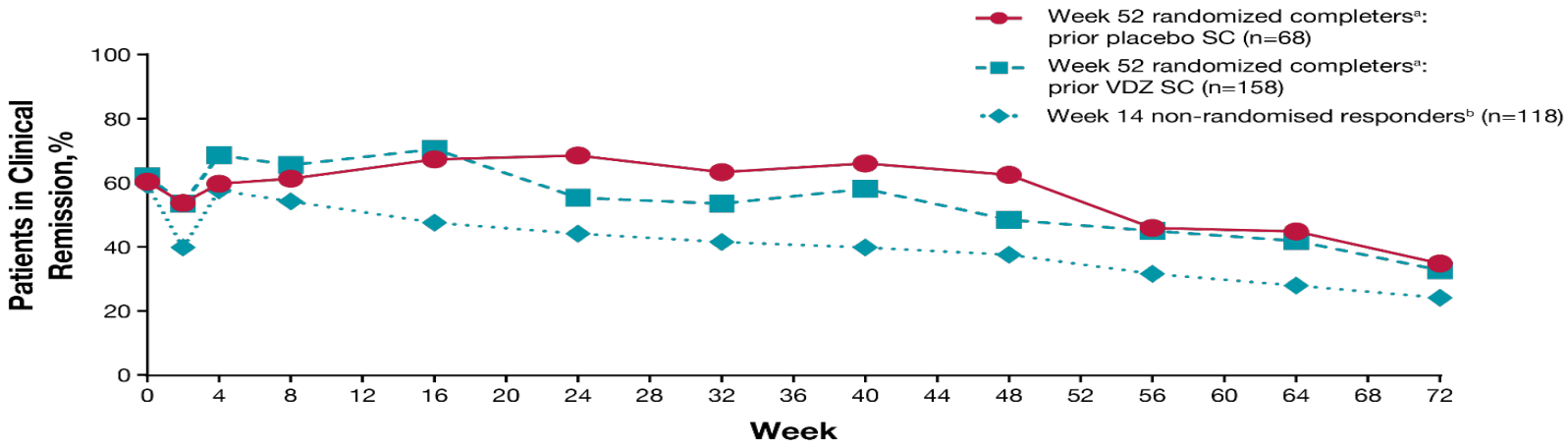
*CR was defined as HBI score of ≤4 points. Regardless of dose escalation in the completer and Week 13 non-randomized responder groups. Week 0 corresponds to subject entry into the OLE after Week 52 of VISIBLE 2

AE, adverse event; CD, Crohn's disease; CR, clinical remission; GI, gastrointestinal; HBI, Harvey-Bradshaw Index; OLE, open-label extension; SAE, serious AE; SC, subcutaneous; VDZ, vedolizumab.

Danese S, et al. *United European Gastroenterol J*. 2021;9(8):200–201.

Long-term treatment with subcutaneous vedolizumab in Crohn's disease: Interim results from the visible open-label extension study (3/3)

Proportion of Patients With CD in CR* With VDZ SC Every 2 Weeks During OLE According to Previous Treatment Group



Patients, n											
Week 52 randomised completers											
Prior placebo SC	68	67	62	55	54	49	47	40	37	29	23
Prior VDZ SC 108 mg	158	156	148	132	123	114	105	93	80	67	55
Week 14 non-randomised responders	118	118	118	118	118	118	118	104	95	86	79

*CR was defined as HBI score of ≤4 points. [a]Patients who achieved a clinical response at Week 6 were randomised in the maintenance phase of VISIBLE 2 and completed treatment up to Week 52 with VDZ SC or placebo SC before entering the OLE study.

Conclusion

- These long-term data from VISIBLE OLE demonstrate no new safety signals with long-term treatment with the VDZ SC formulation, which continues to confirm its favorable overall safety/tolerability profile over an extended period
- The clinical benefit of VDZ SC maintenance therapy was sustained beyond the initial 52 weeks during the ongoing OLE
- These results support VDZ SC as an important treatment option for patients who require longer term maintenance therapy for CD

CD, Crohn's disease; CR, clinical remission; HBI, Harvey-Bradshaw Index; OLE, open-label extension; SC, subcutaneous; VDZ, vedolizumab.

Danese S, et al. *United European Gastroenterol J*. 2021;9(8):200–201.

GASTROENTEROLOGY

Simplified rules to identify bio-naïve patients with Crohn's disease with higher likelihood of clinical remission when initiating vedolizumab vs anti-TNFα therapies: Analysis of EVOLVE study data

G.J. Mantzaris[1], A. Yarur[2], S. Wang[3], S. Adsul[4], P. Kamble[5], M. Luo[6], A. Guerin[7], E. Billmyer[7], H. Nguyen[7], B. Bressler[8]

[1]Evangelismos Hospital, 1st Dept. of Gastroenterology, Athens, Greece; [2]Medical College of Wisconsin, Milwaukee, United States; [3]Takeda Pharmaceuticals International Co., Global Outcomes Research & Epidemiology, Cambridge, United States; [4]Takeda, Zurich, Switzerland; [5]Takeda Pharmaceuticals Inc., Global Evidence and Outcomes-Gastroenterology, Cambridge, United States; [6]Takeda, Cambridge, United States; [7]Analysis Group, Boston, United States; [8]University of British Columbia, Vancouver, Canada

TNF, tumour necrosis factor.

Simplified rules to identify bio-naïve patients with Crohn's disease with higher likelihood of clinical remission when initiating vedolizumab vs anti-TNFα therapies: Analysis of EVOLVE study data (1/4)[1]

Background

- Previously, the subsets of biologic-naïve patients with CD from the EVOLVE study had higher rates of CR when initiating VDZ vs anti-TNFα treatment were identified using prediction models based on multiple baseline characteristics[2,3]

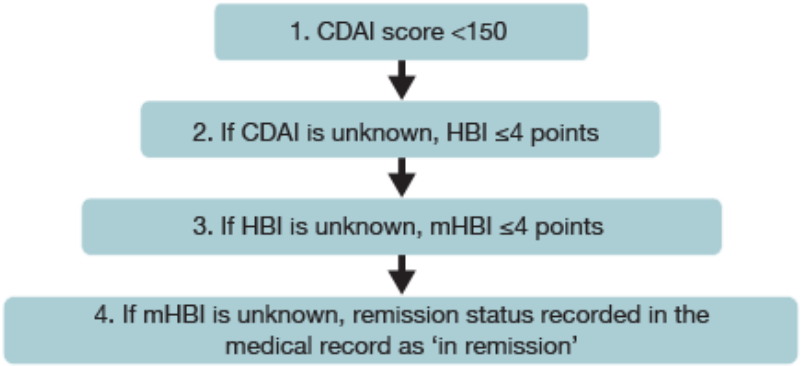
Aim

- To aid use in practice, the study investigated whether these subsets could be identified using simpler rules based on fewer baseline characteristics.

Methods

- Using data from EVOLVE, RPART classification was used to predict membership in the previously identified higher CR subsets for VDZ.
- Simplified rules were developed from the resulting RPART decision trees

CR Algorithm



CDAI, Crohn's disease activity index; HBI, Harvey-Bradshaw index; mHBI, modified Harvey-Bradshaw index.

CD, Crohn's disease; CR, clinical remission; RPART, recursive partitioning and regression tree; TNF, tumor necrosis factor; VDZ, vedolizumab.

1. Mantzaris GJ, et al. *United European Gastroenterol J.* 2021;9(8):565–566; 2. Bressler B, et al. *DDW*; May 21-23, 2021. Abs: 3522599; 3. Bressler B, et al. *J Crohn's and Colitis*. 2021;DOI: 10.1093/ecco-jcc/jjab058.

Simplified rules to identify bio-naïve patients with Crohn's disease with higher likelihood of clinical remission when initiating vedolizumab vs anti-TNFα therapies: Analysis of EVOLVE study data (2/4)

Results

- Patients with data on CR and candidate predictors were included (VDZ [n=195]; anti-TNFα [n=245]). Three simplified rules (A, B, and C) were identified.

Rule	Description of simplified rule	Population covered by rule, %	Sample size based on rule		Median time to remission (months), unadjusted (CI)		Unadjusted logrank test p-value	Adjusted Cox HR and 95% CI
			VDZ	Anti-TNFα	**VDZ**	**Anti-TNFα**		VDZ vs Anti-TNFα
A	1) Patients who had a exacerbation ongoing at index=Yes 2) Patients with ED/ER visits prior to index=No 3) Pre-index disease behavior: Stricturing with/without perianal disease=No	32	55	86	**6.74 (4.04, 8.55)**	**18.08 (9.53, 25.94)**	<0.001	2.9 (1.7, 5.0)
B	1) Patients with ED/ER visits prior to index=No 2) Patients who had a exacerbation ongoing at index=Yes 3) Fistulae at most recent assessment prior to index event=No	41	81	99	**7.17 (5.75, 9.70)**	**14.07 (8.51, 25.51)**	<0.01	2.1 (1.3, 3.4)
C	1) Patients with ED/ER visits prior to index=No 2) Fistulae at most recent assessment prior to index event=No	81	174	182	**8.48 (6.97, 10.55)**	**11.05 (8.42, 18.08)**	<0.05	1.7 (1.2, 2.3)

CI, confidence interval; CR, clinical remission; ED, emergency department; ER, emergency room; HR, hazard ratio; TNF, tumor necrosis factor; VDZ, vedolizumab.

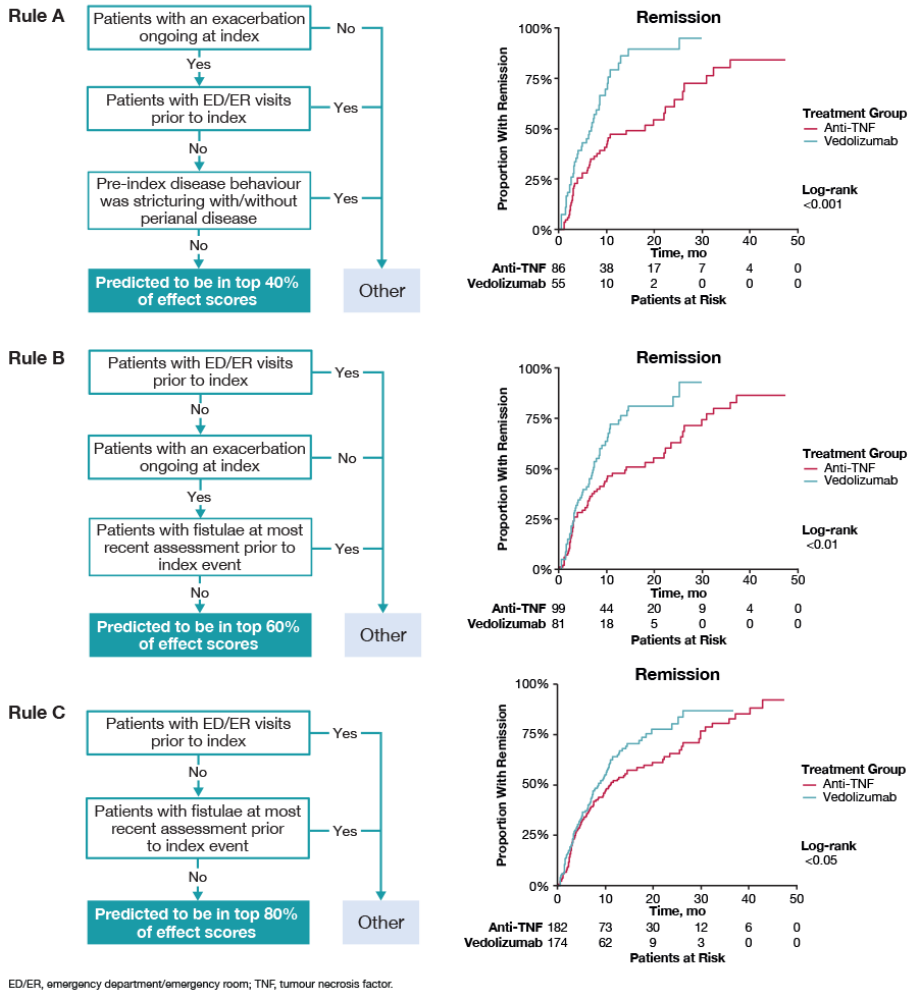
Mantzaris GJ, et al. *United European Gastroenterol J.* 2021;9(8):565–566.

Simplified rules to identify bio-naïve patients with Crohn's disease with higher likelihood of clinical remission when initiating vedolizumab vs anti-TNFα therapies: Analysis of EVOLVE study data (3/4)

Results

- Patient characteristics identified previously as predictors of CR in VDZ treated patients were included in the rules:
  - Exacerbation ongoing at treatment initiation
  - No ED/ER visits prior to treatment initiation
  - No fistulae at most recent assessment prior to treatment initiation
  - Pre-initiation disease behaviour

Examples of Simplified Rules A, B and C



CR, clinical remission; ED, emergency department; ER, emergency room; TNF, tumor necrosis factor; VDZ, vedolizumab.

Mantzaris GJ, et al. *United European Gastroenterol J.* 2021;9(8):565–566.

Simplified rules to identify bio-naïve patients with Crohn's disease with higher likelihood of clinical remission when initiating vedolizumab vs anti-TNFα therapies: Analysis of EVOLVE study data (4/4)

Results

- Patients identified by Rule A comprised 32% of the EVOLVE population, and were those who
  1) Had an exacerbation ongoing at index
  2) Did not have ED/ER visits prior to initiation and
  3) Had pre-initiation disease behaviour classified as other than stricturing with/without perianal disease.
- Among these patients, median time to CR for VDZ and anti-TNFα patients were 6.7 and 18.1 months, respectively (unadjusted log-rank $p<0.001$), and the adjusted HR of CR for VDZ vs anti-TNFα was 2.9 (95% CI: 1.7, 5.0).
- Rules B and C identified larger subsets in which VDZ vs anti-TNFα treatment differences were smaller but still statistically significant.

Conclusion

- Simple rules were developed to identify biologic-naïve, CD patients in whom VDZ initiation appeared to have a larger effect on CR relative to anti-TNFα initiation.
- Validation of these rules in other data sources is important to confirm these findings; if validated, these simplified rules can inform targeting of treatment and optimization of outcomes for patients with CD treated with VDZ

CD, Crohn's disease; CI, confidence interval; CR, clinical remission; ED, emergency department; ER, emergency room; HR, hazard ratio; TNF, tumor necrosis factor; VDZ, vedolizumab.

Mantzaris GJ, et al. *United European Gastroenterol J*. 2021;9(8):565–566.

GASTROENTEROLOGY

Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial

S. Travis[1], M. Silverberg[2], S. Danese[3], P. Gionchetti[4], M. Löwenberg[5], D. Lindner[6], A. Escher[6], S. Jones[6], B. Shen[7]

[1]John Radcliffe Hospital, Translational Gastroenterology Unit, Oxford, United Kingdom; [2]Mount Sinai Hospital Inflammatory Bowel Disease Centre, Division of Gastroenterology, Toronto, Canada; [3]Humanitas Clinical and Research Center, Milan, Italy; [4]University of Bologna, S. Orsola-Malpighi Hospital, IBD Unit, Department of Medicine and Surgery (DIMEC), Bologna, Italy; [5]Amsterdam University Medical Centre, Location Academic Medical Centre, Department of Gastroenterology and Hepatology, Amsterdam, Netherlands; [6]Takeda Pharmaceuticals International, Zurich, Switzerland; [7]Columbia University Irving Medical Center/Herbert Irving Pavilion, New York, United States

VV-MEDMAT-55395

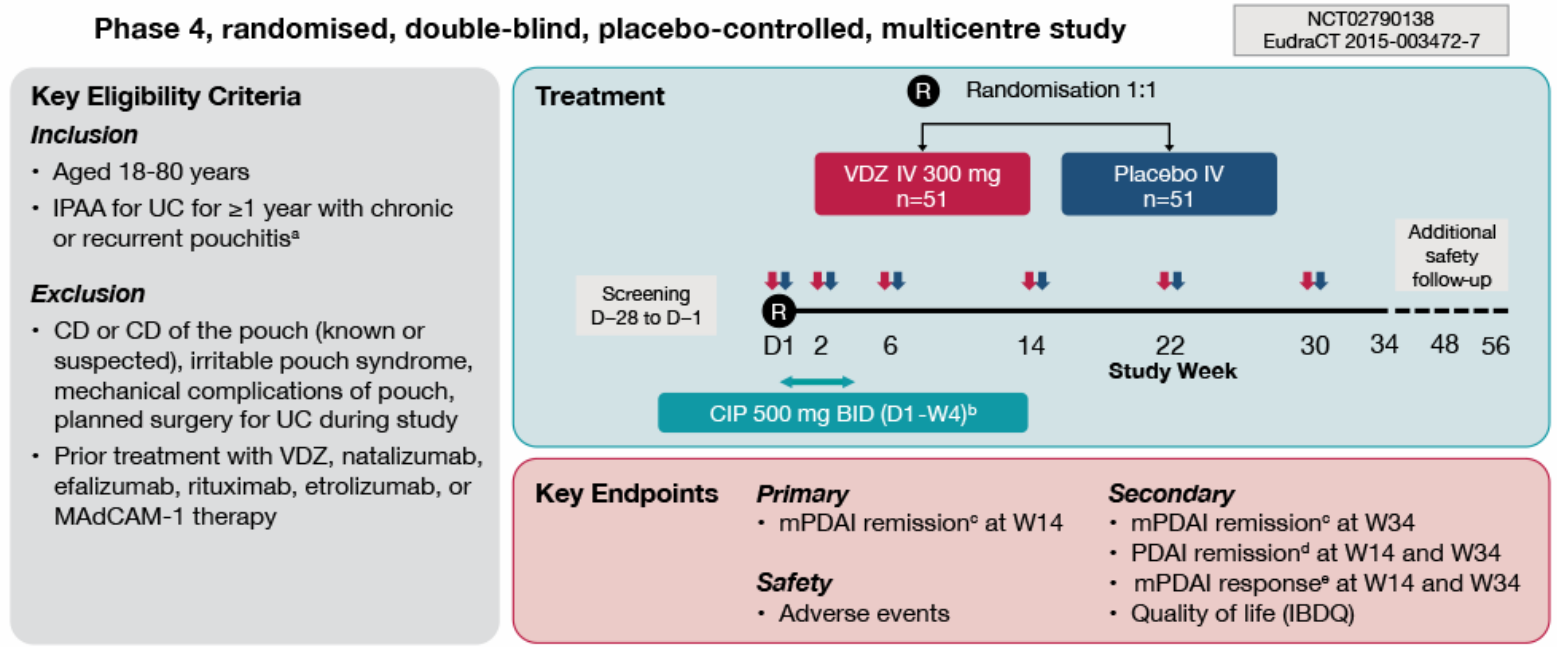
Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial (1/5)

Aim

- To report the efficacy and safety of VDZ IV in patients with UC who developed chronic or recurrent pouchitis after IPAA.

Methods

Study Design



BID, twice daily; CD, Crohn's disease; CIP, ciprofloxacin; D, Day; IBDQ, inflammatory bowel disease questionnaire; IPAA, ileal pouch-anal anastomosis; IV, intravenous; MAdCAM-1, mucosal addressin cell adhesion molecule-1; (m)PDAI, (modified) Pouchitis Disease Activity Index; UC, ulcerative colitis; VDZ, vedolizumab; W, Week.
[a]mPDAI score of ≥5 and endoscopic subscore of ≥2 with either: a) ≥3 recurrent episodes within 1 year before screening visit, each treated with ≥2 weeks of antibiotic or other prescription therapy, or b) requiring maintenance antibiotic therapy taken continuously for ≥4 weeks immediately prior to baseline endoscopy. [b]All patients received concomitant antibiotic treatment with oral ciprofloxacin 500 mg BID from randomisation through W4. [c]Defined as mPDAI score of <5 and a ≥2-point reduction from baseline. [d]PDAI score of <7 and a ≥3-point reduction from baseline. [e]≥2-point reduction from baseline in mPDAI score.

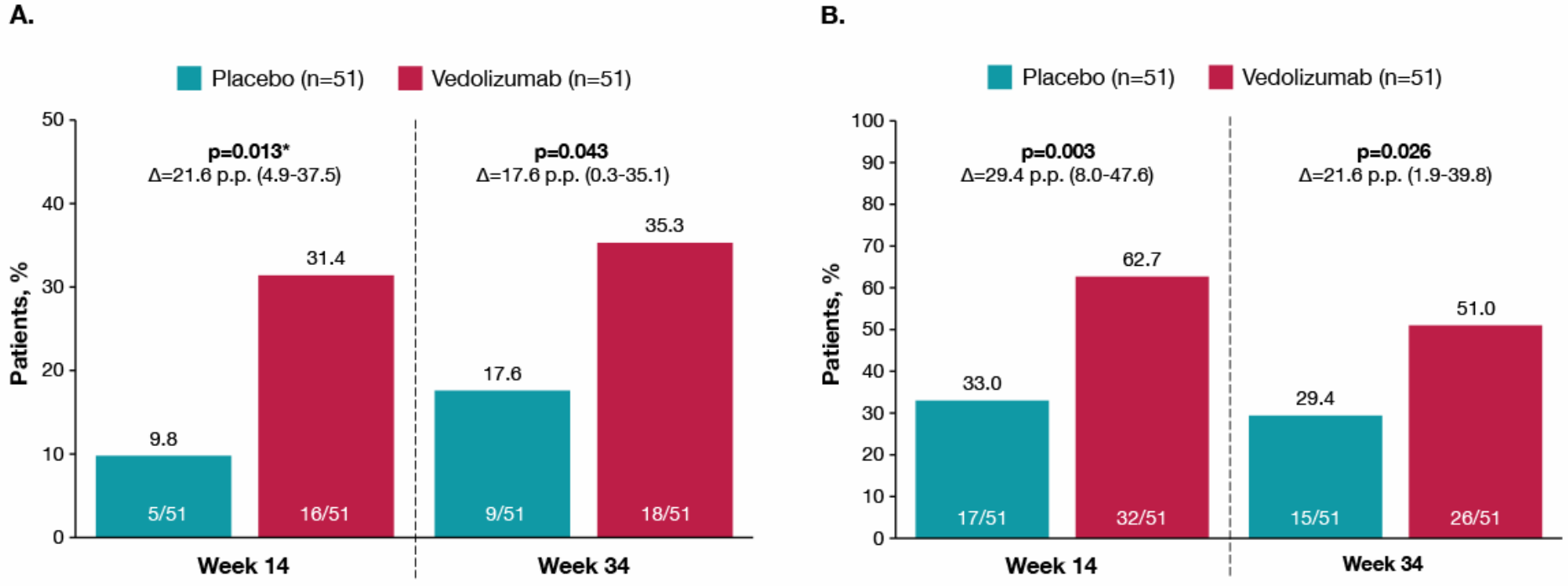
IPAA, ileal pouch-anal anastomosis; IV, intravenous; UC, ulcerative colitis; VDZ, vedolizumab. Travis S, et al. *United European Gastroenterol J.* 2021;9(8):531–532.

Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial (2/5)

Results

- mPDAI CR rates at Week 14 were 31.4% (16/51) with VDZ vs 9.8% (5/51) with placebo (Δ=21.6 percentage points, 95% CI: 4.9, 37.5; p=0.013)

A) mPDAI remission[a] and B) mPDAI response[b] rates (Full analysis set)



Δ=vedolizumab–placebo (exact 95% confidence interval). p values from chi-squared test (or from Fisher's exact test, if number of responders was ≤5 in any arm); nominal p values shown for secondary endpoints (no multiplicity adjustment performed).
Patients with mPDAI missing at a visit were counted as non-remitters/non-responders.
mPDAI, modified Pouchitis Disease Activity Index; p.p., percentage points.
[a]mPDAI remission (includes clinical and endoscopic subscores) defined as mPDAI score of <5 and reduction in overall score of ≥2 points from baseline. mPDAI remission at Week 14 was the primary endpoint. [b]mPDAI response defined as a ≥2-point reduction from baseline in mPDAI.
*Statistically significant at α=0.05 (2-sided).

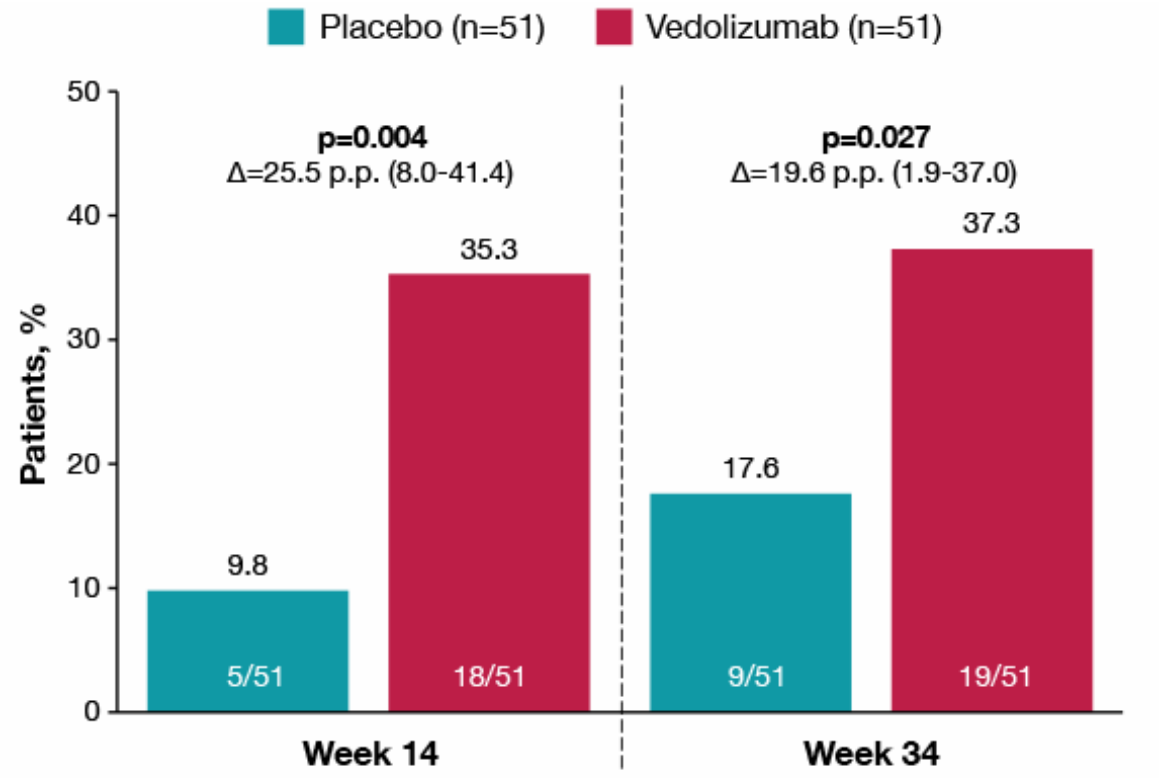
CI, confidence interval; CR, clinical remission; mPDAI, modified Pouchitis Disease Activity Index; VDZ, vedolizumab. Travis S, et al. *United European Gastroenterol J.* 2021;9(8):531–532.

Takeda has no approved therapies to treat or prevent chronic pouchitis. The information provided is in the public domain. Regulatory approval of this indication is dependent on the completion of the study program and review by regulatory authorities pending. Currently there is no biologic to treat this condition. Takeda does not recommend the use of unapproved products.

Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial (3/5)

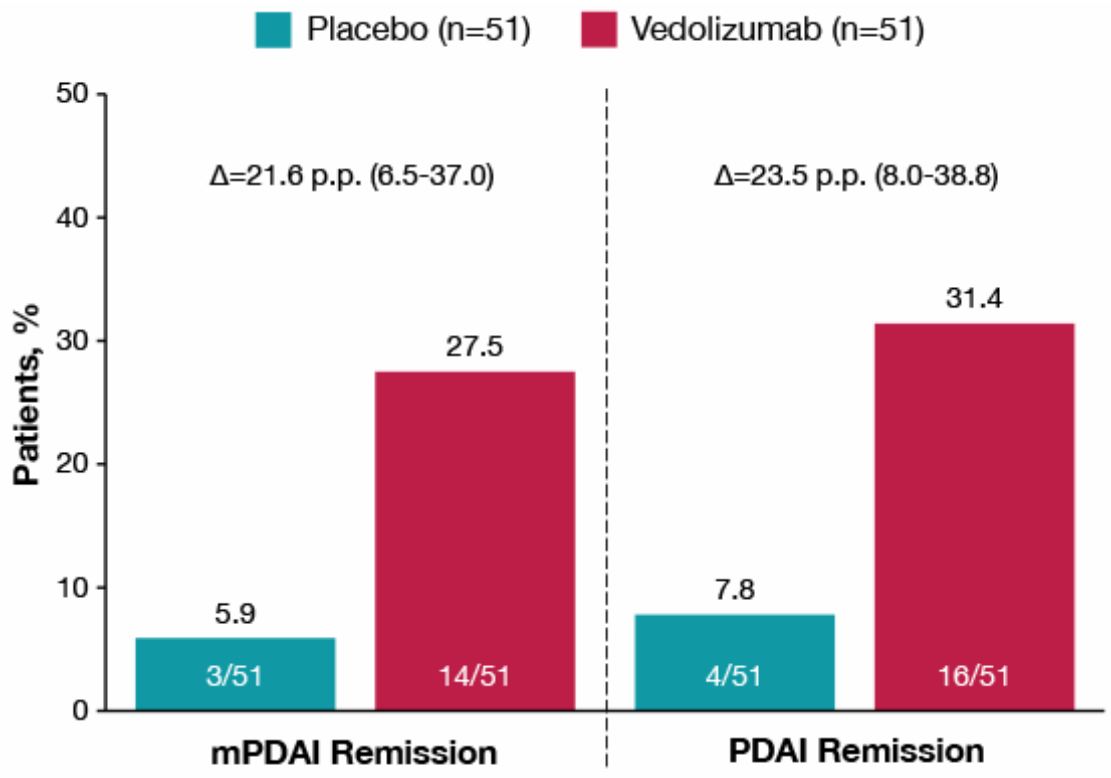
Results

PDAI remission[a] rates (Full analysis set)



Δ=vedolizumab–placebo (exact 95% confidence interval). p values from chi-squared test (or from Fisher's exact test, if number of responders was ≤5 in any arm); nominal p values shown for secondary endpoints because multiplicity adjustment for inferential testing was not performed. Patients with PDAI missing at a visit were counted as non-remitters.
PDAI, Pouchitis Disease Activity Index; p.p., percentage points.
[a]PDAI remission defined as a PDAI score of <7 and a decrease in PDAI score of ≥3 points from baseline.

Sustained remission rates (Full analysis set)



Δ=vedolizumab–placebo (exact 95% confidence interval). Patients with data missing at a visit were counted as non-remitters.
(m)PDAI, (modified) Pouchitis Disease Activity Index; p.p., percentage points.

Travis S, et al. *United European Gastroenterol J.* 2021;9(8):531–532.

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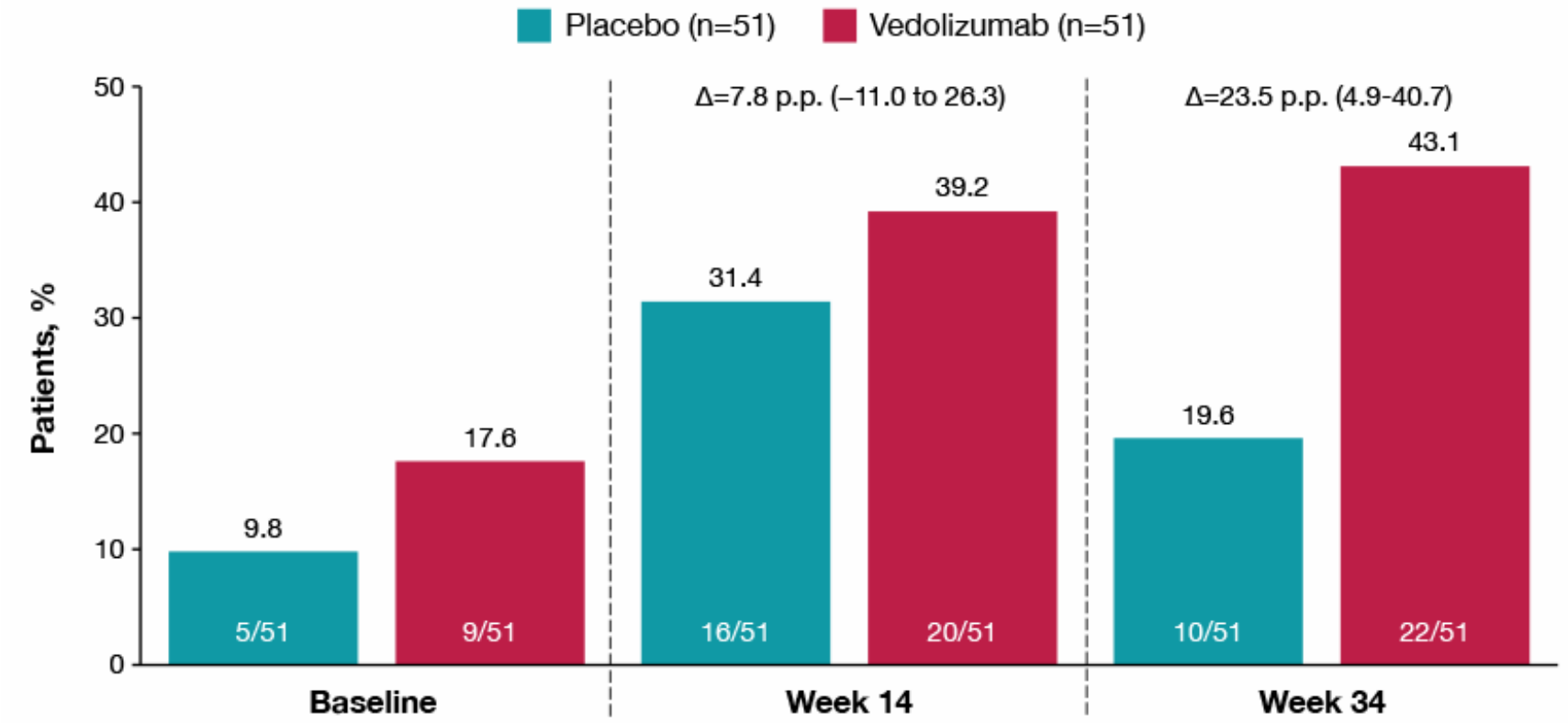
Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial (4/5)

Results

IBDQ remission[a] rates (Full analysis set)



Δ=vedolizumab–placebo (exact 95% confidence interval).
IBDQ, Inflammatory Bowel Disease Questionnaire; p.p, percentage points.
[a]IBDQ remission defined as total IBDQ score of ≥170; patients with missing data at a visit were counted as non-remitters.

Travis S, et al. *United European Gastroenterol J.* 2021;9(8):531–532.

Takeda has no approved therapies to treat or prevent chronic pouchitis. The information provided is in the public domain. Regulatory approval of this indication is dependent on the completion of the study program and review by regulatory authorities pending. Currently there is no biologic to treat this condition. Takeda does not recommend the use of unapproved products.

Efficacy and safety of intravenous vedolizumab for treatment of chronic pouchitis: Results of the Phase 4 EARNEST Trial (5/5)

Results

Summary of AEs (Safety analysis set[a])

	Number of Patients, n (%)	
Preferred Term	**VDZ (n=51)**	**Placebo (n=51)**
Any AE	47 (92.2)	44 (86.3)
Treatment-related AE	12 (23.5)	11 (21.6)
AE leading to study drug discontinuation	1 (2.0)	5 (9.8)
Any serious AE	3 (5.9)	4 (7.8)
Serious AE related to study treatment	0	1 (2.0)
Serious AE leading to study drug discontinuation	0	0
Deaths	0	0

[a]Safety analysis set comprised all patients who received ≥1 dose of study drug.

Conclusion

- In this randomised, double-blind, placebo-controlled trial in patients with chronic or recurrent pouchitis, VDZ was statistically superior to placebo at achieving remission
- The improvements in pouchitis disease activity observed with VDZ treatment were associated with improvements in quality of life
- No new safety signals were identified; most AEs were mild to moderate in severity and considered unrelated to treatment

AE, adverse event; VDZ, vedolizumab.

Travis S, et al. *United European Gastroenterol J.* 2021;9(8):531–532.

Fachkurzinformation

Entyvio® 300 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Entyvio® 108 mg Injektionslösung in einer Fertigspritze
Entyvio® 108 mg Injektionslösung in einem Fertigpen

Qualitative und Quantitative Zusammensetzung: Entyvio® 300 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung: Jede Durchstechflasche enthält 300 mg Vedolizumab. Nach Rekonstitution enthält 1 ml Infusionslösung 60 mg Vedolizumab. Entyvio® 108 mg Injektionslösung: Jede Fertigspritze / Jeder Fertigpen enthält 108 mg Vedolizumab in 0,68 ml. Vedolizumab ist ein humanisierter monoklonaler IgG_1-Antikörper, der durch rekombinante DNA-Technik in Ovarialzellen des chinesischen Hamsters (CHO-Zellen) produziert wird. **Liste der sonstigen Bestandteile:** Entyvio® 300 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung: L-Histidin, L-Histidin-Monohydrochlorid, L-Arginin-Hydrochlorid, Saccharose, Polysorbat 80. Entyvio® 108 mg Injektionslösung: Citronensäure-Monohydrat, Natriumcitrat-Dihydrat, L-Histidin, L-Histidin-Monohydrochlorid, L-Arginin-Hydrochlorid, Polysorbat 80, Wasser für Injektionszwecke. **Anwendungsgebiete:** Colitis ulcerosa: Entyvio ist indiziert für die Behandlung von erwachsenen Patienten mit mittelschwerer bis schwerer aktiver Colitis ulcerosa, die entweder auf konventionelle Therapie oder einen der Tumornekrosefaktor-alpha (TNFα)-Antagonisten unzureichend angesprochen haben, nicht mehr darauf ansprechen oder eine Unverträglichkeit gegen eine entsprechende Behandlung aufweisen. Morbus Crohn: Entyvio ist indiziert für die Behandlung von erwachsenen Patienten mit mittelschwerem bis schwerem aktiven Morbus Crohn, die entweder auf konventionelle Therapie oder einen der Tumornekrosefaktor-alpha (TNFα)-Antagonisten unzureichend angesprochen haben, nicht mehr darauf ansprechen oder eine Unverträglichkeit gegen eine entsprechende Behandlung aufweisen. **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. Aktive schwere Infektionen wie Tuberkulose (TBC), Sepsis, Cytomegalievirus, Listeriose und opportunistische Infektionen, wie z. B. progressive multifokale Leukoenzephalopathie (PML). **Pharmakotherapeutische Gruppe:** Immunsuppressiva, selektive Immunsuppressiva, ATC-Code: L04AA33. **Inhaber der Zulassung:** Takeda Pharma A/S, Delta Park 45, 2665 Vallensbaek Strand, Dänemark. **Abgabe:** rezept- und apothekenpflichtig.
Informationen zu Besonderen Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln und sonstige Wechselwirkungen, Fertilität, Schwangerschaft und Stillzeit sowie Nebenwirkungen sind der veröffentlichten Fachinformation zu entnehmen. [04]

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