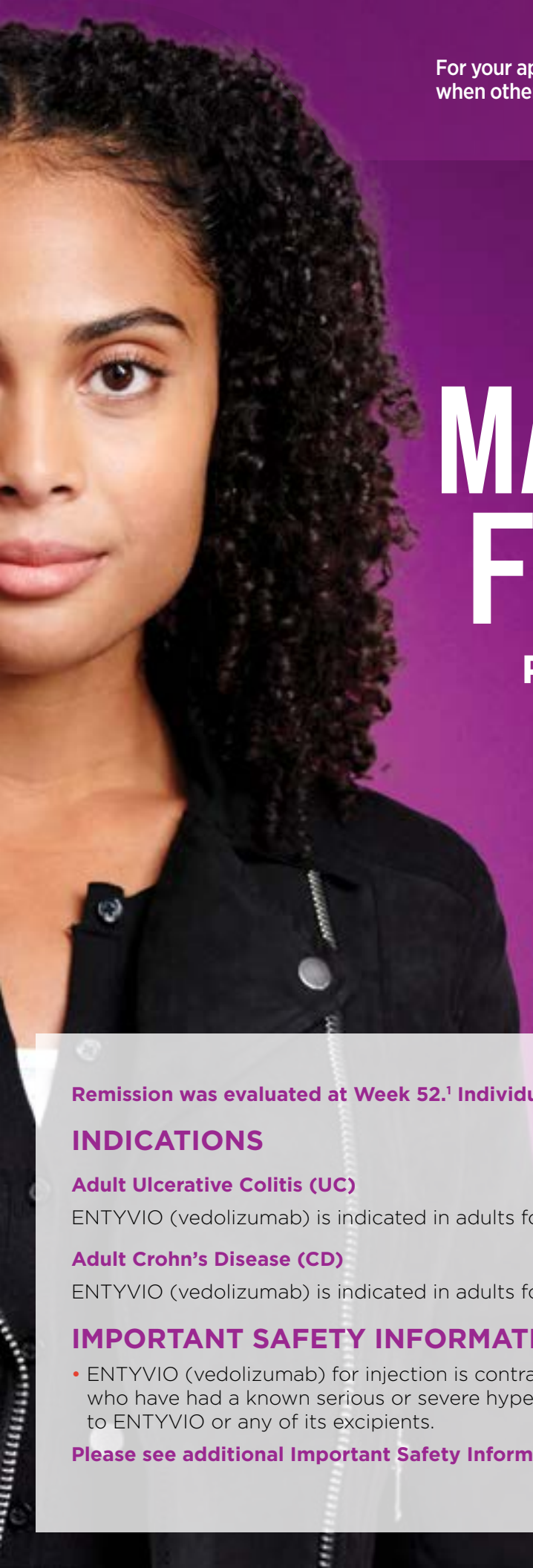


For your appropriate adult patients with moderately to severely active UC or CD when other therapies have not worked well enough or cannot be tolerated

MADE FOR NOW

Post-hoc analysis of patient-reported outcomes

Remission was evaluated at Week 52.[1] Individual results may vary.

INDICATIONS

Adult Ulcerative Colitis (UC)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

Adult Crohn's Disease (CD)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD.

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see additional Important Safety Information on pages 14 and 15.

Entyvio®
vedolizumab

UC TRIALS I AND II STUDY DESIGN[1,2]

Two randomized, double-blind, placebo-controlled studies enrolled adult patients with moderately to severely active UC who had failed at least 1 conventional therapy, including corticosteroids or immunomodulators and/or ≥1 anti-TNFα therapy. Concomitant aminosalicylates, corticosteroids, and immunomodulators were permitted in both trials.

In UC Trial I (N=374), patients were randomized (3:2) to receive Entyvio (vedolizumab) 300 mg or placebo by intravenous infusion at Weeks 0 and 2. The primary end point for UC Trial I was the proportion of patients with clinical response (reduction in complete Mayo score of ≥3 points and ≥30% from baseline with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point) at Week 6.

In UC Trial II (N=373), patients receiving Entyvio who demonstrated clinical response at Week 6 (from UC Trial I or an open-label cohort) were randomized (1:1:1) to receive Entyvio 300 mg every 8 weeks (Q8W), Entyvio 300 mg every 4 weeks (Q4W), or placebo every 4 weeks. The primary end point for UC Trial II was the proportion of patients in clinical remission (complete Mayo score ≤2 and no individual subscore >1) at Week 52.

The Entyvio Q4W dosing regimen did not demonstrate additional clinical benefit over the Q8W dosing regimen. The Q4W dosing regimen is not the recommended dosing regimen.

IMPORTANT SAFETY INFORMATION

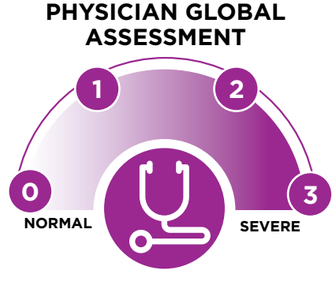
- Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

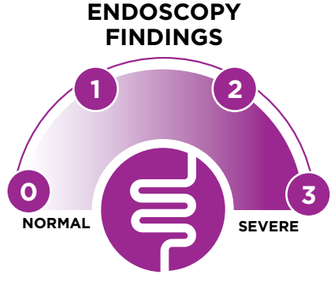
Please see additional Important Safety Information on pages 14 and 15.

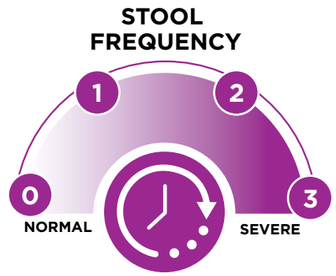
TNFα = tumor necrosis factor alpha.

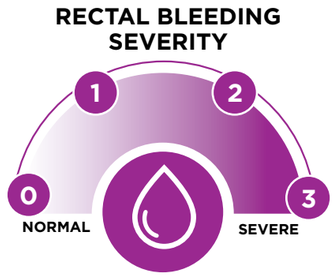
THE MAYO SCORE IS USED TO ASSESS THE SEVERITY OF UC[3,4]

The Mayo score ranges from 0 to 12 and has 4 subscales that are each scored from 0 (normal) to 3 (most severe). The rectal bleeding and stool frequency subscores are patient-reported outcomes (PROs) of the Mayo score.









The 2 individual patient-reported components (stool frequency subscore and rectal bleeding subscore) are part of the Mayo score and were not powered for statistical significance.

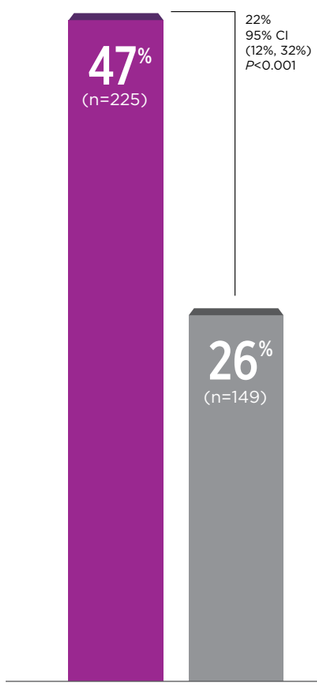
IMPORTANT SAFETY INFORMATION

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

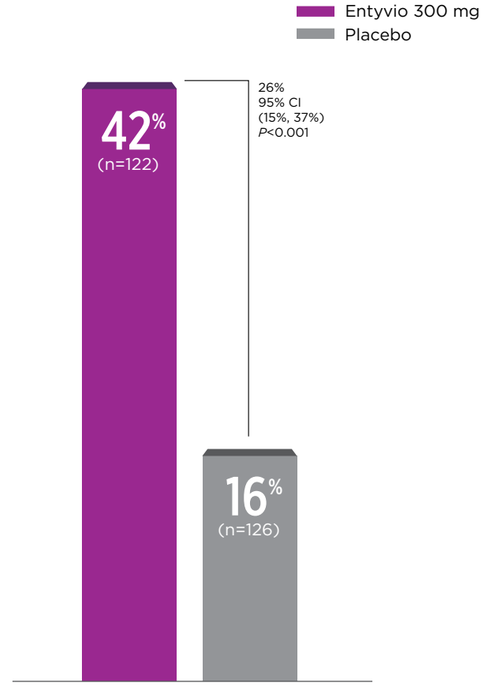
Please see additional Important Safety Information on pages 14 and 15.

TURN TO ENTYVIO (vedolizumab) FOR RAPID RESPONSE AND LASTING REMISSION[1]

Clinical Response at Week 6*



Clinical Remission at Week 52†



*Clinical response = reduction in complete Mayo score of ≥3 points and ≥30% from baseline with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point.
†Clinical remission = complete Mayo score of ≤2 points and no individual subscore >1 point.

IMPORTANT SAFETY INFORMATION

- Progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported in the postmarketing setting (e.g., human immunodeficiency virus [HIV] infection with a CD4 count of 300 cells/mm^3 and prior and concomitant immunosuppression). Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.

Please see additional Important Safety Information on pages 14 and 15.

CI = confidence interval.

POST-HOC ANALYSIS OF PATIENT-REPORTED MAYO SCORE COMPONENTS AT WEEKS 2, 4, 6[4*†]

The 2 individual patient-reported components (stool frequency and rectal bleeding) are part of the Mayo score and were not powered for statistical significance.

Correlation of depicted PROs to Week 6 and Week 52 primary end points was not evaluated in the analysis.

ANALYSIS OF RECTAL BLEEDING SUBSCORE (RBS): DIFFERENCE ADJUSTED MEAN PERCENTAGE CHANGE FOR ENTYVIO MINUS PLACEBO (95% CI)

- **Anti-TNFα Naïve**
- **Anti-TNFα Exposed**
- **Overall**

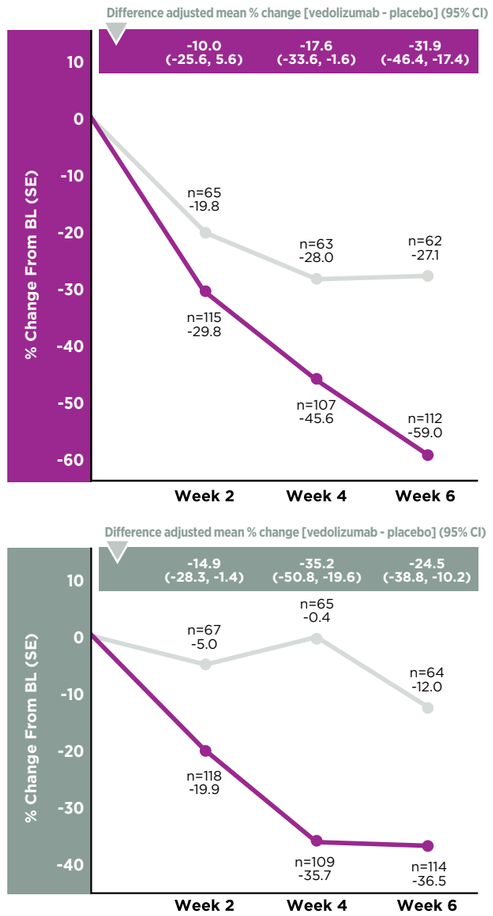
ANALYSIS OF STOOL FREQUENCY SUBSCORE (SFS): DIFFERENCE ADJUSTED MEAN PERCENTAGE CHANGE FOR ENTYVIO MINUS PLACEBO (95% CI)

- **Anti-TNFα Naïve**
- **Anti-TNFα Exposed**
- **Overall**

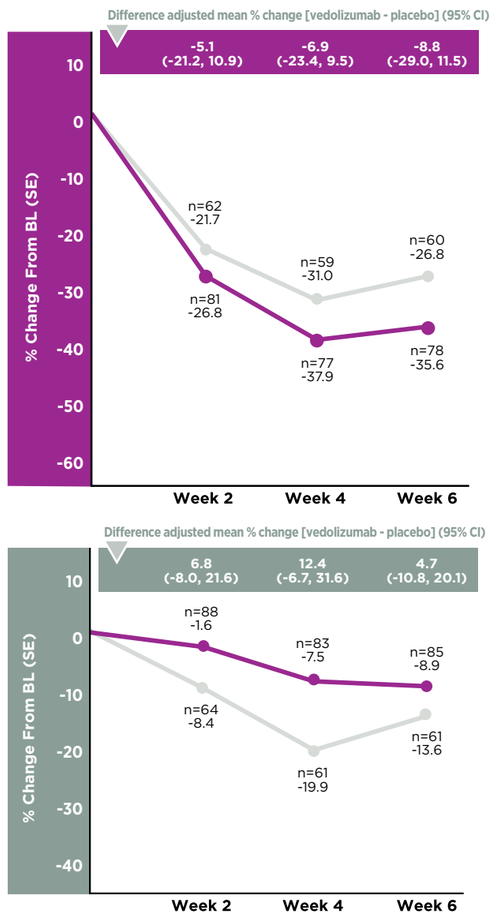
Entyvio
Placebo

EXPLORATORY ANALYSIS OF UC TRIAL I

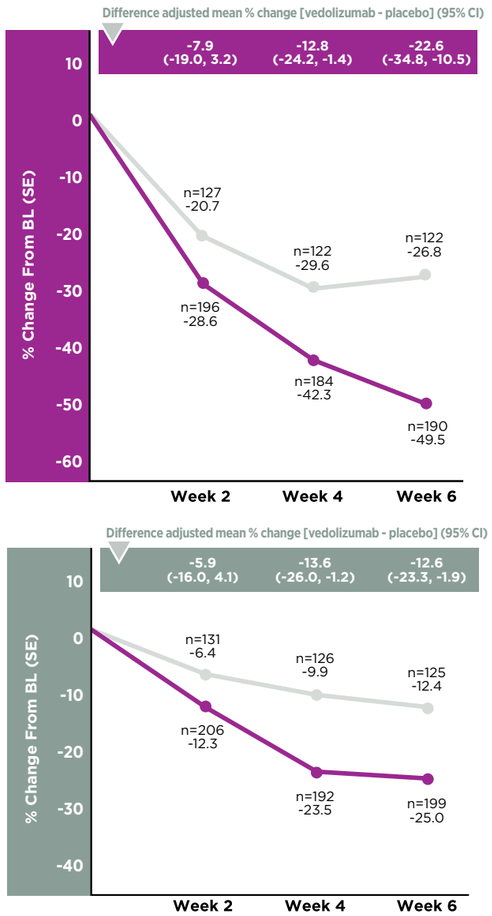
ANTI-TNFα NAÏVE



ANTI-TNFα EXPOSED



OVERALL



UC TRIAL I: PRIMARY END POINT
Clinical Response at Week 6 in Overall Population

Defined as reduction in complete Mayo score of ≥3 points and ≥30% from baseline with an accompanying decrease in rectal bleeding subscore of ≥1 point or absolute rectal bleeding subscore of ≤1 point

- Entyvio 300 mg (Weeks 0, 2): 47% (n=225)
- Placebo: 26% (n=149)
- Δ = 22%; 95% CI (12%, 32%); *P*<0.001

UC TRIAL II: PRIMARY END POINT
Clinical Remission at Week 52 in Overall Population

Defined as complete Mayo score of ≤2 points and no individual subscore >1 point

- Entyvio 300 mg Q8W: 42% (n=122)
- Placebo: 16% (n=126)
- Δ = 26%; 95% CI (15%, 37%); *P*<0.001

For the primary end points of clinical response at Week 6 and clinical remission at Week 52, please see page 5.

*Data are derived from a post-hoc analysis of UC Trial I and therefore not powered for statistical significance and should be considered exploratory.
†Patients with baseline RBS=0 or SFS=0 were excluded from the analysis.

IMPORTANT SAFETY INFORMATION

- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

Please see additional Important Safety Information on pages 14 and 15.

BL = baseline.

CD TRIALS I, II, AND III STUDY DESIGN[1,5]

Three randomized, double-blind, placebo-controlled studies enrolled adult patients with moderately to severely active CD who had failed at least 1 conventional therapy, including corticosteroids, immunomodulators, and/or ≥1 anti-TNFα therapy. Concomitant aminosalicylates, corticosteroids, and immunomodulators were permitted in all trials.

In CD Trial I (N=368), patients were randomized (3:2) to receive Entyvio (vedolizumab) 300 mg or placebo by intravenous infusion at Weeks 0 and 2. One primary end point for CD Trial I was the proportion of patients with clinical remission (CDAI score ≤150) at Week 6. Another primary end point, the difference in percentage of patients who demonstrated clinical response (≥100-point decrease in CDAI score from baseline), was not statistically significant at Week 6.

In CD Trial II (N=416), patients were randomized (1:1) to receive either Entyvio 300 mg or placebo at Weeks 0, 2, and 6. A majority (76%) of enrolled patients had an inadequate response, loss of response, or intolerance to ≥1 TNF blockers; this was the primary analysis population. The primary end point for CD Trial II was the proportion of patients achieving clinical remission (CDAI score ≤150) at Week 6. Treatment with Entyvio did not result in statistically significant improvement over placebo.

In CD Trial III (N=461), patients receiving Entyvio who demonstrated clinical response (≥70-point decrease in CDAI score from baseline) at Week 6 (from CD Trial I or an open-label cohort) were randomized (1:1:1) to receive either Entyvio 300 mg every 8 weeks, Entyvio 300 mg every 4 weeks, or placebo every 4 weeks. The primary end point for CD Trial III was the proportion of patients achieving clinical remission (CDAI score ≤150) at Week 52.

The Entyvio Q4W dosing regimen did not demonstrate additional clinical benefit over the Q8W dosing regimen. The Q4W dosing regimen is not the recommended dosing regimen.

IMPORTANT SAFETY INFORMATION

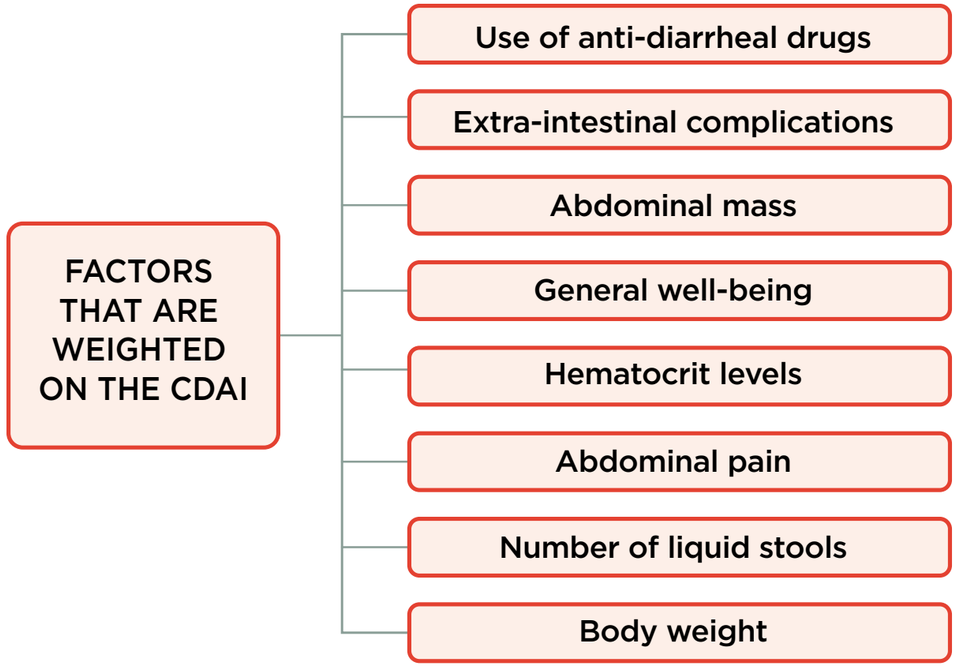
- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

Please see additional Important Safety Information on pages 14 and 15.

CDAI = Crohn's Disease Activity Index.

THE CDAI IS USED TO ASSESS SEVERITY OF CD[4,6]

The CDAI consists of 8 factors that are used to assess the severity of CD.
The loose stool frequency and abdominal pain subscores are PROs of the CDAI.



The 2 individual patient-reported components (loose stool frequency subscore and abdominal pain subscore) are part of the CDAI and were not powered for statistical significance.

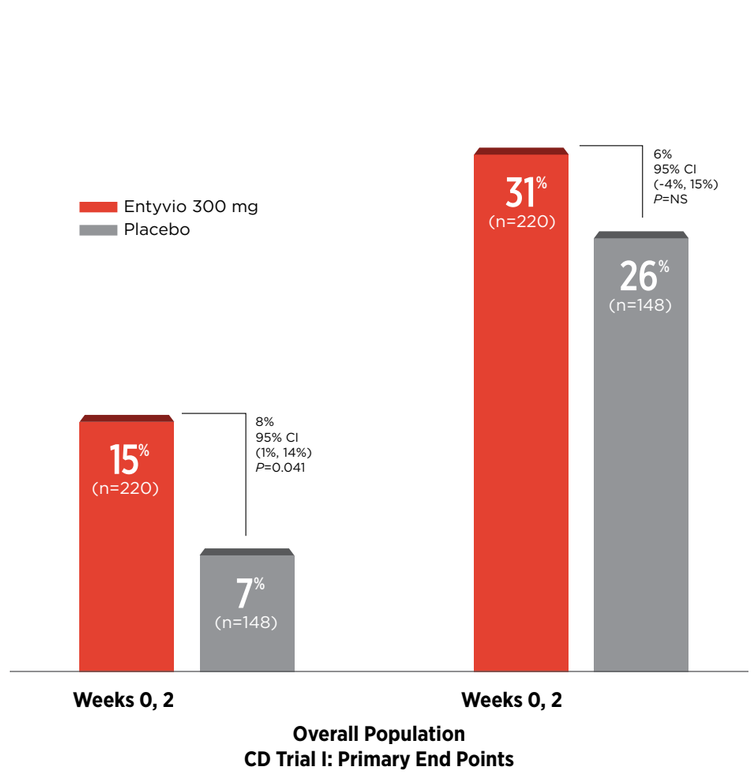
IMPORTANT SAFETY INFORMATION

- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please see additional Important Safety Information on pages 14 and 15.

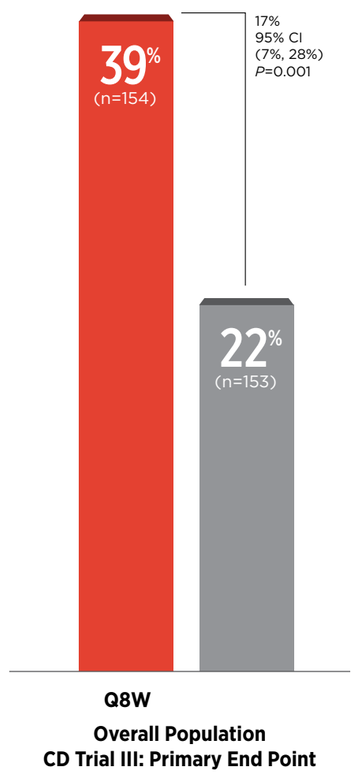
TURN TO ENTYVIO (vedolizumab) TO ACHIEVE REMISSION[1,5,7]

Clinical Remission Rates at Week 6*



Clinical Response Rates at Week 6†

Clinical Remission Rates at Week 52*



- In a separate study (CD Trial II), 15% (n=158) of patients taking Entyvio who had a suboptimal response to ≥1 anti-TNFα therapy achieved clinical remission at Week 6 vs 12% (n=157) with placebo (*P*=NS) (primary end point, CD Trial II)

*Clinical remission = CDAI score ≤150.
†Clinical response = ≥100-point decrease in CDAI from baseline.
NS = not significant.

IMPORTANT SAFETY INFORMATION

- Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Please see additional Important Safety Information on pages 14 and 15.

POST-HOC ANALYSIS OF PATIENT-REPORTED CDAI COMPONENTS AT WEEKS 2, 4, 6[4*†]

The 2 individual patient-reported components (loose stool frequency and abdominal pain) are part of the CDAI and not powered for statistical significance.

Correlation of depicted PROs to Week 6 and Week 52 primary end points was not evaluated in the analysis.

ANALYSIS OF ABDOMINAL PAIN SUBSCORE (APS): DIFFERENCE ADJUSTED MEAN PERCENTAGE CHANGE FOR ENTYVIO MINUS PLACEBO (95% CI)

- **Anti-TNFα Naïve**
- **Anti-TNFα Exposed**
- **Overall**

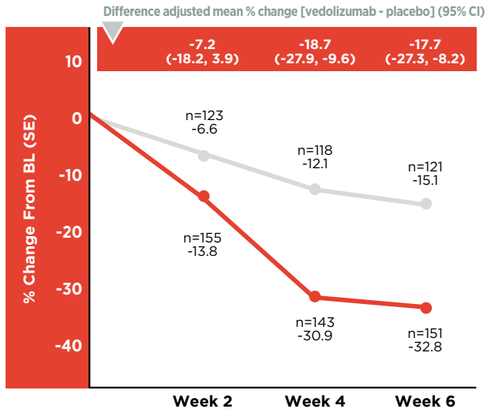
ANALYSIS OF LOOSE STOOL FREQUENCY SUBSCORE (LSFS): DIFFERENCE ADJUSTED MEAN PERCENTAGE CHANGE FOR ENTYVIO MINUS PLACEBO (95% CI)

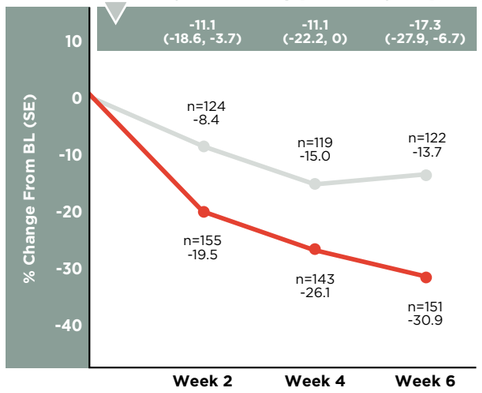
- **Anti-TNFα Naïve**
- **Anti-TNFα Exposed**
- **Overall**

Entyvio
Placebo

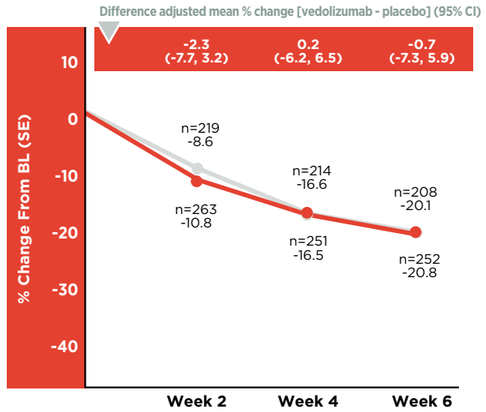
POOLED EXPLORATORY ANALYSIS OF CD TRIALS I AND II

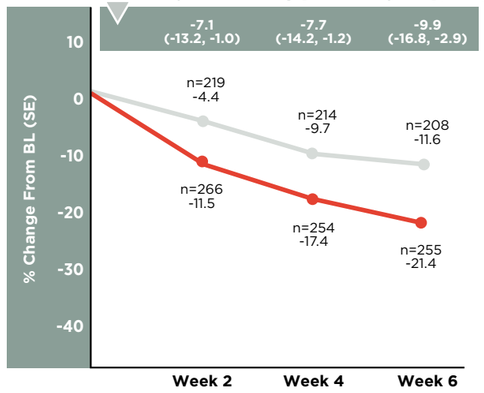
ANTI-TNFα NAÏVE



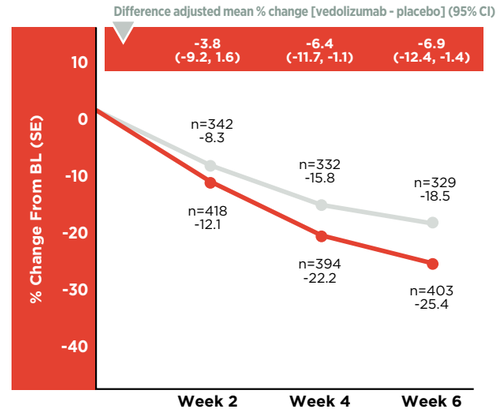


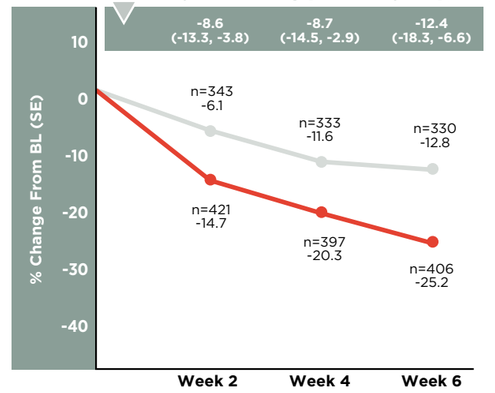
ANTI-TNFα EXPOSED





OVERALL





*Data are derived from a post-hoc pooled analysis of CD Trials I and II and therefore not powered for statistical significance and should be considered exploratory.
†Patients with baseline APS=0 and LSFS=0 were excluded from the analysis.

CD TRIALS I AND II: PRIMARY END POINTS
Clinical Remission at Week 6 in Overall Population
Defined as CDAI score ≤150
- Entyvio 300 mg (Weeks 0, 2) (CD Trial I): 15% (n=220)
- Placebo (CD Trial I): 7% (n=148)
- Δ (CD Trial I) = 8%; 95% CI (1%, 14%); *P*=0.041
- Entyvio 300 mg (Weeks 0, 2) (CD Trial II): 15% (n=158)
- Placebo (CD Trial II): 12% (n=157)
- Δ (CD Trial II) = 3%; 95% CI (-5%, 11%); *P*=NS

CD TRIAL I: PRIMARY END POINT
Clinical Response at Week 6 in Overall Population
Defined as ≥100-point decrease in CDAI from BL
- Entyvio 300 mg (Weeks 0, 2): 31% (n=220)
- Placebo: 26% (n=148)
- Δ = 5%.; 95% CI (-4%, 15%); *P*=NS

For the primary end points of clinical remission at Week 6, clinical response at Week 6, and clinical remission at Week 52, please see page 11.

IMPORTANT SAFETY INFORMATION

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

Please see additional Important Safety Information on pages 14 and 15.

INDICATIONS

Adult Ulcerative Colitis (UC)
ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

Adult Crohn's Disease (CD)
ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD.

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

- Infusion-related reactions and hypersensitivity reactions including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have been reported. These reactions may occur with the first or subsequent infusions and may vary in their time of onset from during infusion or up to several hours post-infusion. If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

Entyvio® vedolizumab

IMPORTANT SAFETY INFORMATION *(continued)*

- Progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system (CNS), has been reported with systemic immunosuppressants, including another integrin receptor antagonist. PML is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported in the postmarketing setting (e.g., human immunodeficiency virus [HIV] infection with a CD4 count of 300 cells/mm^3 and prior and concomitant immunosuppression). Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.

- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please click to see full Prescribing Information and Medication Guide.

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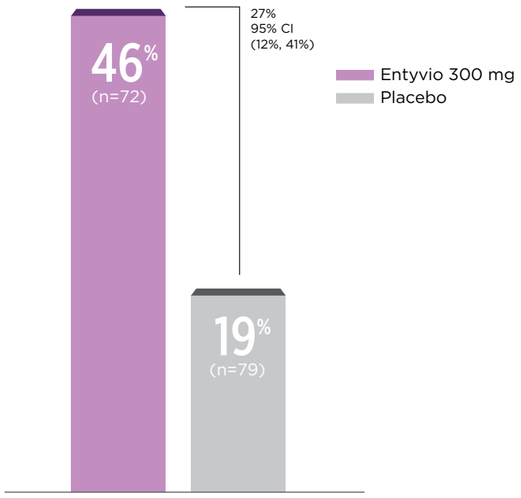
1. Entyvio (vedolizumab) prescribing information. Takeda Pharmaceuticals. **2.** Feagan BG, Rutgeerts P, Sands BE, et al; for the GEMINI 1 Study Group. *N Engl J Med.* 2013;369(8):699-710. **3.** Schroeder KW, Tremaine WJ, Ilstrup DM. *N Engl J Med.* 1987;317(26):1625-1629. **4.** Feagan B, Lasch K, Lissoos T, et al. *Clin Gastroenterol Hepatol.* 2019;17:130-138. Published correction appears in *Clin Gastroenterol Hepatol.* 2020;18(3):759. **5.** Sandborn WJ, Feagan BG, Rutgeerts P, et al for the GEMINI 2 Study Group. *N Engl J Med.* 2013;369(8):711-721. **6.** Best WR, Becktel JM, Singleton JW, et al. *Gastroenterology.* 1976;70:439-444. **7.** Data on file. MLN0002, Final CSR C13007, October 2012. Takeda Pharmaceuticals USA, Inc. **8.** Data on file. MLN0002, Final CSR C13006, September 2012. Takeda Pharmaceuticals USA Inc. **9.** Fedyk E, Wyant T, Yang LL, et al. *Inflamm Bowel Dis.* 2012;18(11):2107-2119. **10.** Soler D, Chapman T, Yang LL, et al. *J Pharmacol Exp Ther.* 2009;330(3):864-875. **11.** Wyant T, Fedyk E, Abhyankar B. *J Crohns Colitis.* 2016;10(12):1437-1444. **12.** Wyant T, Leach T, Sankoh S, et al. *Gut.* 2015;64(1):77-83. **13.** Milch C, Wyant T, Xu J, et al. *J Neuroimmunol.* 2013;264:123-126. **14.** Briskin M, Winsor-Hines D, Shyjan A, et al. *Am J Pathol.* 1997;151(1):97-110. **15.** Loftus EV, Feagan BG, Panaccione R, et al; for the GEMINI LTS study team. *Aliment Pharmacol Ther.* 2020; 52(8):1353-1365. **16.** Data on file. MLN0002, Final CSR C13008, July 2018. Takeda Pharmaceuticals USA, Inc. **17.** Data on file. Internal communication, October 2020. Takeda Pharmaceuticals USA, Inc.

FROM THE BEGINNING OF THE JOURNEY TO WHAT MATTERS MOST—LONG-TERM REMISSION[1]

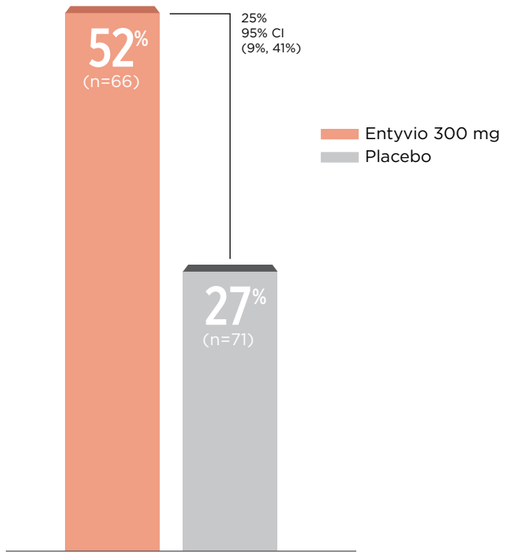
Clinical Remission Rates at Week 52 in UC[8]*



Anti-TNFα Naïve Subpopulation

UC Trial II: Exploratory End Point
Not powered for statistical significance.

Clinical Remission Rates at Week 52 in CD[7]†



Anti-TNFα Naïve Subpopulation

CD Trial III: Exploratory End Point
Not powered for statistical significance.

UC TRIAL II: PRIMARY END POINT
Clinical Remission at Week 52 in Overall Population*
- Entyvio 300 mg Q8W: 42% (n=122)
- Placebo: 16% (n=126)
- Δ = 26%; 95% CI (15%, 37%); *P*<0.001

UC TRIAL II: EXPLORATORY END POINT
Clinical Remission at Week 52 in Anti-TNFα-experienced Subpopulation*
- Entyvio 300 mg Q8W: 37% (n=43); 95% CI (23%, 53%)
- Placebo: 5% (n=38); 95% CI (1%, 18%)
- Δ = 32%; 95% CI (10%, 51%)

CD TRIAL III: PRIMARY END POINT
Clinical Remission at Week 52 in Overall Population†
- Entyvio 300 mg Q8W: 39% (n=154)
- Placebo: 22% (n=153)
- Δ = 17%; 95% CI (7%, 28%); *P*=0.001

CD TRIAL III: EXPLORATORY END POINT
Clinical Remission at Week 52 in Anti-TNFα-experienced Subpopulation†
- Entyvio 300 mg Q8W: 28% (n=82); 95% CI (18%, 38%)
- Placebo: 13% (n=78); 95% CI (5%, 20%)
- Δ = 15%; 95% CI (3%, 28%)

For the primary end points of clinical response at Week 6 and clinical remission at Week 52 in UC, please see page 5.
For the primary end points of clinical remission at Week 6, clinical response at Week 6, and clinical remission at Week 52 in CD, please see page 11.

*Clinical remission (UC) = complete Mayo score of ≤2 points and no individual subscore >1 point.
†Clinical remission (CD) = CDAI score ≤150.

For your appropriate adult patients with moderately to severely active UC or CD

ONLY ENTYVIO COMBINES

GUT SELECTIVITY[9-14]

Entyvio helps address inflammation where it occurs—in the gut.[1]

Entyvio specifically binds to the α4β7 integrin and blocks the interaction between the α4β7 integrin and MAdCAM-1, which is mainly expressed on the GI tract endothelial cells.

LONG-TERM REMISSION[1]

UC and CD patients achieved remission at Week 52 vs placebo in study populations that included bio-naïve and anti-TNFα-experienced patients.[1,7,8]

Individual results may vary.

SAFETY FOR THE LONG TERM[15-17]

Clinical trials evaluated safety in more than 3300 adults (UC, CD, and healthy volunteers).[1] A separate open-label study of up to 7 years demonstrated consistent results across safety parameters.[15-17‡]

NO BOXED WARNINGS

‡In a single-arm, open-label extension study of 2243 patients who received Entyvio with a median exposure of 1072 days (range 1 to 3412 days).[15-17]

IMPORTANT SAFETY INFORMATION

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

SELECTED SAFETY INFORMATION

- If anaphylaxis or other serious infusion-related or hypersensitivity reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.
- ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled.
- Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms.
- ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

Please see Important Safety Information on pages 14 and 15.

GI = gastrointestinal; MAdCAM-1 = mucosal addressin cell adhesion molecule-1.

For your appropriate adult patients with moderately to severely active UC or CD when other therapies have not worked well enough or cannot be tolerated

MADE FOR SELECTIVITY
MADE FOR REMISSION
MADE FOR NOW

Entyvio® vedolizumab

Entyvio works through a gut-selective MOA by specifically binding to the α4β7 integrin and blocking its interaction with MAdCAM-1, which is mainly expressed on gut endothelial cells.[1]

Remission was evaluated at Week 52.[1] Individual results may vary.

INDICATIONS

Adult Ulcerative Colitis (UC)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active UC.

Adult Crohn's Disease (CD)

ENTYVIO (vedolizumab) is indicated in adults for the treatment of moderately to severely active CD.

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see Important Safety Information on pages 14 and 15.

MOA = mechanism of action.

If you are a Colorado prescriber, please see the WAC disclosure form at Takeda.com/EntyvioCOPricing

Takeda