ENTYVIO is for adults with moderately to severely active ulcerative colitis (UC).

THE GI PERSPECTIVE

ISSUE 5

The VARSITY trial in UC established

ENTYVIO's SUPERIORITY TO HUMIRA® (adalimumab)

in clinical remission at Week 52[1]*†

VARSITY primary end point (overall population):
ENTYVIO IV 31% (n=383) vs 23% (n=386) with Humira® (*P*=0.006; 95% CI: 3%, 15%)[1]

*Humira® is a registered trademark of AbbVie Inc., North Chicago, IL. For information related to Humira®, please see AbbVie.com.
†Clinical remission was defined as a complete Mayo Score of ≤2 points and no subscore >1 point.

Featuring Aja McCutchen, MD

Dr. Aja McCutchen is a paid consultant of Takeda Pharmaceuticals, Inc.

> **"As a physician treating ulcerative colitis, I want to know which treatments may be more effective for my patients to help reach remission."**
>
> **– AJA MCCUTCHEN, MD**

Entyvio® vedolizumab

INSIDE

- GEMINI I pivotal trial and VARSITY trial data and analyses
- Results in overall population and bio-naïve patients
- Maintenance treatment options

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see page 15 or click for additional Important Safety Information.

Aja McCutchen, MD

- Gastroenterologist at United Digestive
- Vice Chair of AGA Research Foundation
- Co-Founder of Pandora Health

Dr. McCutchen discusses the role of head-to-head data in selecting a treatment for moderate to severe ulcerative colitis

How do head-to-head studies inform your treatment decisions?

"As a physician treating ulcerative colitis, my top priority is understanding which treatments may be more effective for my patients. However, there are few studies directly comparing one treatment to another.[2]

"Randomized head-to-head trials remain the gold standard in helping to determine which treatments may be more effective and how to position them in the treatment sequence.[3]

"The VARSITY trial marked a milestone study in the medical literature as the first head-to-head study of biologics in ulcerative colitis.[1,2] The data showed that ENTYVIO demonstrated superiority to Humira® in clinical remission at Week 52 in the overall population."[1]*

*Clinical remission=complete Mayo Score of ≤2 points and no individual subscore >1 point.

How did the VARSITY trial change how you sequence biologics?

"My approach to patients with moderate to severe UC has always been treating patients holistically using a shared decision-making plan in selecting therapies.

"I always complete an assessment of a patient's individual clinical presentation, including individual patient characteristics, preferences, and previous medication history. This, along with the efficacy and safety of available advanced therapies, will always be at the forefront of my decision tree. With VARSITY, I have an additional piece of data when assessing treatments for my patients."

CLICK HERE to get a deeper dive into the first head-to-head study in UC and the role that it may play in treatment decisions

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** 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.

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Please see page 15 or click for additional Important Safety Information.

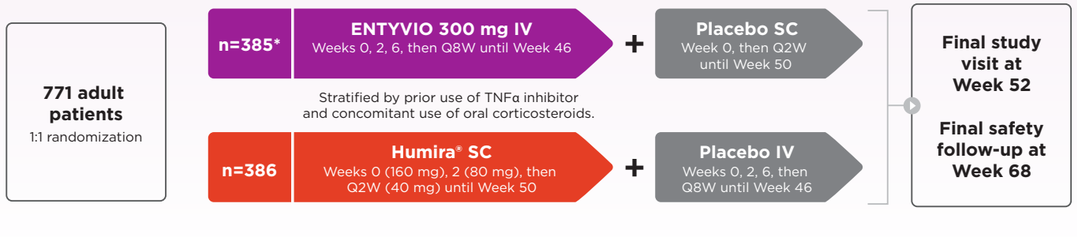
ENTYVIO: Superior to HUMIRA® in clinical remission at Week 52

"VARSITY was a double-blind, double-dummy, active-controlled study of ENTYVIO vs Humira® in adults with moderately to severely active ulcerative colitis.[1]

"A key aspect of this study is its treat-through design, meaning that patients remained in their initial treatment group after starting therapy, rather than being re-randomized based on their treatment response.[1]

"The treat-through design resonates with me because it reflects how we treat patients in real-world clinical practice."

STUDY DESIGN[1,4,5]



Study details

- Eligible patients were adults (aged 18 to 85 years) with moderately to severely active ulcerative colitis, defined as a complete Mayo Score of 6 to 12 (range 0 to 12; higher scores represent more active disease), an endoscopic subscore of ≥2, colonic involvement of ≥15 cm, and a confirmed diagnosis of ulcerative colitis for ≥3 months. Anti-TNFα-naïve patients who had not responded or lost response to conventional treatments were eligible. Centrally read endoscopies were performed at Weeks 14 and 52
- Dosing was consistent with the US product label for both ENTYVIO and Humira®; no dose escalation was permitted for either treatment group. After induction, patients stayed in their treatment group throughout the maintenance phase (treat-through design)
- Enrollment of patients who discontinued treatment with an anti-TNFα (except adalimumab) due to documented reasons other than safety was capped at 25% (~21% was reached). Most of the trial population (97.3%) had moderately to severely active disease (Mayo Score 6-12). Patients with mild disease represented significant protocol deviations. Per-protocol sensitivity analyses indicated no change from overall population results
- Patients naïve to anti-TNFα therapy were enrolled if they were failing current treatment (eg, CS, 5-ASA, or immunomodulators). Per-protocol sensitivity analyses indicated no change from overall population results. Patients on a 5-ASA or immunomodulator at baseline maintained stable doses throughout the study

*Includes 2 patients who were randomized but never received any study drug.

5-ASA=5-aminosalicylate; CS=corticosteroids; IV=intravenous; Q2W=every 2 weeks; Q8W=every 8 weeks; SC=subcutaneous; TNFα=tumor necrosis factor alpha.

"Patients in the VARSITY trial had ulcerative colitis for 6 to 7 years on average and an average Mayo Score of 8.7.[1]

"Notably, the study's time frame was 2015-2019, when only a few FDA-approved biologics were available for UC. **Aside from fewer than 5% of patients with non–anti-TNF biologics experience, patients without TNF exposure were bio-naïve."**[6-11]

BASELINE CHARACTERISTICS OF OVERALL STUDY POPULATION[1]

Patient Baseline Characteristics Characteristic	ENTYVIO (n=385)	Humira® (adalimumab) (n=386)
Age - year	40.8 ± 13.7	40.5 ± 13.4
Male sex - n (%)	234 (60.8)	216 (56.0)
White race - n (%)	345 (89.6)	341 (88.3)
Body weight - kg (mean ± SD)	72.7 ± 17.0	73.4 ± 18.4
Current smoker - n (%)*	19 (4.9)	23 (6.0)
Duration of UC-year (mean ± SD)†	7.3 ± 7.2	6.4 ± 6.0
Total score on the Mayo scale (mean ± SD)‡	8.7 ± 1.6	8.7 ± 1.5
Fecal calprotectin - µg/g (mean ± SD)§	2929 ± 5920	2771 ± 4064
Previous anti-TNFα treatment with documented discontinuation - n (%)	80 (20.8)	81 (21.0)
Previous anti-TNFα treatment with documented failure - n (%)	72 (18.7)	79 (20.5)
Inadequate response	36 (50.0)	40 (50.6)
Loss of response	24 (33.3)	29 (36.7)
Side effects	7 (9.7)	3 (3.8)
Missing data	5 (6.9)	7 (8.9)
Concomitant medication for UC - n (%)		
Corticosteroids only	139 (36.1)	140 (36.3)
Immunomodulators only‖	101 (26.2)	100 (25.9)

*Data on smoking status were missing for 2 patients in the ENTYVIO group.

†One patient in the Humira® group had ulcerative colitis of unknown duration.

‡Scores were available for 384 patients in the Humira® group and 380 patients in the ENTYVIO group.

§Data on fecal calprotectin were available for 332 patients in the Humira® group and 341 patients in the ENTYVIO group.

‖The commonly used immunomodulators in the order of greatest to least were azathioprine, mercaptopurine, and methotrexate.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- **Infections:** 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

Please see page 15 or click for additional Important Safety Information.

ENTYVIO: Superior to HUMIRA® in clinical remission at Week 52

Primary end point

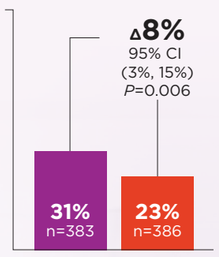
How do you interpret the primary end point results?

"Long-term remission is an important outcome in treating ulcerative colitis, so these results provide invaluable information when I'm making treatment decisions on behalf of my patients."[12]

ENTYVIO IV
Humira® (adalimumab)

PRIMARY END POINT

Here we see ENTYVIO: SUPERIOR TO HUMIRA®, with 31% vs 23% achieving long-term remission, respectively.[1]*



Overall population
Primary end point Week 52

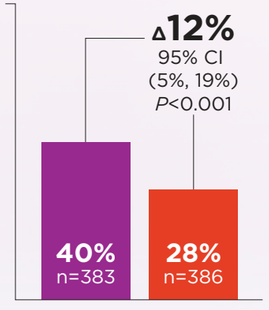
Secondary end points

What were other takeaways from the trial?

"ENTYVIO was also **superior to Humira® in endoscopic improvement at Week 52**. However, there was no statistically significant difference between ENTYVIO and Humira® in corticosteroid-free remission at Week 52."[1]

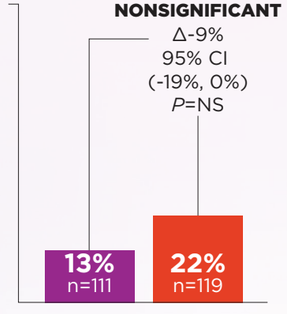
SECONDARY END POINTS

ENTYVIO demonstrated SUPERIORITY TO HUMIRA® in endoscopic improvement[1*]



ENTYVIO IV
Humira® (adalimumab)

Nonsignificant differences in corticosteroid-free remission[1†]



Approximately 36% of randomized patients were on corticosteroids at baseline.

*Clinical remission was defined as a complete Mayo Score of ≤2 points and no subscore >1 point.
CI=confidence interval.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- **Progressive Multifocal Leukoencephalopathy (PML):** 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 typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may 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 neurologist; if confirmed, discontinue ENTYVIO dosing permanently.

Please see page 15 or click for additional Important Safety Information.

*Endoscopic improvement was defined as a Mayo endoscopic subscore of ≤1 point.
†CS-free clinical remission rates were assessed in patients who were receiving corticosteroids at baseline (as reported in electronic case report form). CS-free clinical remission was defined as the population of patients in this subgroup who discontinued corticosteroids by Week 52 and were in clinical remission (defined as complete Mayo Score ≤2 points and no subscore >1 point at Week 52). For patients on corticosteroids at baseline: Doses must have been stable for ≥2 weeks prior to the first dose and remained unaltered through Week 6. After Week 6, a nonfixed dose tapering was started upon achieving response. During tapering, patients could return to baseline doses only once for loss of response before repeating tapering. Per protocol, patients unable to taper were withdrawn from the study and considered treatment failures for each of the outcomes.
CS=corticosteroid.

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VARSITY trial

Exploratory end points

What trends do you see in the subgroup analyses for the subpopulation of patients who were anti-TNFα-naïve?

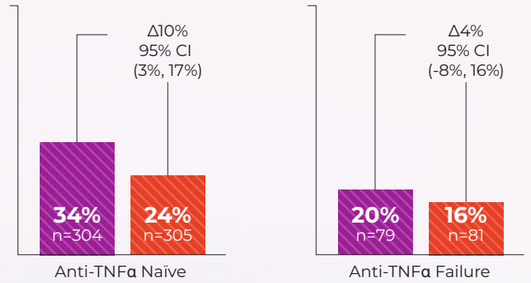
"Nearly 80% of the trial population was anti-TNFα-naïve. The results in **anti-TNFα-naïve patients provides certain insight into the subgroups of the data**."[1]

Subgroup analyses not powered for statistical significance.

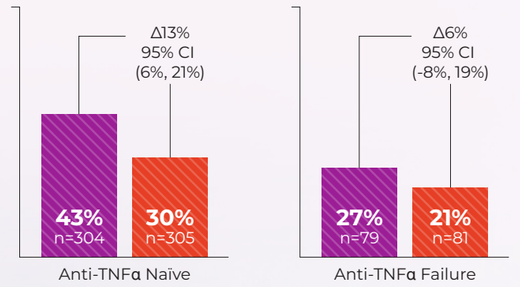
WEEK 52

ENTYVIO IV Humira® (adalimumab)

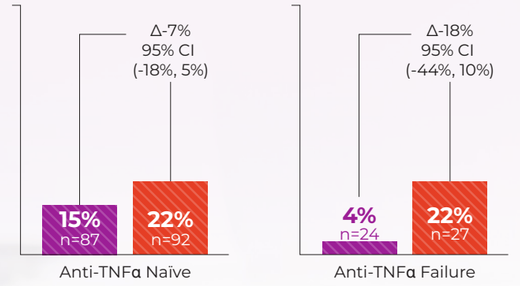
Clinical remission*



Endoscopic improvement†



Corticosteroid-free remission‡



*Clinical remission=complete Mayo Score of ≤2 points and no individual subscore >1 point.
† Endoscopic improvement was defined as a Mayo endoscopic subscore of ≤1 point.
‡ CS-free clinical remission rates were assessed in patients who were receiving corticosteroids at baseline (as reported in electronic case report form). CS-free clinical remission was defined as the population of patients in this subgroup who discontinued corticosteroids by Week 52 and were in clinical remission (defined as complete Mayo Score ≤2 points and no subscore >1 point at Week 52).
CI=confidence interval; CS=corticosteroid; TNFα=tumor necrosis factor alpha.

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IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- **Liver Injury:** 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 page 15 or click for additional Important Safety Information.

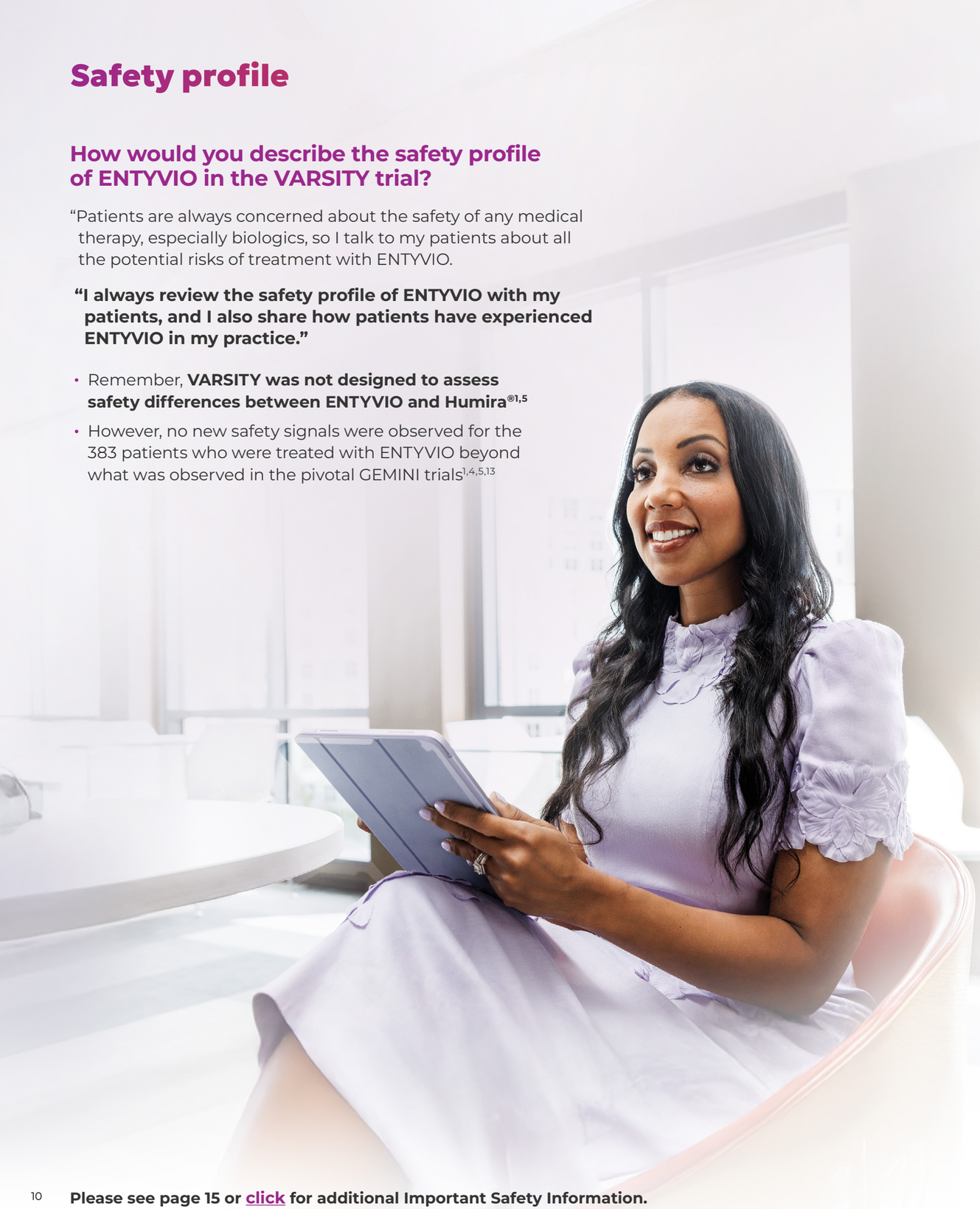
Safety profile

How would you describe the safety profile of ENTYVIO in the VARSITY trial?

"Patients are always concerned about the safety of any medical therapy, especially biologics, so I talk to my patients about all the potential risks of treatment with ENTYVIO.

"I always review the safety profile of ENTYVIO with my patients, and I also share how patients have experienced ENTYVIO in my practice."

- Remember, **VARSITY was not designed to assess safety differences between ENTYVIO and Humira®[1,5]**
- However, no new safety signals were observed for the 383 patients who were treated with ENTYVIO beyond what was observed in the pivotal GEMINI trials[1,4,5,13]



VARSITY was not designed to assess safety differences between ENTYVIO and Humira®

ADVERSE REACTIONS[1]

Adverse Events From VARSITY Trial	ENTYVIO (vedolizumab) (N=383)	Humira® (adalimumab) (N=386)
Event[§]	Patients, n (%)	
Any adverse event	240 (62.7)	267 (69.2)
Mild	111 (29.0)	118 (30.6)
Moderate	92 (24.0)	109 (28.2)
Severe	37 (9.7)	40 (10.4)
Leading to study drug discontinuation	17 (4.4)	25 (6.5)
Adverse events (excluding UC)	229 (59.8)	250 (64.8)
Serious adverse events[‖]	42 (11.0)	53 (13.7)
Leading to study drug discontinuation	10 (2.6)	13 (3.4)
Serious adverse events (excluding UC)	28 (7.3)	27 (7.0)
Deaths[¶]	1 (0.3)	0
Exposure-adjusted incidence rates of adverse events[#]	Number of patients/incidence rate per 100 patient-years	
Infections and infestations	103/23.4	124/34.6
Clostridia	5/1.1	2/0.6
Herpes virus	2/0.5	15/4.2
Lower respiratory tract	5/1.1	7/2.0
Upper respiratory tract	55/12.5	65/18.1
Serious infections and infestations	7/1.6	8/2.2
Musculoskeletal and connective tissue disorders	50/11.4	44/12.3
Arthralgia	18/4.1	16/4.5
Skin and subcutaneous tissue disorders	38/8.6	52/14.5
Psoriasis	1/0.2	6/1.7

- The most frequent AEs[§] for adalimumab and ENTYVIO were as follows: ≥1 TEAE, 35.8% and 32.9%; ulcerative colitis, 16.3% and 11.5%; nasopharyngitis, 7.8% and 7.0%; headache, 5.4% and 7.0%; anemia, 6.7% and 5.2%; abdominal pain, 5.2% and 4.7%; upper respiratory tract infection, 4.4% and 5.2%

*Adverse events that occurred during the trial period. Trial period was the time from the first dose of a trial drug and up to 126 days after the last dose. Adverse events were classified according to the Medical Dictionary for Regulatory Activities System Organ Class categorization and preferred terms (version 21.0). The safety population was defined as all patients who received at least 1 dose of the study drug.
†No cases of progressive multifocal leukoencephalopathy.
‡Not related to ENTYVIO.
§Updated to include final 68-week safety follow-up.
AE=adverse event; TEAE=treatment-emergent adverse event; TNFα=tumor necrosis factor alpha; UC=ulcerative colitis.

Entyvio® vedolizumab

Please see page 15 or click for additional Important Safety Information.

GEMINI I trial

What other data from ENTYVIO's clinical profile do prescribers need to consider?

"It's important to note that the VARSITY trial builds on the data from GEMINI I, the pivotal trial that established the efficacy and safety profile of ENTYVIO IV.

"In this trial, significantly more **ENTYVIO-treated patients achieved rapid response measured at Week 6 and long-term remission measured at Week 52 vs placebo."**[13]

WEEK 6

47% (n=225) of patients on ENTYVIO IV achieved clinical response vs 26% (n=149) with placebo (*P*<0.001; 95% CI: 12%, 32%)*

WEEK 52

42% (n=122) of patients on ENTYVIO IV achieved clinical remission vs 16% (n=126) with placebo (*P*<0.001; 95% CI: 15%, 37%)†

Study Design[13]

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. In UC Trial I, patients were randomized (3:2) to receive ENTYVIO 300 mg or placebo by intravenous infusion at Weeks 0 and 2. In UC Trial II, 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 either ENTYVIO 300 mg every 8 weeks, ENTYVIO 300 mg every 4 weeks, or placebo every 4 weeks. 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.

Results U Need

Lasting relief and CS-free remission at Week 52[13‡]

Rapid symptom relief as early as Week 6[13‡]

Individual results may vary.

*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.
‡Many patients taking ENTYVIO IV achieved remission at Week 52 vs placebo, some without steroids. Some achieved remission at Week 6. Clinical remission was defined as UC complete Mayo Score of ≤2 points and no individual subscore of >1 point. CS-free remission is the proportion of patients receiving corticosteroids at baseline and who discontinued steroids and achieved clinical remission.
CI=confidence interval; IV=intravenous; Q4W=every 4 weeks; Q8W=every 8 weeks.

Summarizing the body of evidence for ENTYVIO

"The pivotal GEMINI I trial demonstrated that ENTYVIO-treated patients achieved both rapid response and long-term remission.[13]

"The landmark VARSITY trial then went on to show that ENTYVIO is superior to Humira® in clinical remission at 52 weeks.[1,2]

"Taken together with ENTYVIO's well-studied clinical profile, I feel confident prescribing ENTYVIO as a first-line biologic for my adult patients with moderate to severe ulcerative colitis after failing or losing response to other conventional therapies, like corticosteroids and immunomodulators."

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- **Live and Oral Vaccines:** 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 page 15 or click for additional Important Safety Information.

Entyvio® vedolizumab

ENTYVIO has 2 options for maintenance therapy: IV and the ENTYVIO Pen

The ENTYVIO Pen for SC injection is a maintenance option after at least 2 IV infusions

What's been your experience with the ENTYVIO Pen in your practice?

"I typically recommend maintenance therapy with IV infusions for patients who prefer the every-8-week dosing schedule or want their treatment administered by a healthcare professional.

"Other patients like to self-administer their maintenance treatment with a subcutaneous injection under the skin every 2 weeks. I recommend the ENTYVIO Pen for patients like this."

"Having 2 options for administration supports our shared decision-making models and gives us the flexibility to recommend the route of administration that better aligns with the patient's preference and lifestyle."

The ENTYVIO Pen was studied in the VISIBLE 1 and VISIBLE 2 trials.[13]

IV=intravenous; SC=subcutaneous.

The efficacy and safety of switching from ENTYVIO SC to ENTYVIO IV have not been studied.

CLICK HERE for dosing and administration information

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Infusion-Related and Hypersensitivity Reactions:** 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.
- **Infections:** 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.
- **Progressive Multifocal Leukoencephalopathy (PML):** 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 typically only occurs in patients who are immunocompromised. One case of PML in an ENTYVIO-treated patient with multiple contributory factors has been reported. Although unlikely, a risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms that may 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 neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- **Liver Injury:** 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.
- **Live and Oral Vaccines:** 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.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥3% and ≥1% higher than placebo) were: nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, pain in extremities, and injection site reactions with subcutaneous administration.

DRUG INTERACTIONS

Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYVIO with natalizumab products and with TNF blockers. Upon initiation or discontinuation of ENTYVIO in patients treated with CYP450 substrates, monitor drug concentrations or other therapeutic parameters, and adjust the dosage of the CYP substrate as needed.

INDICATIONS

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

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

DOSAGE FORMS & STRENGTHS:

- ENTYVIO Intravenous (IV) Infusion: 300 mg vedolizumab
- ENTYVIO Subcutaneous (SC) Injection: 108 mg vedolizumab

Please click for Full Prescribing Information.

Entyvio® vedolizumab

ENTYVIO is for adults with moderately to severely active ulcerative colitis (UC).

> **For patients with moderate to severe ulcerative colitis that have failed conventional therapies, I use ENTYVIO as a first-line biologic.**
>
> **"Plus, with its established safety profile and flexible maintenance treatment options, ENTYVIO is an appropriate treatment option for many of my patients."[13]**
>
> – AJA MCCUTCHEN, MD

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References:
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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENTYVIO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.

Please see page 15 or click for additional Important Safety Information.

Entyvio® vedolizumab

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If you are a Colorado prescriber, please see the Colorado WAC disclosure form.
If you are a Connecticut prescriber or pharmacist, please see the Connecticut WAC disclosure form.