EIGHT different award types; INCREASED Junior Faculty FUNDING; NEW Health Equity Research Award; Med Resident and Student Awards

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Participating in the Webinar

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.
How to Receive CME and MOC Points

LIVE VIRTUAL GRAND ROUNDS WEBINAR
ACG will send a link to a CME & MOC evaluation to all attendees on the live webinar.

ABIM Board Certified physicians need to complete their MOC activities by December 31, 2021 in order for the MOC points to count toward any MOC requirements that are due by the end of the year. No MOC credit may be awarded after March 1, 2022 for this activity.

MOC QUESTION
If you plan to claim MOC Points for this activity, you will be asked to: Please list specific changes you will make in your practice as a result of the information you received from this activity.

Include specific strategies or changes that you plan to implement.
THESE ANSWERS WILL BE REVIEWED.
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Week 42, 2021
*H. pylori: What it Does and Doesn't Cause and How Best to Treat It*

Colin W. Howden, MD, FACC
November 11, 2021 at Noon Eastern

Week 43, 2021
*PSC and Transplantation*

Fredric D. Gordon, MD
November 11, 2021 at Noon Eastern

Visit gi.org/ACGVR to Register

Disclosures:

**Moderator**
Sunanda V. Kane, MD, FACC
Advisory Committee/Board Member: BMS, Boehringer Ingelheim; Consultant: Janssen, Seres Therapeutics, Techfich, United HealthCare, sphere Health, AvenAI; Other: Section editor for UpToDate

**Speaker**
Jean Paul Achkar, MD, FACC
Dr. Achkar, faculty for this educational event, has no relevant financial relationships with ineligible companies to disclose.

**Speaker**
Anita Aftahi, MD, FACC
Advisory Committee/Board Member: AbbVie, Janssen, Pfizer, Takeda, Gilead, Lilly, Bristol Myers Squibb, TLL Pharmaceuticals; Consultant: AbbVie, Janssen, Pfizer, Takeda, Gilead, Lilly, Bristol Myers Squibb, TLL Pharmaceuticals; Other: DiSorin, Arena Pharmaceuticals, Grant/Research Support: AbbVie, Janssen, Bristol Myers Squibb, Lilly, Pfizer; Speakers Bureau: AbbVie, Janssen, Takeda, Pfizer; Other: IBD Horizon (Founder, not for profit education organization); Scrubs & Heels, LLC (Founder, women in gastroenterology organization)

**Speaker**
Tauseef Ali, MD, FACC
Advisory Committee/Board Member: AbbVie, Janssen, Takeda; Consultant: AbbVie, Janssen, Takeda, BMS, Pfizer; Speakers Bureau: AbbVie, Janssen, Takeda, Pfizer, BMS

*All of the relevant financial relationships listed for these individuals have been mitigated*
Agenda

8 pm  Welcome, Sunanda Kane, MD, FACG

8:05-8:25 pm  IBD Therapies, Jean-Paul Achkar, MD, FACG

8:25-8:45 pm  IBD Complications/Medication Safety, Anita Afzali, MD, FACG

8:45-9:05 pm  IBD Potpourri, Tauseef Ali, MD, FACG

9:05-9:30 pm  Discussion & Questions
IBD Therapies

Jean-Paul Achkar, MD, FACG

@JP Achkar MD

Efficacy and safety of upadacitinib induction therapy in patients with moderately to severely active Ulcerative Colitis: Results from the phase 3 U-Achieve study

Silvio Danese,1 Séverine Vermeire,2 Wen Zhou,3 Aileen Pangan,3 Jesse Siffledean,4 Xavier Hébuterne,5 Hiroshi Nakase,6 Peter D.R. Higgins,7 Min-Hu Chen,8 Yuri Sanchez Gonzalez,3 Bidan Huang,3 Wangang Xie,3 John Liu,3 Michael A. Weinreich,9 Remo Panaccione9

1Humanitas University and Humanitas Research Hospital, IRCCS, Milan, Italy; 2Department of Gastroenterology & Hepatology, University Hospital Leuven, KU Leuven, Leuven, Belgium; 3AbbVie Inc., North Chicago, IL, USA; 4University of Alberta, Edmonton, Canada; 5Université Côte d'Azur, CHU de Nice, Nice, France; 6Department of Gastroenterology and Hepatology, Sapporo Medical University School of Medicine, Sapporo, Japan; 7Department of Medicine, Division of Gastroenterology, University of Michigan, Ann Arbor, MI, USA; 8Division of Gastroenterology, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, China; 9Division of Gastroenterology, University of Calgary, Calgary, Alberta
Cytokine signaling and intracellular JAK-STAT signaling cascades

**In vitro inhibition profiles:**
- Tofacitinib - pan-JAK
- Upacitinib, Filgotinib - selective JAK1 inhibition

**U-ACHIEVE STUDY DESIGN**

- 2:1 randomization of 474 patients w/ moderately-severe UC:
  - 319 upacitinib at 45 mg qd
  - 155 placebo
- **Primary endpoint:** proportion of patients in clinical remission at week 8
  - Per adapted Mayo Score (stool frequency subscore ≤1 and not greater than baseline, rectal bleeding subscore of 0, and Mayo endoscopic subscore ≤1)
- **Ranked secondary endpoints**
  - Endoscopic improvement at week 8 (Mayo endoscopic subscore ≤1)
  - Endoscopic remission at week 8 (Mayo endoscopic subscore = 0)
  - Clinical response per adapted Mayo Score at week 8
  - Clinical response per partial adapted Mayo Score at week 2
  - Histologic-endoscopic mucosal improvement at week 8
- Safety was assessed through week 8
**Induction study: Patient disposition**

**ITT population N=473**

- **PBO**
  - n=154
  - Discontinued study drug: 19 (12.3%)
    - Adverse event: 7 (4.5%)
    - Withdrew consent: 2 (1.3%)
    - Lack of efficacy: 9 (5.8%)
    - Other: 1 (0.6)

- **UPA 45 mg QD**
  - n=319
  - Discontinued study drug: 12 (3.8%)
    - Adverse event: 7 (2.2%)
    - Withdrew consent: 1 (0.3%)
    - Lack of efficacy: 2 (0.6%)
    - Lost to follow-up: 1 (0.3%)
    - Other: 1 (0.3)

- Completed
  - n=135 (87.7%)
  - n=307 (96.2%)

ITT, intent-to-treat population, consisting of all randomized patients who received at least one dose of study drug.

*aOne subject treated with placebo was excluded from the efficacy analysis due to significant non-compliance issue at the site. This patient was included in safety analysis.*

~50% of patients had prior biologic therapy- most >1 biologic

---

**Clinical remission (primary endpoint) and clinical response (ranked secondary endpoint) at week 8**

**Clinical Remission at Week 8 (Primary Endpoint)**

<table>
<thead>
<tr>
<th></th>
<th>PBO (n=154)</th>
<th>UPA 45 mg QD (n=319)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>4.8</td>
<td>26.1</td>
</tr>
</tbody>
</table>

Adjusted treatment difference (95% CI): 21.6% (15.8, 27.4); P<0.001

**Clinical Response at Week 8**

<table>
<thead>
<tr>
<th></th>
<th>PBO (n=154)</th>
<th>UPA 45 mg QD (n=319)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>27.3</td>
<td>72.6</td>
</tr>
</tbody>
</table>

Adjusted treatment difference (95% CI): 46.3% (38.4, 54.2); P<0.001

Primary endpoint per adapted Mayo score (defined as stool frequency subscore ≤1 and not greater than baseline, rectal bleeding subscore of 0, and Mayo endoscopic subscore ≤1) at week 8. Clinical response at week 8 based on adapted Mayo score (defined as decrease in adapted Mayo score ≥2 points and ≥30% from baseline and a decrease in rectal bleeding subscore ≤1 or an absolute rectal bleeding score ≤1).

*aOne PBO patient was excluded from efficacy analyses because of site non-compliance.*
Clinical response (per partial adapted Mayo Score) over time

Clinical response based on partial adapted Mayo score (defined as decrease in partial adapted Mayo score ≥ 1 points and ≥ 30% from baseline and a decrease in rectal bleeding subscore ≥ 1 or an absolute rectal bleeding score ≤ 1); nominal P values except week 2.

aOne PBO patient was excluded from efficacy analyses because of site non-compliance.

Ranked secondary endpoints at week 8

Endoscopic improvement (defined as Mayo endoscopic subscore ≤ 1). Endoscopic remission defined as Mayo endoscopic subscore 0. Histologic-endoscopic mucosal improvement (HEMI) defined as endoscopic subscore of 0 or 1 and Geboes score ≤ 3.1. Adjusted treatment difference and 95% CI were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for randomization stratification factors.

aOne PBO patient was excluded from efficacy analyses because of site non-compliance.
Tofacitinib in UC: OCTAVE Trial Results

Clinical Response and Remission: Week 8

Take Home Points

• U-ACHIEVE: studied patients with moderately-to-severely active UC-50% had prior biologic tx:
  • UPA 45 mg qd superior to PBO in improvement of clinical, endoscopic, and histologic endpoints over 8 weeks
  • Rapid onset of efficacy
  • Adverse events similar between the 2 groups
• Results consistent with another Phase 3 induction trial of UPA 45 mg qd (U-ACCOMPLISH; ECCO presentation #OP23)

• Given more selective JAK inhibition will safety profile be better than that of tofacitinib?
Impact of Prior Biologic Exposure on Patient Response to Ozanimod for Moderate-to-Severe Ulcerative Colitis in the Phase 3 True North Study

Bruce E. Sands1, Dianne Nguyen2, Marc Pondel2, Michael Silver2, AnnKatrin Petersen2, Douglas C. Wolf3, Remo Panaccione4, Edward V. Loftus, Jr.5, Jean-Frederic Colombel1, Andreas Sturm6, Geert D’Haens7

1Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; 2Bristol Myers Squibb, Princeton, NJ, USA; 3Center for Crohn’s Disease & Ulcerative Colitis, Atlanta Gastroenterology Associates, Atlanta, GA, USA; 4Inflammatory Bowel Disease Clinic, Gastrointestinal Research, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada; 5Division of Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, MN, USA; 6Division of Gastroenterology, DRK Kliniken Berlin Westend, Berlin, Germany; 7Inflammatory Bowel Disease Center, Amsterdam University Medical Center, Amsterdam, the Netherlands

Mechanisms of Action of IBD Therapies

True North Trial Results

### Medication Use at Baseline During Induction

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Biologic Exposure Status</th>
<th>Placebo</th>
<th>Ozanimod</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cohort 1</td>
<td>Cohort 2</td>
</tr>
<tr>
<td>Corticosteroid Use at Screening, n (%)</td>
<td>Biologic-naive 1 Biologic 2+ Biologics</td>
<td>37 (27.0) 8 (22.2) 25 (62.5)</td>
<td>71 (34.7) 23 (39.7) 49 (60.5)</td>
</tr>
<tr>
<td></td>
<td>Biologic-naive 1 Biologic 2+ Biologics</td>
<td>89 (65.0) 31 (86.1) 39 (97.5)</td>
<td>188 (65.5) 52 (89.7) 79 (97.5)</td>
</tr>
<tr>
<td>Prior Corticosteroid Use, n (%)</td>
<td>Anti-TNF*</td>
<td>63/213 (29.6)</td>
<td>126/426 (29.6)</td>
</tr>
<tr>
<td></td>
<td>Anti-integrin*</td>
<td>40/213 (18.8)</td>
<td>77/426 (18.1)</td>
</tr>
<tr>
<td></td>
<td>Ustekinumab</td>
<td>2/213 (0.9)</td>
<td>1/426 (0.2)</td>
</tr>
<tr>
<td></td>
<td>S1PR (etrasimod)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other*</td>
<td>0</td>
<td>2/426 (0.5)</td>
</tr>
</tbody>
</table>

*Includes adalimumab, certolizumab, guselkumab, infliximab, OPX-106. **Includes abiraterone, anti-maDCAM, etrolizumab, SHP647, and vedolizumab. *Includes AG011, panaliximab, and natalizumab.

SD, standard deviation; TNF, tumor necrosis factor.
**Induction Efficacy Outcomes by Prior Biologic Use**

**Clinical Remission**
- Placebo: 6.6\% (9/137), 8.3\% (9/108), 2.5\% (2/78)
- Ozanimod (Cohort 1): 23\% (21/92), 28.2\% (26/92), 5.4\% (5/92)
- Ozanimod (Cohort 2): 11.2\% (12/107), 22.1\% (23/104), 3.7\% (3/83)

**Clinical Response**
- Placebo: 16.2\% (16/99), 11\% (11/92), 2.2\% (2/88)
- Ozanimod (Cohort 1): 53% (53/100), 61.5% (62/100), 52.9% (53/100)
- Ozanimod (Cohort 2): 18.5\% (19/104), 30.9\% (31/102), 27.2\% (27/100)

*Significant vs placebo.

**Maintenance Efficacy Outcomes by Prior Biologic Use**

**Clinical Remission**
- Placebo: 27.7\% (27/100), 26.3\% (26/100), 41.5\% (42/100)
- Ozanimod: 51.9\% (52/100), 60.5\% (61/100), 52.9\% (53/100)
- Ozanimod/Ozanimod: 60.7\% (61/100), 60.5\% (61/100), 55.3\% (55/100)

**Clinical Response**
- Placebo: 27.7\% (27/100), 26.3\% (26/100), 41.5\% (42/100)
- Ozanimod: 53.6\% (54/100), 61.5\% (62/100), 52.9\% (53/100)
- Ozanimod/Ozanimod: 60.7\% (61/100), 60.5\% (61/100), 55.3\% (55/100)

*Significant vs placebo.

**Definitions**
- **Clinical Remission**: RBS = 0, SFS \(\leq 1\) (plus \(\geq 1\)-point reduction from baseline), and MES \(\leq 1\) without friability.
- **Clinical Response**: reduction in 3-component Mayo score of \(\geq 2\) points and \(\geq 35\%\), and reduction in RBS of \(\geq 1\) point or absolute RBS of \(\leq 1\) point.

**MES, mucosal endoscopy subscore; RBS, rectal bleeding subscore; SFS, stool frequency subscore.**
Take Home Points: Ozanimod in UC

• For induction → greater efficacy seen in biologic-naive patients, followed by patients with prior exposure to 1 biologic

• At end of maintenance → all groups had benefits

Patients with prior biologic use may require additional time to respond to treatment

• Limitation: Post-hoc analysis; study not powered to detect differences between biologic-naive and biologic-exposed groups
IL-12/23 Family

<table>
<thead>
<tr>
<th>Receptor:</th>
<th>Binding chain</th>
<th>Signaling chain</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ustekinumab</td>
<td>p40</td>
<td>p40</td>
<td>Th1 activation &amp; maintenance</td>
</tr>
<tr>
<td>Risankizumab</td>
<td>p19</td>
<td>p19</td>
<td>Th1 activation &amp; inhibition</td>
</tr>
</tbody>
</table>

**Adapted from Brombacher F et al. Trends Immunol 2003;24:207-12**

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**Study Objective and Study Design**

**To evaluate efficacy/safety of subcutaneous (SC) RZB maintenance therapy in patients responding to induction therapy**

- **ADVANCE Induction N=321**
  - Mixed Population
  - Non-Bio-IR & Bio-IR

- **FORTIFY 52 Week Maintenance N=450; Re-randomized 1:1:**
  - RZB 360 mg SC
    - N=184
  - RZB 180 mg SC
    - N=179
  - Withdrawal (PBO) SC
    - N=179

- **MOTIVATE Induction N=568**
  - Bio-IR

**Co-primary endpoints:** Clinical remission & endoscopic response

1. Clinical responders defined as patients with ≥30% decrease in average daily stool frequency (SF) and/or ≥30% decrease in average daily abdominal pain score (APS) and not worse than baseline at week 12 of induction treatment (or week 24 in case of prolonged induction treatment). Patients not achieving clinical response received RZB at Week 12 and entered Induction Period 2. Re-randomization stratified by endoscopic response (NAPCO endoscopic score at least 2 of induction), prior RZB induction dose.

2. Clinical remission defined as CDAI <150 in the US analysis plan and as average daily liquid or very soft SF ≤2.8 and not worse than baseline plus average daily APS ≤1 and not worse than baseline of induction in the outside of US analysis plan. Endoscopic response defined as a decrease in SES-CD ≥50% from baseline (or for patients with isolated ileal disease and a baseline SES-CD of four, at least a two-point reduction from baseline), as scored by a central reviewer, in both the US and OUS analysis plans.

3. Non-Bio-IR, intolerance or inadequate response to conventional therapy; Bio-IR, intolerance or inadequate response to prior biologic therapy and/or conventional therapy; RZB, risankizumab; IV, intravenous; SC, subcutaneous.
FORTIFY Co-Primary Endpoints at Week 52

Includes randomized subjects who received at least one dose of study drug during the 12-Week induction period and had at least one dose of study drug in the 52-week maintenance study (FORTIFY only), received only one 12-week period of induction, and had baseline eligible SES-CD of ≥6 (≥4 for isolated ileal disease). CDAI clinical remission, CDAI < 150; SF/APS clinical remission, average daily SF ≤ 2.8 and not worse than baseline and average daily AP score ≤ 1 and not worse than baseline; endoscopic response, decrease in SES-CD ≥ 50% from baseline of the induction study (or for subjects with isolated ileal disease and a baseline SES-CD of 4, at least a 2-point reduction from baseline of the induction study), as scored by central reviewer.

Objective Endoscopic and Combined Endpoints at Week 52

Includes randomized subjects who received at least one dose of study drug during the 12-Week induction period and had at least one dose of study drug during FORTIFY, received only one 12-week period of induction, and had baseline eligible SES-CD of ≥6 (≥4 for isolated ileal disease; endoscopic remission, SES-CD ≤ 4 and at least a 2-point reduction versus baseline and no subscore greater than 1 in any individual variable, as scored by a central reviewer; deep remission, CDAI remission (CDAI < 150) and endoscopic remission; Week 0 denotes week 0 of the maintenance study (FORTIFY). † denotes comparison between risankizumab 360 mg vs withdrawal (placebo), within timepoint, and * denotes comparison between risankizumab 180 mg vs withdrawal (placebo), within timepoint; † or †† or ††† or *** or ⋆ or ⋆⋆ or ⋆⋆⋆ or ⋆⋆⋆⋆ or ** or *** or **** or ⋆⋆ or ⋆⋆⋆ or ⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆★ or ⋆⋆⋆⋆⋆⋆⋆⋆⋆⋆之星 or ⋆⋆⋆⋆⋆⋆⋆⋆之星 or ⋆⋆⋆⋆⋆⋆⋆之星 or ⋆⋆⋆⋆之星 or ⋆⋆⋆之星 or ⋆⋆之星 or ⋆之星 or † or †† or ††† or †††† or ††††† or †††††† or ††††††† or †††††††† or ††††††††† or †††††††††† or ††††††††††† or ††††††††††† wonderfully.
### Treatment-Emergent Adverse Events of Special Interest

<table>
<thead>
<tr>
<th>AE, exposure adjusted event rate</th>
<th>Withdrawal (PBO SC) (N=184) (PYs=160.4)</th>
<th>RZB 180 mg SC (N=179) (PYs=169.3)</th>
<th>RZB 360 mg SC (N=179) (PYs=166.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn's disease</td>
<td>34 (21.2)</td>
<td>19 (11.2)</td>
<td>23 (13.8)</td>
</tr>
<tr>
<td>Serious infection</td>
<td>8 (5.0)</td>
<td>5 (3.0)</td>
<td>10 (6.0)</td>
</tr>
<tr>
<td>Opportunistic infection excluding TB or herpes zoster</td>
<td>0</td>
<td>1 (0.6)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>1 (0.6)</td>
<td>2 (1.2)</td>
<td>0</td>
</tr>
<tr>
<td>Active TB</td>
<td>1 (0.6)</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Adjudicated MACE events§</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-melanoma skin cancer (NMSC)</td>
<td>1 (0.6)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Malignancies excluding NMSC</td>
<td>0</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Serious hypersensitivity reactions</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Adjudicated anaphylactic reaction</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hepatic events</td>
<td>4 (2.5)</td>
<td>8 (4.7)</td>
<td>9 (5.4)</td>
</tr>
<tr>
<td>Injection site reactions</td>
<td>13 (8.1)</td>
<td>16 (9.5)</td>
<td>23 (13.8)</td>
</tr>
</tbody>
</table>

The safety population includes all subjects who received at least one dose of study drug (including non-randomized subjects)

§ MACE define as cardiovascular death, non-fatal myocardial infarction, and non-fatal myocardial infarction stroke

AE, adverse event; PBO, placebo; SC, subcutaneous; RZB, risankizumab; TB, tuberculosis; NMSC, non-melanoma skin cancer

---

### Take Home Points

- **FORITFY:** In patients responding to IV RZB induction, continued SC RZB treatment (180 mg or 360 mg) maintained clinical remission and endoscopic response through 52 weeks compared to patients who had RZB withdrawn
- Good safety profile (like ustekinumab)
- Once approved, will give another class option for IL 12/23 blockade:
  - Will there be an advantage to more selective IL-23 inhibition?
  - Positioning relative to ustekinumab?
Efficacy of Ustekinumab for Ulcerative Colitis Through 3 Years: UNIFI Long-term Extension


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Background and Objective

- Ustekinumab (UST), a fully human IgG1k monoclonal antibody that binds the p40 subunit shared by interleukin-12 and 23, is approved for the treatment of moderate-to-severe ulcerative colitis (UC)
- The ongoing UNIFI long-term extension (LTE) evaluates subcutaneous (SC) 90 mg UST maintenance therapy
- Here we report efficacy data through 3 years of treatment including the subgroups based on biologic treatment history

Methods

UNIFI Study Design: Maintenance and Long-term Extension

Maintenance Study Randomized Population

UST 90 mg SC q8w (n=176)

UST 90 mg SC q12w (n=172)

PBO SC (n=175)

Long-term Extension (LTE)

UST 90 mg SC q8w (n=143)

UST 90 mg SC q12w (n=141)

PBO SC (n=115)*

Dose adjustment at any time

Patients who completed 6 weeks after UST 90 mg SC induction were randomized in the maintenance study

*Patients who were receiving PBO after maintenance study unblinding were discontinued.
UNIFI 3 Year Long-term Extension

### Symptomatic Remission Through Week 152

**Randomized Patients in Maintenance Who Were Treated in LTE:**
Nonresponder Imputation for Missing Data and Treatment Failures

**Symptomatic Remission:** Mayo stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0

| Weeks | 0 | 4 | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 36 | 40 | 44 | 56 | 68 | 80 | 92 | 104 | 116 | 128 | 140 | 152 |
|-------|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Percent of Patients (%) | ||||| ||||| | ||||| ||||| | ||| | |
| Maintenance Study | | | | | | | | | | | | | | | | | | | | |
| LTE (Dose adjustment allowed from Week 56) | | | | | | | | | | | | | | | | | | | | |
| UST 90 mg SC q12w (n=141)<sup>d</sup> | | | | | | | | | | | | | | | | | | | | |
| UST 90 mg SC q8w (n=143)<sup>d</sup> | | | | | | | | | | | | | | | | | | | | |

* Patients who were in clinical response to UST for induction and were randomized to UST at entry into this maintenance study and continued in the LTE.
* Patients who had both stool frequency and rectal bleeding subscores missing at any dose were considered not to be in symptomatic remission.
* Patients who had a clinical response to UST for induction and were randomized to placebo at entry into this maintenance study and discontinued due to worsening of UC were considered not to have been in symptomatic remission.


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UNIFI 3 Year Long-term Extension

### Symptomatic Remission Through Week 152 in *Biologic Naïve* Patients

**Randomized Patients in Maintenance Who Were Treated in LTE:**
Nonresponder Imputation for Missing Data and Treatment Failures

**Symptomatic Remission:** Mayo stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0

| Weeks | 0 | 4 | 8 | 12 | 16 | 20 | 24 | 28 | 32 | 36 | 40 | 44 | 56 | 68 | 80 | 92 | 104 | 116 | 128 | 140 | 152 |
|-------|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Percent of Patients (%) | ||||| ||||| | ||||| ||||| | ||| | |
| Maintenance Study | | | | | | | | | | | | | | | | | | | | |
| LTE (Dose adjustment allowed from Week 56) | | | | | | | | | | | | | | | | | | | | |
| UST 90 mg SC q12w (n=82)<sup>d</sup> | | | | | | | | | | | | | | | | | | | | |
| UST 90 mg SC q8w (n=67)<sup>d</sup> | | | | | | | | | | | | | | | | | | | | |

* Patients who were in clinical response to UST for induction and were randomized to UST at entry into this maintenance study and continued in the LTE.
* Patients who had both stool frequency and rectal bleeding subscores missing at any dose were considered not to have been in symptomatic remission.
* Patients who had a clinical response to UST for induction and were randomized to placebo at entry into this maintenance study and discontinued due to worsening of UC were considered not to have been in symptomatic remission.


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UNIFI 3 Year Long-term Extension

Symptomatic Remission Through Week 152 in Biologic Failure Patients

Randomized Patients in Maintenance Who Were Treated in LTE: Nonresponder Imputation for Missing Data and Treatment Failures\(^{a,b,c}\)

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Maintenance Study</th>
<th>LTE (Dose adjustment allowed from Week 56)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 4 8 12 16 20 24 28 32 36 40 44</td>
<td>56 68 80 92 104 116 128 140 152</td>
</tr>
<tr>
<td>Percent of Patients (%)</td>
<td>UST 90 mg SC q12w (n=53)(^d)</td>
<td>UST 90 mg SC q8w (n=71)(^d)</td>
</tr>
<tr>
<td>0</td>
<td>66.0</td>
<td>66.0</td>
</tr>
<tr>
<td>4</td>
<td>68.0</td>
<td>67.4</td>
</tr>
<tr>
<td>8</td>
<td>71.0</td>
<td>68.4</td>
</tr>
<tr>
<td>12</td>
<td>73.4</td>
<td>71.8</td>
</tr>
<tr>
<td>16</td>
<td>75.5</td>
<td>73.8</td>
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<tr>
<td>20</td>
<td>75.5</td>
<td>74.6</td>
</tr>
<tr>
<td>24</td>
<td>76.1</td>
<td>75.5</td>
</tr>
<tr>
<td>28</td>
<td>78.9</td>
<td>77.9</td>
</tr>
<tr>
<td>32</td>
<td>81.7</td>
<td>78.9</td>
</tr>
<tr>
<td>36</td>
<td>80.3</td>
<td>76.1</td>
</tr>
<tr>
<td>40</td>
<td>79.2</td>
<td>74.6</td>
</tr>
<tr>
<td>44</td>
<td>77.4</td>
<td>76.1</td>
</tr>
<tr>
<td>56</td>
<td>67.9</td>
<td>69.0</td>
</tr>
<tr>
<td>68</td>
<td>66.0</td>
<td>67.9</td>
</tr>
<tr>
<td>80</td>
<td>66.0</td>
<td>67.9</td>
</tr>
<tr>
<td>92</td>
<td>67.6</td>
<td>67.9</td>
</tr>
<tr>
<td>104</td>
<td>60.4</td>
<td>63.4</td>
</tr>
<tr>
<td>116</td>
<td>54.7</td>
<td>57.7</td>
</tr>
</tbody>
</table>

Symptomatic Remission: Mayo stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0

\(^a\) Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were considered to be in maintenance and not to have failed their induction or maintenance drug. Patients who had clinical response to UST for induction during the Biologic Failure study and discontinued during their induction or maintenance were designated as treatment failures and were included in the analysis of outcome data. Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were designated as treatment failures and were included in the analysis of outcome data.

\(^b\) Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were considered to be in maintenance and not to have failed their induction or maintenance drug. Patients who had clinical response to UST for induction during the Biologic Failure study and discontinued during their induction or maintenance were designated as treatment failures and were included in the analysis of outcome data. Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were designated as treatment failures and were included in the analysis of outcome data.

\(^c\) Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were considered to be in maintenance and not to have failed their induction or maintenance drug. Patients who had clinical response to UST for induction during the Biologic Failure study and discontinued during their induction or maintenance were designated as treatment failures and were included in the analysis of outcome data. Patients who had clinical response to UST for induction during the Biologic Failure study and continued into the LTE study were designated as treatment failures and were included in the analysis of outcome data.

\(^d\) Randomized group at maintenance levels regardless of whether patients had a dose adjustment during the LTE study.


UNIFI 3 Year Long-term Extension

Corticosteroid-free Symptomatic Remission at Week 152

Randomized Patients in Maintenance Who Were Treated in LTE: Nonresponder Imputation for Missing Data and Treatment Failures\(^{a,b,c}\)

**Biologic Naïve**

<table>
<thead>
<tr>
<th>Symptomatic Remission</th>
<th>Corticosteroid-free Symptomatic Remission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of Patients (%)</td>
<td>UST 90 mg SC q12w(^d)</td>
</tr>
<tr>
<td>0</td>
<td>61/82</td>
</tr>
<tr>
<td>15</td>
<td>72/82</td>
</tr>
<tr>
<td>30</td>
<td>72.0</td>
</tr>
<tr>
<td>45</td>
<td>79.1</td>
</tr>
</tbody>
</table>

**Biologic Failure**

<table>
<thead>
<tr>
<th>Symptomatic Remission</th>
<th>Corticosteroid-free Symptomatic Remission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of Patients (%)</td>
<td>UST 90 mg SC q12w(^d)</td>
</tr>
<tr>
<td>0</td>
<td>29/53</td>
</tr>
<tr>
<td>15</td>
<td>41/71</td>
</tr>
<tr>
<td>30</td>
<td>57.7</td>
</tr>
<tr>
<td>45</td>
<td>54.7</td>
</tr>
</tbody>
</table>

\(^a\) Patients who were in clinical response to UST for induction during and were randomized to UST as entry to the maintenance study and continued in the LTE study.

\(^b\) Patients who had clinical response to UST for induction during and were randomized to UST as entry to the maintenance study and continued in the LTE study.

\(^c\) Patients who had clinical response to UST for induction during and were randomized to UST as entry to the maintenance study and continued in the LTE study.

\(^d\) Randomized group at maintenance levels regardless of whether patients had a dose adjustment during the LTE study.

Take Home Points

- In UC patients who responded to UST induction therapy, UST SC therapy maintained efficacy through 3 years:
  - Symptomatic remission
  - Corticosteroid-free symptomatic remission
  - Sustained reductions in CRP and fecal calprotectin
  - Improved quality of life
- Efficacy was observed in both biologic naïve and biologic failure patients BUT efficacy was lower in the biologic failure subgroups
- Implications:
  - Can we decrease maintenance interval to q 12 weeks in select patients for cost savings?
  - Should we take a different approach than biologic monotherapy switches in patients with prior biologic failures?

Summary

- **U-ACHIEVE:** Upacitinib 45 mg qd superior to PBO in improvement of clinical, endoscopic, and histologic endpoints in patients with moderately-to-severely active UC over 8 weeks
- **Ozanimod** treatment for up to 52 weeks in patients with moderate-to-severe UC → greater efficacy was observed in biologic-naïve patients, followed by patients with prior exposure to 1 biologic at Induction; however, all groups had benefits at end of Maintenance
- **FORTIFY:** Risankizumab- In patients responding to IV RZB induction, continued SC RZB treatment (180 mg or 360 mg) maintained clinical remission and endoscopic response through 52 weeks
- UC patients who had responded to ustekinumab induction therapy and entered the LTE:
  - Efficacy of UST SC maintenance was observed through 3 years
  - Efficacy in the biologic failure subgroup was lower
Corticosteroids Are Not Associated with Worse Outcomes for Crohn’s Disease Patients with Phlegmon

Michael Ashamalla, et al. NYU Langone Health

- Phlegmon = vague inflammatory mass, does not meet imaging criteria for abscess. Not drainable.
- Management of phlegmon remains controversial
- **Objective**: Examine effects of corticosteroids (CS) for treatment of CD patients with phlegmon, without an abscess
Corticosteroids Are Not Associated with Worse Outcomes for Crohn’s Disease Patients with Phlegmon

- Retrospective study of all inpatient CT scan reports
- Total 93 patients
  - 1/1/2015 – 12/31/2019: “phlegmon” and “inflammatory mass”
  - Cross referenced for ICD 9/10 codes
  - Direct review of CT reports by radiologist for accuracy

<table>
<thead>
<tr>
<th></th>
<th>Surgery during Index Admission N (%)</th>
<th>Chi-square</th>
<th>Surgery Within One Year N (%)</th>
<th>Chi-square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>14 (15.05)</td>
<td></td>
<td>45 (48.39)</td>
<td></td>
</tr>
<tr>
<td><strong>Pre-Admission Characteristics/Treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7 (17.5)</td>
<td>0.3285</td>
<td>22 (55.00)</td>
<td>0.2676</td>
</tr>
<tr>
<td>Male</td>
<td>7 (13.21)</td>
<td></td>
<td>23 (43.40)</td>
<td></td>
</tr>
<tr>
<td>Smoker **</td>
<td>8 (25.80)</td>
<td><strong>0.0403</strong></td>
<td>19 (61.29)</td>
<td>0.0783</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>8 (20.51)</td>
<td>0.2109</td>
<td>20 (51.28)</td>
<td>0.6350</td>
</tr>
<tr>
<td>Biologics</td>
<td>5 (18.52)</td>
<td>0.2754</td>
<td>18 (66.67)</td>
<td>0.6358</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>2 (15.38)</td>
<td>0.9713</td>
<td>9 (69.23)</td>
<td>0.1049</td>
</tr>
<tr>
<td>Composite No</td>
<td>4 (13.33)</td>
<td>0.7488</td>
<td>12 (40.00)</td>
<td>0.2641</td>
</tr>
<tr>
<td>Prednisone/Biologic/ Antibiotic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Bowel Obstruction</td>
<td>4 (20.00)</td>
<td>0.4851</td>
<td>11 (55.00)</td>
<td>0.5042</td>
</tr>
</tbody>
</table>

**Post Admission Medical Therapy**

<table>
<thead>
<tr>
<th></th>
<th>Surgery during Index Admission N (%)</th>
<th>Chi-square</th>
<th>Surgery Within One Year N (%)</th>
<th>Chi-square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>14 (16.47)</td>
<td>0.2130</td>
<td>43 (50.59)</td>
<td>0.1662</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>9 (15.52)</td>
<td>0.8722</td>
<td>30 (51.72)</td>
<td>0.4071</td>
</tr>
<tr>
<td>Antibiotics followed by corticosteroids</td>
<td>1 (20.00)</td>
<td>0.8592</td>
<td>3 (60.00)</td>
<td>0.7358</td>
</tr>
<tr>
<td>Biologic **</td>
<td>7 (17.95)</td>
<td>0.5070</td>
<td>25 (64.10)</td>
<td>0.0100</td>
</tr>
</tbody>
</table>
CS Does Not Impact 30-Day Readmissions

<table>
<thead>
<tr>
<th></th>
<th>30-day readmission N (%)</th>
<th>Chi-square</th>
<th>90-day readmission N (%)</th>
<th>Chi-square</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>29 (31.18)</td>
<td></td>
<td>48 (51.61)</td>
<td></td>
</tr>
<tr>
<td>By Pre-admission Characteristics/Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15 (37.50)</td>
<td>0.2533</td>
<td>21 (52.50)</td>
<td>0.8818</td>
</tr>
<tr>
<td>Male</td>
<td>14 (26.42)</td>
<td></td>
<td>27 (50.94)</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>8 (25.81)</td>
<td>0.4287</td>
<td>18 (58.06)</td>
<td>0.3787</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>10 (25.64)</td>
<td>0.3269</td>
<td>18 (46.15)</td>
<td>0.3706</td>
</tr>
<tr>
<td>Biologics</td>
<td>8 (29.33)</td>
<td>0.0494</td>
<td>15 (55.56)</td>
<td>0.3985</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>5 (38.46)</td>
<td>0.5413</td>
<td>8 (61.54)</td>
<td>0.4400</td>
</tr>
<tr>
<td>Composite No</td>
<td>11 (56.67)</td>
<td>0.4308</td>
<td>15 (50.00)</td>
<td>0.8299</td>
</tr>
<tr>
<td>Prednisone/Biologic/Antibiotic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Bowel Obstruction</td>
<td>9 (45.00)</td>
<td>0.1322</td>
<td>11 (55.00)</td>
<td>0.1763</td>
</tr>
<tr>
<td>By Post Admission Medical Therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotics</td>
<td>29 (34.12)</td>
<td>0.0539</td>
<td>42 (47.06)</td>
<td>0.1662</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>19 (57.76)</td>
<td>0.6728</td>
<td>31 (53.45)</td>
<td>0.6484</td>
</tr>
<tr>
<td>Antibiotics followed by Corticosteroids</td>
<td>1 (20.00)</td>
<td>0.4885</td>
<td>1 (20.00)</td>
<td>0.1720</td>
</tr>
<tr>
<td>Biologic</td>
<td>14 (35.90)</td>
<td>0.2576</td>
<td>23 (58.57)</td>
<td>0.2273</td>
</tr>
</tbody>
</table>

Take Home Points

- Corticosteroids was not associated with increased adverse outcomes for CD patients with phlegmon
  - Surgery at index or one year; Readmissions
- Steroids in combination with antibiotics may be appropriate
- Biologic use and increased surgical intervention risk likely related to treatment refractory subgroup

- Limitations:
  - Small patient size; cohort not controlled for disease severity; mix of treatment exposures pre-hospitalization (antibiotics, CS, biologics)
Comparative Safety of Biologic Agents in Patients with IBD with Active or Recent Malignancy: A multi-center cohort study
Ariela K. Holmer, et al. UCSD

- Up to 30% of IBD patients are over the age of 60 yrs old
- Risk of cancer in this age group also increases
- Prior studies on safety of biologics with a history of cancer focused primarily on remote cancer
- Risk of cancer with newer, non-TNF agents not well known
- Risk in active cancer or with recent (<5 years) cancer not well described

Comparative Safety of Biologic Agents in Patients with IBD with Active or Recent Malignancy: A multi-center cohort study

- **Objectives:** Evaluate comparative rate of cancer progression with exposure to TNF vs non-TNF agents vs IMM monotherapy in both ACTIVE and RECENT cancer cohorts
- Retrospective, multicenter: 11 centers through REACH – Rising Educators Academics and Clinicians Helping IBD – Crohn’s and Colitis Foundation
- Follow up time was until time to recurrence in those who experienced the event or discontinuation of IBD therapy (whichever came first)
Results: Active Cancer Cohort

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Total n = 125</th>
<th>TNFα n = 55</th>
<th>*Non-TNFα n = 40</th>
<th>IMM n = 30</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBD Subtype, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>35 (28)</td>
<td>11 (20)</td>
<td>15 (38)</td>
<td>9 (30)</td>
<td>0.17</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>90 (72)</td>
<td>44 (80)</td>
<td>25 (63)</td>
<td>21 (70)</td>
<td></td>
</tr>
<tr>
<td>Age at cohort entry, mean (SD), y (%)</td>
<td>54 (15)</td>
<td>51 (14)</td>
<td>55 (17)</td>
<td>57 (15)</td>
<td>0.29</td>
</tr>
<tr>
<td>Disease duration, mean (SD), y (%)</td>
<td>14 (13)</td>
<td>13 (12)</td>
<td>15 (14)</td>
<td>16 (14)</td>
<td>0.59</td>
</tr>
<tr>
<td>PSC Diagnosis, n (%)</td>
<td>8 (6)</td>
<td>4 (7)</td>
<td>2 (5)</td>
<td>2 (7)</td>
<td>1.0</td>
</tr>
<tr>
<td>Index Combination Therapy, n (%)</td>
<td>28 (22)</td>
<td>18 (33)</td>
<td>10 (25)</td>
<td>-</td>
<td>0.002</td>
</tr>
</tbody>
</table>

*vedolizumab = 31 patients, ustekinumab = 9 patients

Results: Active Cancer Cohort

- Overall, 75% of patients were diagnosed with a solid tumor cancer; 6% with stage IV disease
- 481.8 person-years of follow-up
- 24 patients had evidence of progression (19%)
- 13 patients died (10%)
- 21 patients (17%) hospitalized for serious infection

<table>
<thead>
<tr>
<th>Index Drug</th>
<th>n=patients</th>
<th>n=events (%)</th>
<th>Incidence rate (events/100 PY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNF</td>
<td>55</td>
<td>10 (18.2%)</td>
<td>4.35</td>
</tr>
<tr>
<td>non-TNF</td>
<td>40</td>
<td>9 (22.5%)</td>
<td>10.4</td>
</tr>
<tr>
<td>IMM</td>
<td>30</td>
<td>7 (23.3%)</td>
<td>4.23</td>
</tr>
<tr>
<td>Overall</td>
<td>125</td>
<td>26 (20.8%)</td>
<td>5.39</td>
</tr>
</tbody>
</table>
Results: Active Cancer Cohort

Cancer Progression:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>HR</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Progression</td>
<td>1.74</td>
<td>0.68-4.48</td>
<td>0.25</td>
</tr>
<tr>
<td>Mortality</td>
<td>1.83</td>
<td>0.49-6.84</td>
<td>0.37</td>
</tr>
<tr>
<td>Serious Infection</td>
<td>1.85</td>
<td>0.65-5.22</td>
<td>0.25</td>
</tr>
</tbody>
</table>

*Adjusted for age, IMM status, type of cancer

Results: Recent Cancer Cohort

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Total n = 170</th>
<th>TNFα n = 78</th>
<th>*Non-TNFα n = 66</th>
<th>IMM n = 26</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBD Subtype, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>28 (16)</td>
<td>7 (16)</td>
<td>12 (34)</td>
<td>9 (33)</td>
<td>0.1</td>
</tr>
<tr>
<td>Crohn's disease</td>
<td>79 (74)</td>
<td>38 (84)</td>
<td>23 (66)</td>
<td>18 (67)</td>
<td></td>
</tr>
<tr>
<td>Age at cohort entry, mean (SD), y (%)</td>
<td>54 (16)</td>
<td>52 (15)</td>
<td>55 (17)</td>
<td>57 (15)</td>
<td>0.36</td>
</tr>
<tr>
<td>Disease duration, mean (SD), y (%)</td>
<td>13 (12)</td>
<td>11 (12)</td>
<td>13 (13)</td>
<td>16 (14)</td>
<td>0.28</td>
</tr>
<tr>
<td>PSC Diagnosis, n (%)</td>
<td>7 (7)</td>
<td>4 (9)</td>
<td>2 (6)</td>
<td>1 (4)</td>
<td>0.67</td>
</tr>
<tr>
<td>Index Combination Therapy, n (%)</td>
<td>20 (19)</td>
<td>14 (31)</td>
<td>5 (14)</td>
<td>1 (4)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*vedolizumab = 51 patients, ustekinumab = 15 patients
Results: Recent Cancer Cohort

- Overall, 84% of patients had prior history of a solid tumor cancer
- 492.3 person-years of follow-up
- Mean duration of cancer remission prior to starting therapy was 18.8 months
- 16 patients developed an incident cancer (9.4%)
- 6 patients died (3.5%)

<table>
<thead>
<tr>
<th>Index Drug</th>
<th>n=patients</th>
<th>n=events (%)</th>
<th>Incidence rate (events/100 PY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNF</td>
<td>78</td>
<td>7 (9.0)</td>
<td>4.35</td>
</tr>
<tr>
<td>non-TNF</td>
<td>66</td>
<td>3 (4.6)</td>
<td>2.21</td>
</tr>
<tr>
<td>IMM</td>
<td>26</td>
<td>6 (23.1)</td>
<td>5.06</td>
</tr>
<tr>
<td>Overall</td>
<td>170</td>
<td>16 (9.4)</td>
<td>3.25</td>
</tr>
</tbody>
</table>

Results: Recent Cancer Cohort

<table>
<thead>
<tr>
<th>Outcome</th>
<th>HR</th>
<th>95% CI</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Cancer</td>
<td>0.627</td>
<td>0.15-2.58</td>
<td>0.52</td>
</tr>
<tr>
<td>Mortality</td>
<td>1.07</td>
<td>0.24-4.68</td>
<td>0.93</td>
</tr>
</tbody>
</table>

*Adjusted for age, IMM status, type of cancer

HR=0.79, p value 0.74

Oral Plenary 4B, O65
Take Home Points

- No difference in cancer progression-free survival among TNF, non-TNF and IMM exposed groups for ACTIVE or RECENT Cancer Cohorts
- Ongoing prospective SAPPHIRE study to further inform decision making for these patients

Limitations:
- Observational, treatment choice biases, low number of events in active/prior cancer groups, differences in outcomes across multiple types of cancers

Paternal Biologic and Thiopurine Exposure in Inflammatory Bowel Disease and Association With Adverse Pregnancy Outcomes and Semen Parameters: A Systematic Review and Meta-Analysis

John Gubatan, et al. University of Toronto

- Safety of biologics and thiopurine for both maternal and birth outcomes well described
- Limited studies on reproductive outcomes in paternal, including adverse pregnancy outcomes and semen parameters
- Studies from Medline, Embase, Scopus and Web of Science from inception to March 2021: reporting adverse pregnancy outcomes and semen parameters in male IBD patients exposed to biologics
  - Compared biologic versus thiopurine users
  - 8 studies reported adverse pregnancy outcomes (735 IBD pts); 4 studies with semen parameters (68 pts) with biologics (5 TNFs, 2 VDZ, 1 mixed exposure)
Pooled Prevalence of Adverse Pregnancy Outcomes in Males Exposed to Biologics

- Early pregnancy loss – 4% (95% CI 1-8%)
- Preterm birth – 5% (95% CI 0-10%)
- Congenital malformations – 3% (95% CI 0-6%)

- Biologic use NOT associated with:
  - Early pregnancy loss (OR 1.26, 95% 0.61-2.61)
  - Preterm birth (OR 1.10, 95% 0.96-1.26)
  - Congenital malformations (OR 1.03, 95% 0.89-1.19)

- Risk of adverse outcomes did not differ between biologic versus thiopurine use

Comparison of Biologic versus Thiopurine Exposure with Change in Semen Parameters

- Sperm Count
  - Thiopurines, not biologics, associated with higher sperm count

- Sperm Morphology
  - Biologics and thiopurines not associated with morphology, no difference

- Sperm Motility
  - Biologics and thiopurines not associated with motility, no difference
Take Home Points

• Biologics or thiopurine use in males with IBD are not associated with adverse pregnancy outcomes or impairment in semen parameters
• Safety profile of biologics and thiopurines are comparable
• Systematic review with inherent limitations

The Vedolizumab Pregnancy Exposure Registry: An OTIS Pregnancy Study Update
Christina D. Chambers, et al. UCSD

• Limited published studies on effect of vedolizumab in pregnancy
• Vedolizumab pregnancy exposure registry in U.S. and Canada collected by MotherToBaby studies - conducted by Organization of Teratology Information Specialists (OTIS)
• Prospective observational cohort
The Vedolizumab Pregnancy Exposure Registry: An OTIS Pregnancy Study Update

- December 2015 – March 2021
- Pregnant women treated with at least one vedolizumab dose in first trimester = Vedo group (n=93)
- No exposure to vedolizumab in UC, CD = DM group (n=104)
- No biologic and no IMID = HC group (n=98)
- Data collected by telephone interviews, medical records and infant follow up to one year with dysmorphological and developmental screening

### Pregnancy Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Vedo-Total (N=93)</th>
<th>DM-Total (N=104)</th>
<th>HC-Total (N=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancies ending with live born infant - n/N (%)</td>
<td>88/93 (94.6)</td>
<td>99/104 (95.2)</td>
<td>85/98 (86.7)</td>
</tr>
<tr>
<td>Spontaneous abortion – N (Left Truncation Accounted Rate)</td>
<td>3 (9.4%)</td>
<td>3 (6.1%)</td>
<td>1 (5.7%)</td>
</tr>
<tr>
<td>Termination - n/N (%)</td>
<td>0/93 (0.0)</td>
<td>0/104 (0.0)</td>
<td>0/98 (0.0)</td>
</tr>
<tr>
<td>Stillbirth - n/N (%)</td>
<td>0/93 (0.0)</td>
<td>1/104 (1.0)</td>
<td>0/98 (0.0)</td>
</tr>
<tr>
<td>Lost to follow-up (LTFU) - n/N (%)</td>
<td>2/93 (2.2)</td>
<td>1/104 (1.0)</td>
<td>12/98 (12.2)</td>
</tr>
<tr>
<td>Preterm delivery – N (Rate)</td>
<td>13 (15.3%)</td>
<td>6 (6.1%)</td>
<td>6 (7.3%)</td>
</tr>
<tr>
<td>Birth weight full term infants – mean (SD)</td>
<td>3405.4 (437.2)</td>
<td>3427.9 (454.1)</td>
<td>3307.4 (433.6)</td>
</tr>
<tr>
<td>Number of pregnancies with major birth defects among all pregnancies excluding LTFU – n/N (%)</td>
<td>5/91 (5.5)</td>
<td>7/103 (6.8)</td>
<td>4/86 (4.7)</td>
</tr>
<tr>
<td>Serious infections in live born infants up to 1 year of age – n/N (%)</td>
<td>3/92 (3.3)</td>
<td>1/99 (1.0)</td>
<td>1/88 (1.1)</td>
</tr>
<tr>
<td>Ages and Stages Screening at 1 year of age with concern – n/N (%)</td>
<td>9/48 (18.8)</td>
<td>19/85 (22.4)</td>
<td>8/56 (14.3)</td>
</tr>
</tbody>
</table>

81% of vedolizumab treated patients received treatment at all 3 trimesters
Take Home Points

• Preliminary data for vedolizumab exposure during pregnancy reassuring

• Proportion of pregnancies with vedolizumab exposure resulting in major birth defects comparable to general population (3-5%)

• Registry is ongoing

• Limitations:
  • Many other factors including disease severity impacts both maternal and birth outcomes; association with vedolizumab drug levels

IBD Potpourri

Tauseef Ali MD FACG
@ibdtweets
SSM Health, Oklahoma City
Oklahoma
Overview

- Response to COVID-19 Vaccine in IBD Patients
- Risk and complications of Herpes Zoster
- GI symptoms after COVID Vaccine

P1608-Humoral Immune Response After Completion of COVID-19 Vaccine Series Among Patients With IBD

Kimberly N. Weaver, MD1, Margie Boccieri MA2, Ann Firestine MS2, Xian Zhang PhD2, Michael D. Kappelman MD, MPH2,3*, Millie D. Long MD1,3*

1Department of Medicine, Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Chapel Hill, NC; 2Department of Pediatrics, Division of Pediatric Gastroenterology, University of North Carolina at Chapel Hill, Chapel Hill, NC; 3Center for Gastrointestinal Biology and Disease, University of North Carolina at Chapel Hill, Chapel Hill, NC
Background

• Individuals on immunosuppression were excluded from the SARS-CoV-2 vaccine clinical trials
• Patients with IBD on immunosuppressive medications have the potential for attenuated response to the SARS-CoV-2 vaccination
• Individuals on infliximab and immunomodulator showed blunted antibody response following single SARS-CoV-2 vaccination in a European IBD cohort

Aim

• To evaluate antibody response after completion of mRNA SARS-CoV-2 vaccine series in a large IBD population across

Methods/Study Design

• Partnership to Report Effectiveness of Vaccination in populations Excluded from Initial Trials of COVID (PREVENT-COVID) is a prospective, observational cohort study of IBD patients who received any SARS-CoV-2 vaccine granted EUA in the US
  • BNT162b2 (Pfizer-BioNTech), mRNA-1273 (NIH-Moderna), Ad26.COV2.S (J&J)
• Participants receive surveys at baseline, monthly x 2 months, then quarterly thereafter x 2 years
• All participants have the option to provide serum samples to evaluate antibody development ~8 weeks following completion of the SARS-CoV-2 vaccine series
• Results of ≥ 1.0 μg/mL suggest vaccination and/or prior COVID-19 infection
• Individuals who reported prior COVID infection and/or had positive nucleocapsid antibody were excluded

Treatment characteristics and humoral immune response to SARS-CoV-2 vaccine among patients with IBD in PREVENT-COVID

<table>
<thead>
<tr>
<th>Treatment characteristics</th>
<th>Anti-TNF monoclonal N N %</th>
<th>Anti-TNF combination N N %</th>
<th>6MP/AZA/MTX alone N N %</th>
<th>SASA, SSZ, budes mono, or no med N N %</th>
<th>Vedolizumab N N %</th>
<th>Ustekinumab N N %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>787</td>
<td>270</td>
<td>67</td>
<td>143</td>
<td>83</td>
<td>102</td>
</tr>
<tr>
<td>Mean anti-RBD antibody level (SD)</td>
<td>29 41.8</td>
<td>17 20.7</td>
<td>10 10.0</td>
<td>38 47.8</td>
<td>38 57.9</td>
<td>51 51.4</td>
</tr>
<tr>
<td>Median anti-RBD antibody level (IQ Range)</td>
<td>17.0 8.0, 31.0</td>
<td>11.0 5.8, 19.0</td>
<td>6.9 3.0, 14.0</td>
<td>23.0 12.0, 37.0</td>
<td>25.0 12.0, 43.0</td>
<td>31.0 24.0, 67.0</td>
</tr>
<tr>
<td>Proportion with detectable antibody</td>
<td>752 95%</td>
<td>260 96%</td>
<td>65 86%</td>
<td>65 97%</td>
<td>136 95%</td>
<td>82 99%</td>
</tr>
</tbody>
</table>

5-ASA = mesalamine, 6-MP = mercaptopurine, AZA = azathioprine, budes = budesonide, combo = combination therapy, IQ = interquartile, mono = monotherapy, MTX = methotrexate, SD = standard deviation, SSZ = sulfasalazine, TNF = tumor necrosis factor

Anti-receptor binding domain (RBD) antibody levels by medication class

*Individuals receiving corticosteroids (n=35) had ↓ antibody response
Steroid users 85.7% (95% CI 70.6-93.7) vs 95.9% (95% CI 94.2-97.1) in non-steroid users
Strengths

• Generalizability due to geographically diverse population including IBD patients from 49 states
• Largest US IBD cohort to date evaluating humoral immune response following SARS-CoV-2 vaccination

Limitations

• IBD diagnosis by participant self-report
• Lack of ethnic and racial diversity
• No established threshold for protective immunity in quantitative antibody testing
• Cell mediated immunity (T cell response) not assessed
Take Home Message

• A vast majority (95%) of IBD patients had detectable anti-RBD IgG antibodies after completing mRNA SARS-CoV-2 vaccine series
• Most IBD medications do not prevent an initial antibody response after SARS-CoV-2 vaccination, unlike other classes of immune suppression such as B-cell depletion therapy
• Additional data forthcoming on larger subset of participants in PREVENT-COVID study which will allow for analysis of factors associated with humoral immune response, potential optimization of immunization strategies

P2622 - Burden of Herpes Zoster Among Patients With Ulcerative Colitis and Crohn’s Disease in the United States: A Retrospective Cohort Study Using a Large Administrative Claims Database

David Singer, PharmD, MS
GSK
Philadelphia, PA, United States
**Background**

- Herpes zoster (HZ) is a disease characterized by a painful dermatomal rash caused by reactivation of the varicella-zoster virus
- HZ incidence is higher in patients (pts) with ulcerative colitis (UC) and Crohn’s disease (CD) than in the general population

**Aim**

- To examine the burden associated with HZ in pts with UC and CD in the United States

**Methods**

- A retrospective cohort study using administrative claims data (2015-2020)
- Separate cohorts of pts with UC+HZ or CD+HZ were identified with ICD-10 codes
- The 1st HZ diagnosis was the index date and at least 1 UC or CD diagnosis was required within 12 months prior to index (baseline)
- Control cohorts of pts with UC or CD but no HZ during the study period were identified and randomly assigned an index date based on the distribution of the durations of pre-index eligibility in the HZ cohorts (i.e., UC+HZ or CD+HZ cohorts, respectively)
- Outcomes were reported comparing pts with UC+HZ to UC only and, separately, pts with CD+HZ to CD only
Results

• The study included
  • 431 and 10,285 pts with UC+HZ and UC only
  • 435 and 9,797 pts with CD+HZ and CD only
• Mean ages for the cohorts ranged between 56-65 years
• Comorbidity burden and baseline costs were slightly higher in the HZ vs control cohorts.
• Adjusted incidence rates of health care resource use over 12 months were higher in the cohorts with HZ
• Mean (95% confidence interval [CI]) adjusted cost differences over 12-month follow-up:
  • $8,393 (-468;17,350) for the UC+HZ vs UC only
  • $5,299 (-3,019;14,966) for the CD+HZ vs CD only
• Mean (95% CI) adjusted cost differences during the 1st quarter following HZ:
  • $2,574 (415;5,062) for the UC+HZ vs UC
  • $5,497 (2,300;11,487) for the CD+HZ vs CD

Take Home Message

• These results suggest that HZ poses a significant burden in UC and CD pts, being associated with higher health care resource use and costs even after adjusting for baseline differences
• These findings highlight the need for interventions to reduce this burden
P2620 - Patients With Inflammatory Bowel Disease Are at Increased Risk for Complications From Herpes Zoster

Freddy Caldera, DO, MS
University of Wisconsin Hospital and Clinics
Madison, WI, United States

Background

• Patients with inflammatory bowel disease (IBD) are at an increased risk for vaccine preventable infections such as herpes zoster (HZ)

• Immunosuppressed populations are at increased risk for complications from HZ such as post-herpetic neuralgia (PHN)

Aim

• The aim of this study was to determine if complications of HZ are more frequent in patients with IBD than in the general population
Methods

• A retrospective age matched cohort study using the Optum Research Database from 2007 through 2020 using pharmacy and administrative data
• Patients were identified with IBD who had ≥ 2 medical claims for IBD and had 12 months baseline coverage and 3 months after index date which was defined as a diagnosis of HZ
• Complications of HZ (PHN, ophthalmic, neurologic, or disseminated) that occurred up to 90 days after the index date were studied
• Patients with IBD with HZ compared to patients without IBD or on a medication used to treat IBD with HZ and evaluated 90-days risk of HZ complications
• Cases were matched based on age, gender, and index year

Results

• 16,969 patients with IBD met the inclusion criteria and were matched to controls
• Patients with IBD were more likely to have any HZ complications than matched controls [2811 (17.49%) vs 2220 (13.8%) p value < 0.0001]
• They were also more likely to be hospitalized, have disseminated HZ, develop PHN, or neurologic complications compared to matched controls
• Those with higher comorbidity scores were more likely to have HZ complications (2.68 vs. 2.01 p value < 0.0001)
• In logistic regression analysis, Hispanic ethnicity, anti-TNF therapy, thiopurine use, prednisone and increased age were all associated with an increased risk for any HZ complication
Take Home Message

• Patients with IBD are more likely to have complications of HZ compared to controls and these complications are common
• Efforts are needed to increase HZ vaccine uptake among patients with IBD to potentially prevent HZ complications

P2678 - Symptomology Following SARS-CoV-2 mRNA Vaccination Among Patients With Inflammatory Bowel Disease Relative to Healthcare Workers

Angela Mujukian, MD
Cedars-Sinai Medical Center
Los Angeles, CA, United States

P2632 - Gastrointestinal Symptoms in Patients With Inflammatory Bowel Disease After SARS-CoV-2 mRNA Vaccination

Rashmi Kumar, MD
Cedars-Sinai Medical Center
Los Angeles, CA, United States
Background

• A common reason for SARS-CoV-2 vaccine hesitancy among patients with inflammatory bowel disease (IBD) is fear of post-vaccination adverse events

• However, post-vaccination symptomology in IBD relative to a non-IBD population is unknown

Aim

• To study the post-vaccination symptoms between healthcare workers (HCW) without IBD and compared to adult IBD patients

Methods

• Post-vaccination symptoms between healthcare workers (HCW) without IBD at an academic medical center and adult IBD patients both at the same center and across the United States were compared

• Recipients of BNT162b2 (Pfizer) or mRNA-1273 (Moderna) vaccines received automated electronic surveys one week after each dose to assess frequency, severity and duration of local and systemic post-vaccine symptoms

• Significant symptoms were defined as moderate severity (at least some interference with daily activities) or greater, or duration lasting ≥2 days
Results

- 2324 subjects
  - 1391 with IBD (65% CD, 35% UC) and 933 HCW
- After each dose, IBD patients reported fewer injection site symptoms, fever or chills, fatigue or malaise, headache, dizziness, or lightheadedness, and muscle, bone, joint or nerve symptoms compared to HCW (p< 0.001 for each)
- IBD patients experienced more gastrointestinal (GI) symptoms after D1 but not after D2
  - D1: 2.9% vs 6.0%, p=0.001
  - D2: 12.1% vs 12.7%, p=0.75
- Most symptoms were non-severe and lasted < 2 days

Take Home Message

- IBD patients had overall fewer local and systemic symptoms after each dose, except for more frequent GI symptoms after D1 only
- People with IBD can be reassured that post-vaccination symptoms are significantly reduced compared to HCW
- Further study of post-vaccination GI symptoms in IBD is warranted
P2632 - Gastrointestinal Symptoms post Covid-19 Vaccination

**Background**

- In the SARS-CoV2 mRNA vaccine trials, post-vaccination gastrointestinal (GI) symptoms were reported in 10-20% of participants.
- These symptoms could be perceived as inflammatory bowel disease (IBD) flare which could lead to patient anxiety, and unnecessary tests or treatment.

**Aim**

- To assess GI symptoms after SARS-CoV2 mRNA vaccination in patients with IBD relative to non-IBD healthcare workers (HCW).

**Methods**

- GI symptoms (frequency, severity, and duration) assessed in adults with IBD and HCW at baseline and after each dose of a SARS-CoV-2 mRNA vaccine.
- Stool frequency (SF) and rectal bleeding for ulcerative colitis (UC).
- SF and abdominal pain for Crohn’s disease (CD).
- Severity was defined by impact on daily activities (mild, did not interfere; moderate, some interference; severe, prevented routine activity; extreme, required hospitalization). Severe and extreme were combined and designated as severe+.
- Duration was classified as < 2 days, 2-7 days, or >7 days.
Results

- Post-vaccination GI symptoms were assessed after dose 1 (D1) and dose 2 (D2)
- New GI symptoms after D1 were more frequent among IBD than HCW (6.0% vs 2.9%, p=0.001) but not after D2 (12.1% vs 12.7%, p=NS).
- Relative to HCW, IBD patients reported more diarrhea (3.8% vs. 1% (p< 0.001) after D1 and 7.5% vs 4.2% (p=0.003) after D2) and abdominal pain (2.2% vs. 0.4% (p=0.001) after D1 and 6.2% vs 3% (p=0.002) after D2).

Results

- Severe+ symptoms:
  - 1.5% IBD and 0.3% HCW (p=NS) after D1
  - 3.3% IBD and 0.1% HCW (p< 0.001) after D2
- Longer GI symptom duration was more common in IBD than HCW after D1 (2.1% vs 0.5%, p=0.002) and D2 (5.4% vs. 2.1%, p< 0.001)
- Patients in clinical remission at baseline, after D1 and after D2 respectively:
  - 71%, 68%, and 65% of 423 CD
  - 86%, 86%, and 83% of 300 UC
Take Home Message

• The frequency of GI symptoms in IBD was greater than HCW after D1, but similar after D2
• More severe and longer duration of GI symptoms were noted in a small number of IBD patients
• Reassuringly, the mRNA vaccines do not seem to increase the risk of a disease flare in the vast majority of IBD patients

Questions?

Moderator
Sunanda V. Kane, MD, FACG

Speaker
Jean-Paul Achkar, MD, FACG

Speaker
Anita Afzali, MD, FACG

Speaker
Tauseef Ali, MD, FACG
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