**P-009**

Response and Remission After 16 Weeks of Ustekinumab—An All Patients Analysis From the UNITI Crohn's Studies

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**BACKGROUND:** Ustekinumab (UST) has been shown to induce and maintain clinical response and remission in moderate-severe Crohn's disease (CD) in 2 induction [(UNITI-1(anti-TNF failures) & UNITI-2 (anti-TNF non-failures)] & 1 maintenance (IM-UNITI) randomized (RCT) trials. In this analysis, we evaluated efficacy (response & remission) for all pts who received an IV induction dose of approximately 6 mg/kg, including responders (CDAI decrease ≥100) or non-responders, 8wks after first UST induction dose of 90 mg SC. Patients with a total decrease of ≥50 points were included in an analysis of clinical response (CR) and CR at 12wks. Endoscopic assessments were read by an imaging core lab in a blinded manner. Daily stool frequency). SES-CD was evaluated at baseline and Week 12, and CDAI was assessed at baseline, respectively. Reductions from baseline of ≥25% and ≥50% in SES-CD score were seen in 48.1% and 36.2% of patients, respectively. Long-term treatment with 1 mg ozanimod in patients with moderate to severe CD was well tolerated and efficacious in patients with moderate to severe UC in the Phase 2 trial EUCALYPTUS. BERGAMOT (NCT03298048), a Phase 3, was designed with 5 sequential induction cohorts and a 1 maintenance cohort to evaluate the safety and efficacy of etrolizumab in patients with moderate to severe CD. This abstract describes the results for the exploratory induction cohort of 300 patients.

**METHODS:** Eligible patients with moderate to severe CD (confirmed at baseline with centrally read de- Morales) were randomized to anti-TNF non-failures or anti-TNF failures. A greater proportion of patients achieved remission in moderate-severe CD in 2 induction [(UNITI-1(anti-TNF failures) & UNITI-2 (anti-TNF non-failures)] & 1 maintenance (IM-UNITI) randomized (RCT) trials. End points asse ssment included CDAI remission (CDAI<150), CDAI-100 response, CDAI-70 response, PRO2 remission (weighted combined score ≤11, based on patient report of liquid/very soft stool frequency [SF]) and abdominal pain [AP], symptomatic remission (unweighted SF ≤ 3 and AP ≤ 1), and endoscopic improvement (≥50% reduction from baseline SES-CD using central reading) at week 14.

**CONCLUSION(S):** In this exploratory induction cohort, treatment with etrolizumab was well tolerated and resulted in clinically meaningful endoscopic improvement, with rapid symptomatic remission as early as week 6 that was sustained through week 14. These early results are indicative of the efficacy of etrolizumab in treating CD. Enrollment into subsequent induction cohorts and into the maintenance phase of BERGAMOT is ongoing.

**P-010**

Endoscopic and Clinical Efficacy Demonstrated with Oral Ozanimod in Active Crohn's Disease in Biologic-Naive and Biologic-Experienced Patients

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**BACKGROUND:** Ozanimod, an oral, once-daily immunomodulator that selectively targets S1P1 and S1P3, has demonstrated efficacy in ulcerative colitis (UC) (Sandborn NEM 2016) is being evaluated in patients with active Crohn's disease (CD) (Crohn's). Phase 2 open-label study examined endoscopic and clinical outcomes following treatment with ozanimod 1 mg daily for 12 weeks in biologic-naive and biologic-experienced CD patients.

**METHODS:** Patients with active CD defined as Crohn’s Disease Activity Index (CDAI) score 220-450 and simple endoscopic score for CD (SES-CD) ≥6 were included. Patients were randomized (1:1:1) and treated with placebo (PBO) or ozanimod 1 mg for 16 weeks. End points asse ssment included CDAI remission (CDAI<150), CDAI-100 response, CDAI-70 response, PRO2 remission (weighted combined score ≤11, based on patient report of liquid/very soft stool frequency [SF]) and abdominal pain [AP], symptomatic remission (unweighted SF ≤ 3 and AP ≤ 1), and endoscopic improvement (≥50% reduction from baseline SES-CD using central reading) at week 14.

**CONCLUSION(S):** In this exploratory induction cohort, treatment with etrolizumab was well tolerated and resulted in clinically meaningful endoscopic improvement, with rapid symptomatic remission as early as week 6 that was sustained through week 14. These early results are indicative of the efficacy of etrolizumab in treating CD. Enrollment into subsequent induction cohorts and into the maintenance phase of BERGAMOT is ongoing.

**P-011**

Etrolizumab as Induction Therapy in Moderate to Severe Crohn's Disease: Results From UNITI Cohort 1

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**BACKGROUND:** Etrolizumab, a humanized anti-β7 monoclonal antibody currently undergoing Phase 3 evaluation in ulcerative colitis (UC) and Crohn’s disease (CD), was demonstrated to be well tolerated and efficacious in patients with moderate to severe UC in the Phase 2 trial EUCALYPTUS. BERGAMOT (NCT03298048), a Phase 3, was designed with 5 sequential induction cohorts and a 1 maintenance cohort to evaluate the safety and efficacy of etrolizumab in patients with moderate to severe CD. This abstract describes the results for the exploratory induction cohort of 300 patients.

**METHODS:** Eligible patients with moderate to severe CD (confirmed at baseline with centrally read de- Morales) were randomized to anti-TNF non-failures or anti-TNF failures. A greater proportion of patients achieved remission in moderate-severe CD in 2 induction [(UNITI-1(anti-TNF failures) & UNITI-2 (anti-TNF non-failures)] & 1 maintenance (IM-UNITI) randomized (RCT) trials. End points asse ssment included CDAI remission (CDAI<150), CDAI-100 response, CDAI-70 response, PRO2 remission (weighted combined score ≤11, based on patient report of liquid/very soft stool frequency [SF]) and abdominal pain [AP], symptomatic remission (unweighted SF ≤ 3 and AP ≤ 1), and endoscopic improvement (≥50% reduction from baseline SES-CD using central reading) at week 14.

**CONCLUSION(S):** In this exploratory induction cohort, treatment with etrolizumab was well tolerated and resulted in clinically meaningful endoscopic improvement, with rapid symptomatic remission as early as week 6 that was sustained through week 14. These early results are indicative of the efficacy of etrolizumab in treating CD. Enrollment into subsequent induction cohorts and into the maintenance phase of BERGAMOT is ongoing.

**P-012**

Ozanimod, an Oral S1P Receptor Modulator, Is Effective and Well-Tolerated in the Long-Term Treatment of Moderate to Severe Ulcerative Colitis

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**BACKGROUND:** Ozanimod, an oral, once-daily immunomodulator that selectively targets S1P1 and S1P3, has demonstrated clinical efficacy in UC induction (Sandborn NEM 2016) and Crohn’s disease (CD), was demonstrated to be well tolerated and efficacious in patients with moderate to severe UC in the Phase 2 trial EUCALYPTUS. BERGAMOT (NCT03298048), a Phase 3, was designed with 5 sequential induction cohorts and a 1 maintenance cohort to evaluate the safety and efficacy of etrolizumab in patients with moderate to severe CD. This abstract describes the results for the exploratory induction cohort of 300 patients.

**METHODS:** Eligible patients with moderate to severe CD (confirmed at baseline with centrally read de- Morales) were randomized to anti-TNF non-failures or anti-TNF failures. A greater proportion of patients achieved remission in moderate-severe CD in 2 induction [(UNITI-1(anti-TNF failures) & UNITI-2 (anti-TNF non-failures)] & 1 maintenance (IM-UNITI) randomized (RCT) trials. End points asse ssment included CDAI remission (CDAI<150), CDAI-100 response, CDAI-70 response, PRO2 remission (weighted combined score ≤11, based on patient report of liquid/very soft stool frequency [SF]) and abdominal pain [AP], symptomatic remission (unweighted SF ≤ 3 and AP ≤ 1), and endoscopic improvement (≥50% reduction from baseline SES-CD using central reading) at week 14.

**CONCLUSION(S):** In this exploratory induction cohort, treatment with etrolizumab was well tolerated and resulted in clinically meaningful endoscopic improvement, with rapid symptomatic remission as early as week 6 that was sustained through week 14. These early results are indicative of the efficacy of etrolizumab in treating CD. Enrollment into subsequent induction cohorts and into the maintenance phase of BERGAMOT is ongoing.

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