Etrolizumab Induction in Moderate/Severe Anti-TNF Intolerant/Refractory (IR) Ulcerative Colitis (UC): The HICKORY Open-Label Induction (OLI) Trial

In the Phase 2 EUCALYPTUS trial, etrolizumab was well tolerated and efficacious in patients with moderate to severe UC1

HICKORY FACTOR (2018)2 is an ongoing phase 3 clinical trial assessing the safety and efficacy of etrolizumab in patients with refractory to severely active UC and prior TNF antagonist (aTNF) failure.

At ECCO 2017, the HICKORY open-label induction (OLI) cohort demonstrated remission of rectal bleeding (RB) in 50% of etrolizumab-treated patients at week 8, which was observed consistently through Week 14.

Embarrassing assessments of disease activity and treatment response in UC clinical trials now rely on assessments by blinded clinical readers and were used in this analysis.

A complete efficacy analysis for the difficult-to-treat patients enrolled in the HICKORY OLI cohort includes endoscopic subscore, as well as patient-reported assessments of symptoms and inflammatory biomarkers

In the Phase 2 EUCALYPTUS trial, etrolizumab was well tolerated and efficacious in patients with moderate to severe UC.

Clinical response in 50.8% of patients RB remission 14

Patient outcomes were reported changes of symptoms and endoscopy results at Week 14 included:

- Clinical response
- Stool frequency and rectal bleeding remission
- Endoscopic improvement
- Inflammatory biomarkers

The baseline characteristics highlight a population with significant disease burden (Table 1)

Baseline demographics and disease characteristics

- The baseline characteristics highlight a population with significant disease burden (Table 1)

Table 1. Baseline demographics and disease characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HICKORY Cohort N=130</th>
<th>Median age 56.1 years (range 18-92)</th>
<th>Median age 56.1 years (range 18-92)</th>
<th>Median age 56.1 years (range 18-92)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, % male</td>
<td>51</td>
<td>51</td>
<td>51</td>
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<tr>
<td>Disease duration (median)</td>
<td>11.4 years</td>
<td>11.4 years</td>
<td>11.4 years</td>
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<tr>
<td>Perianal fistulae, %</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td></td>
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<tr>
<td>IBD hospitalisation</td>
<td>26</td>
<td>26</td>
<td>26</td>
<td></td>
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<td>IBD-related surgery, %</td>
<td>13</td>
<td>13</td>
<td>13</td>
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<tr>
<td>Severe disease, %</td>
<td>66</td>
<td>66</td>
<td>66</td>
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<tr>
<td>Mucosal extension, %</td>
<td>73</td>
<td>73</td>
<td>73</td>
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<tr>
<td>Endoscopic subscore (median [range])</td>
<td>1 [0-5]</td>
<td>1 [0-5]</td>
<td>1 [0-5]</td>
<td></td>
</tr>
</tbody>
</table>

疗效和可接受性

- 该研究是HICKORY研究的一部分
- 患者对治疗的满意度和可接受性
- 患者的活动性
- 患者的活动性

CONCLUSIONS

- In a difficult-to-treat population of patients with prior aTNF failure, etrolizumab treatment resulted in:
  - Clinical improvements
  - Symptomatic remission
  - Inflammatory biomarker improvements

Safety and tolerability

- Etrolizumab treatment was well tolerated in patients with moderate to severe UC who have experienced aTNF failure.
- The most common adverse events (AEs) reported were:
  - Ulcerative colitis (11%)
  - Nasopharyngitis (10%)
  - Headache (8%)
  - Fatigue (5%)

REFERENCES

2. Peyrin-Biroulet L et al. 12th Congress of ECCO; February 2017; Barcelona, Spain