Efficacy and Safety Results From ASCEMBL, a Multicenter, Open-Label, Phase 3 Study of Asciminib, a First-in-Class STAMP Inhibitor, vs Bosutinib in Patients With Chronic Myeloid Leukemia in Chronic Phase After ≥2 Prior Tyrosine Kinase Inhibitors: Update After 48 Weeks

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• Asciminib is the first BCR::ABL1 inhibitor that works by specifically targeting the ABL myristoyl pocket (STAMP)\(^1\)

• Asciminib was recently approved by the FDA for the treatment of adults with Ph+ CML-CP previously treated with ≥2 TKIs and in those with the T315I mutation\(^2\)

• In the phase 3 ASCEMBL study, after a median follow-up of 14.9 months, asciminib demonstrated superior efficacy with better safety and tolerability compared with bosutinib in patients with CML-CP after ≥2 prior ATP-binding TKIs\(^1\)
  - MMR rate at week 24 (primary endpoint) was 25.5% with asciminib vs 13.2% with bosutinib
    - Difference between arms was 12.2% (95% CI, 2.19%-22.30%; \(P=0.029\)) after adjusting for MCyR at baseline
    - Fewer grade ≥3 AEs (50.6% vs 60.5%) and AEs leading to treatment discontinuation (5.8% vs 21.1%) occurred with asciminib than bosutinib

• We report updated efficacy and safety results for patients in ASCEMBL, all of whom had at least 1 year (48 weeks) of treatment or discontinued treatment earlier

ABL1, Abelson tyrosine kinase 1; AE, adverse event; ATP, adenosine triphosphate; BCR, breakpoint cluster region; CML-CP, chronic myeloid leukemia in chronic phase; FDA, US Food and Drug Administration; IS, International Scale; MCyR, major cytogenetic response; MMR, major molecular response (BCR::ABL1 IS ≤0.1%); Ph, Philadelphia chromosome; SH, Src homology; TKI, tyrosine kinase inhibitor.
ASCEMBL Study Design

- Data cutoff for current analysis: January 6, 2021
- Follow-up: 100% of ongoing patients completed week 48 visit and all (except 1) completed week 60 visit
- Median duration of follow-up: 19.2 months from randomization to cutoff
- Primary endpoint: MMR rate at week 24
- Key secondary endpoint: MMR rate at week 96

Key Study Criteria

- Adults with CML-CP, previously treated with ≥2 TKIs
- Failure\(^a\) or intolerance of most recent TKI
- Patients with intolerance of most recent TKI must have BCR::ABL\(^1\) IS >0.1% at screening
- No T315I or V299L mutations

ASCEMBL (NCT03106779)
Randomized 2:1 (stratified by MCyR vs no MCyR at baseline)

N=233

**Asciminib**
40 mg twice daily
n=157

**Bosutinib**
500 mg once daily
n=76

Survival follow-up

Switch allowed for those meeting lack of efficacy criteria on bosutinib\(^b\)

Asciminib 40 mg twice daily

- Treatment duration: ≥96 weeks

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\(2L, 2nd\) line; ELN, European LeukemiaNet.

\(^a\) Must meet lack of efficacy criteria based on 2013 ELN recommendations for 2L TKI therapy.

\(^b\) Patients who discontinued bosutinib treatment due to intolerance or any reason other than lack of efficacy were not allowed to switch to asciminib.
### Patient Disposition

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>Asciminib 40 mg twice daily (n=157)</th>
<th>Bosutinib 500 mg once daily (n=76)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treated</strong></td>
<td>156 (99.4)</td>
<td>76 (100.0)</td>
</tr>
<tr>
<td><strong>Treatment ongoing</strong></td>
<td>89 (56.7)</td>
<td>17 (22.4)</td>
</tr>
<tr>
<td><strong>Discontinued treatment</strong></td>
<td>67 (42.7)</td>
<td>59 (77.6)</td>
</tr>
<tr>
<td>Before week 24</td>
<td>26 (16.6)</td>
<td>25 (32.9)</td>
</tr>
<tr>
<td>Week 24 to before week 48</td>
<td>25 (15.9)</td>
<td>29 (38.2)</td>
</tr>
<tr>
<td>Week 48 to before week 96</td>
<td>15 (9.6)</td>
<td>3 (3.9)</td>
</tr>
<tr>
<td>After week 96</td>
<td>1 (0.6)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td><strong>Reason for discontinuation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of efficacy</td>
<td>37 (23.6)</td>
<td>27 (35.5)</td>
</tr>
<tr>
<td>Adverse event</td>
<td>9 (5.7)</td>
<td>18 (23.7)</td>
</tr>
<tr>
<td>Physician decision</td>
<td>13 (8.3)</td>
<td>6 (7.9)</td>
</tr>
<tr>
<td>Patient decision</td>
<td>4 (2.5)</td>
<td>3 (3.9)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>1 (0.6)</td>
<td>3 (3.9)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>1 (0.6)</td>
<td>2 (2.6)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Protocol deviation</td>
<td>1 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Switched to receive asciminib</td>
<td>NA</td>
<td>24 (31.6)</td>
</tr>
</tbody>
</table>

NA, not applicable.

a 1 patient in the asciminib arm developed cytopenia after randomization and was not treated per investigator’s decision.

b Ongoing at the time of data cutoff: January 6, 2021.

- Treatment was ongoing in more than double the proportion of patients receiving asciminib than bosutinib after longer follow-up.
• Response rates continued to be higher with asciminib than bosutinib with longer follow-up

\[ a \text{ The treatment difference after adjusting for MCyR status at baseline was } 16.1\% (95\% CI, 5.7\%-26.6\%). \]

\[ b \text{ BCR::ABL}^{I\text{S}} \leq 1\% \text{ at week 48 was based on 142 of 157 patients (90.4\%) receiving asciminib and 72 of 76 (94.7\%) receiving bosutinib who did not have this level of response at baseline.} \]
MMR Rate at Week 48 by Line of Therapy

- A consistent treatment effect in favor of asciminib was seen across all lines of therapy.
The MMR rate was consistently higher with asciminib than bosutinib.

Duration of MMR

- The probability of maintaining MMR for at least 48 weeks with asciminib was 96.1% (95% CI, 85.4%-99.0%) vs 90.0% (95% CI, 47.3%-98.5%) with bosutinib.
- 60 of 62 patients receiving asciminib and 17 of 18 receiving bosutinib maintained MMR at the time of their last assessment.
  - At data cutoff, the K-M–estimated median duration of MMR was not reached in both treatment arms.

K-M, Kaplan-Meier.

a Nonresponders were censored at their last molecular assessment date.

b Discontinuation from treatment for any reason without prior achievement of MMR is considered a competing event.
Oral presentation at: 63rd ASH Annual Meeting & Exposition; December 11-14, 2021; Atlanta, GA, and virtual.

More patients receiving asciminib than bosutinib continued to achieve $BCR::ABL1^{IS} \leq 1\%$ over time.

- More patients receiving asciminib than bosutinib continued to achieve $BCR::ABL1^{IS} \leq 1\%$ over time.

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**Cumulative Incidence of $BCR::ABL1^{IS} \leq 1\%$**

<table>
<thead>
<tr>
<th>Time, weeks</th>
<th>Asciminib</th>
<th>Bosutinib</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>142</td>
<td>72</td>
</tr>
<tr>
<td>4</td>
<td>136</td>
<td>67</td>
</tr>
<tr>
<td>8</td>
<td>120</td>
<td>59</td>
</tr>
<tr>
<td>12</td>
<td>91</td>
<td>54</td>
</tr>
<tr>
<td>16</td>
<td>70</td>
<td>40</td>
</tr>
<tr>
<td>20</td>
<td>61</td>
<td>35</td>
</tr>
<tr>
<td>24</td>
<td>54</td>
<td>31</td>
</tr>
<tr>
<td>28</td>
<td>35</td>
<td>23</td>
</tr>
<tr>
<td>32</td>
<td>25</td>
<td>12</td>
</tr>
<tr>
<td>36</td>
<td>21</td>
<td>9</td>
</tr>
<tr>
<td>40</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>44</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>48</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>52</td>
<td>12</td>
<td>4</td>
</tr>
<tr>
<td>56</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>60</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>64</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>68</td>
<td>6</td>
<td>2</td>
</tr>
</tbody>
</table>

- No. of patients still at risk:
  - Asciminib: 142, 136, 120, 91, 70, 61, 54, 35, 25, 21, 16, 16, 14, 12, 11, 9, 7, 6
  - Bosutinib: 72, 67, 59, 54, 40, 35, 31, 23, 12, 6, 6, 4, 4, 4, 3, 2, 2

- Cumulative No. of competing events:
  - Asciminib: 0, 5, 8, 14, 17, 23, 27, 35, 44, 47, 49, 49, 51, 52, 53, 54, 54, 55
  - Bosutinib: 0, 4, 7, 10, 15, 18, 22, 27, 38, 40, 42, 42, 43, 43, 43, 44, 44, 44

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$BCR::ABL1^{IS} \leq 1\%$ by week 48 was based on 142 of 157 patients (90.4%) receiving asciminib and 72 of 76 (94.7%) receiving bosutinib who did not have this level of response at baseline.

Nonresponders were censored at their last molecular assessment date.

Discontinuation from treatment for any reason, without prior achievement of $BCR::ABL1^{IS} \leq 1\%$, is considered a competing event.
MR⁴ and MR⁴.⁵ Rates at Week 48

- Deep molecular response rates continued to be higher with asciminib than bosutinib after longer follow-up.

MR⁴, BCR::ABL¹IS ≤0.01%; MR⁴.⁵, BCR::ABL¹IS ≤0.0032%.
Censoring times

- Treatment failure was defined as lack of efficacy (per 2013 ELN recommendations for 2L patients) or discontinuation for any reason
- By data cutoff, fewer patients experienced treatment failure with asciminib (48.4%) than bosutinib (80.3%)
- The K-M–estimated proportion of patients without treatment failure by 12 months was 57.7% (95% CI, 49.5%-65.0%) with asciminib vs 25.0% (95% CI, 15.9%-35.1%) with bosutinib
- Median time to treatment failure was not reached with asciminib and 6 months with bosutinib
• Median duration of exposure was 15.4 months (range, 0.0-37.3 months) for asciminib and 6.8 months (range, 0.2-34.3 months) for bosutinib

• Safety and tolerability of asciminib remained consistent with longer follow-up, with fewer grade ≥3 AEs with asciminib (54.5%) than bosutinib (67.1%)

• No patients died in either treatment arm since the primary analysis cutoff

• Most common all-grade AEs leading to treatment discontinuation included thrombocytopenia (3.2%) and neutropenia (2.6%) with asciminib and increased alanine aminotransferase level (5.3%) and neutropenia (3.9%) with bosutinib

• AEs leading to dose reduction and interruption, respectively, occurred in 23.1% and 40.4% of patients receiving asciminib and 44.7% and 60.5% of those receiving bosutinib

**Overview of Adverse Events**

<table>
<thead>
<tr>
<th></th>
<th>AEs</th>
<th>AEs leading to discontinuation</th>
<th>Fatal AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All grade</td>
<td>Grade ≥3</td>
<td>All grade</td>
</tr>
<tr>
<td>Asciminib (N=156)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All grade</td>
<td>91.0</td>
<td>54.5</td>
<td>97.4</td>
</tr>
<tr>
<td>Bosutinib (N=76)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ALT, alanine aminotransferase; AST, aspartate aminotransferase.

*Grade 1/2 AEs leading to discontinuation were as follows: with asciminib (n=1): amylase level increased; and with bosutinib (n=5): ALT/AST level increased, creatinine level increased, diarrhea, drug eruption, and pleural effusion.*
• Despite the longer duration of exposure, the safety and tolerability profile of asciminib continued to be better than that of bosutinib after longer follow-up

- Thrombocytopenia:
  - Asciminib: 29.5%
  - Bosutinib: 19.7%
- Neutropenia:
  - Asciminib: 23.1%
  - Bosutinib: 21.1%
- Diarrhea:
  - Asciminib: 11.5%
  - Bosutinib: 11.5%
- Nausea:
  - Asciminib: 46.1%
  - Bosutinib: 23.7%
- Rash:
  - Asciminib: 7.7%
  - Bosutinib: 7.1%
- Vomiting:
  - Asciminib: 7.7%
  - Bosutinib: 3.8%
- Increased ALT:
  - Asciminib: 28.9%
  - Bosutinib: 5.1%
- Increased AST:
  - Asciminib: 21.1%
  - Bosutinib: 21.1%

a Includes thrombocytopenia and platelet count decreased.
b Includes neutropenia and neutrophil count decreased.
**All-Grade Hematologic AEs by Time Period on Asciminib**

- Most AEs with asciminib initially presented in the first 6 months of treatment
- Recurring hematologic AEs were manageable, with low rates of asciminib discontinuation due to thrombocytopenia (3.2%) and neutropenia (2.6%)

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- Includes thrombocytopenia and platelet count decreased.
- Includes neutropenia and neutrophil count decreased.
- Includes anemia, decreased hemoglobin, and normocytic anemia.
- A patient with multiple occurrences of an AE is counted only once in that time interval.
## Arterial Occlusive Events

<table>
<thead>
<tr>
<th>AOE, n (%)</th>
<th>Asciminib 40 mg twice daily (N=156)</th>
<th>Bosutinib 500 mg once daily (N=76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with AOE, n (%)</td>
<td>7 (4.5)</td>
<td>1 (1.3)</td>
</tr>
</tbody>
</table>

### Patients with events observed by the cutoff for primary analysis

<table>
<thead>
<tr>
<th>Event</th>
<th>Asciminib 40 mg twice daily</th>
<th>Bosutinib 500 mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial ischemia(^a)</td>
<td>2 (1.3)(*,†)</td>
<td>0</td>
</tr>
<tr>
<td>Acute coronary syndrome</td>
<td>0</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Coronary artery disease(^a)</td>
<td>1 (0.6)</td>
<td>0</td>
</tr>
<tr>
<td>Ischemic stroke</td>
<td>1 (0.6)(^*)</td>
<td>0</td>
</tr>
<tr>
<td>Mesenteric artery embolism/thrombosis(^b)</td>
<td>1 (0.6)(*,†)</td>
<td>0</td>
</tr>
</tbody>
</table>

### Additional patients with events observed by cutoff for current analysis

<table>
<thead>
<tr>
<th>Event</th>
<th>Asciminib 40 mg twice daily</th>
<th>Bosutinib 500 mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral infarction</td>
<td>1 (0.6)(*,†)</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (0.6)(^*)</td>
<td>0</td>
</tr>
</tbody>
</table>

### Exposure-adjusted AOE rate (per 100 patient-years)

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Asciminib 40 mg twice daily</th>
<th>Bosutinib 500 mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary analysis</td>
<td>3.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Current analysis</td>
<td>3.4</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Risk of AOE remained constant and did not increase after additional time receiving asciminib

- Exposure-adjusted AOE rate (per 100 patient-years) in the current analysis (3.4) was comparable to that in the primary analysis (3.3)
  - Of the 7 patients with AOE receiving asciminib, 7 had prior exposure to nilotinib, *5 to dasatinib, and †3 to ponatinib\(^b\)
  - The majority of patients receiving bosutinib discontinued early, thus preventing a meaningful comparison between the arms

\(^a\) Myocardial ischemia (n=2) and coronary artery disease (n=1) in patients receiving asciminib occurred without clinical manifestations and was identified based on ECG performed per protocol after dosing and coronary arteriography performed due to medical history, respectively.

\(^b\) Mesenteric artery embolism/thrombosis occurred 15 days after asciminib discontinuation and following ponatinib treatment for 7 days.

AOE, arterial occlusive event; ECG, electrocardiogram.

Oral presentation at: 63rd ASH Annual Meeting & Exposition; December 11-14, 2021; Atlanta, GA, and virtual.
Conclusions

• ASCEMBL is the first randomized controlled study vs a 2nd-generation TKI in patients with CML-CP previously treated with ≥2 TKIs

• After an additional median follow-up of approximately 5 months in ASCEMBL, asciminib continued to demonstrate sustained superior efficacy compared with bosutinib
  
  o The MMR rate was consistently higher with asciminib than bosutinib at week 48
  
  o More patients receiving asciminib than bosutinib achieved BCR::ABL1≤1% by week 48 (50.8% vs 33.7%), which is known to be a predictor of better long-term outcomes in this heavily pretreated patient population3,4
  
  o More patients receiving asciminib than bosutinib achieved deep molecular response (MR4 and MR4.5) at week 48
  
  o More patients receiving asciminib than bosutinib (56.7% vs 22.4%) remained on treatment and continued to meet response milestones by the data cutoff in this heavily pretreated patient population

• The safety profile of asciminib remained consistent with that at the time of primary analysis, and there were no new or worsening safety findings
  
  o The majority of patients receiving bosutinib discontinued early, thus preventing a meaningful comparison of AOEs between the arms

• Updated efficacy and safety results in ASCEMBL continue to support the use of asciminib as a new treatment option in CML, with the potential to transform standard of care in later-line CML
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