Evaluation of a Self-Administered Smart Phone-Based Application as a Wellness Measure in a Clinical Trial of Zanubrutinib

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INTRODUCTION
HEALTH-RELATED QUALITY OF LIFE (HRQOL)

- A multidomain concept that represents the patient’s general perception of the effect of illness and treatment on physical, psychological and social aspects of life (FDA 2009)

PATIENT-REPORTED OUTCOMES (PRO)

- Measures a patient’s health status as reported directly from the patient without added interpretation by a healthcare worker or anyone else (FDA 2022)

- Patient-reported physical functioning and key symptoms are considered efficacy endpoints in the clinical trials by the regulatory and HTA agencies (FDA 2018, EMA 2016)

- Demand is increasing for improved methods of HRQoL measurements by the regulatory and HTA agencies
• Self-administered assessments via smart phone-based applications (apps) can gather patient wellness data

• In recent years technology-based assessment such as smartphone apps has been tested and implemented to collect data in clinical trials

• Potential advantages of app-based PROs: data can be collected in real time, remotely, better compliance, accuracy, completeness and cost-savings

• Data regarding feasibility of self-administered app utilization in clinical trials are limited
OBJECTIVES
• Exploratory analysis to evaluate the engagement and feasibility of using a voluntary device-based, self-administered wellness app as a supplemental tool to assess quality of life in clinical trial patients from study BGB-3111-215

• Study BGB-3111-215 (NCT04116437): phase 2 study including patients with B-cell malignancies treated daily with oral zanubrutinib
METHODS
• Patients enrolled in the trial were invited to download and consent to use a voluntary device-based, self-administered activity and HRQoL questionnaire app (Medable, California, USA).

• The app included:
  • Self-administered questionnaire
  • 6-minute walk test
  • Passive activity tracking
Self-administered Questionnaire

• A series of questions to assess patient health every week
  • Up to Week 13 — once per week
  • After Week 13 — once per 4 weeks until disease progression or end of study
• Results uploaded to a central database
6-Minute Walk Test

• Patients prompted to complete a 6-minute walk test (walk as far as they could for 6 minutes)
  • Up to Week 13 — once per week
  • After Week 13 — once per 4 weeks until disease progression or end of study

• The app collected information on:
  • Motion and fitness data
  • Distance traveled (the app does not view location data)
Passive Activity Tracking

• Step count and distance

• Collected continuously and summarized for each week
Feasibility Measures of App

- **Consent rate**: assessed by the percentage of patients who agreed to app use
- **Utilization rate**: assessed by percentage of patients who engaged with the app
- **Compliance rate**: assessed by actual versus scheduled engagements
RESULTS
App Consent Rate

- As of 1 September 2022, 78 patients had enrolled in the study (median age=71 years)
- 20 enrolled trial patients consented to the app (Consent Rate=26%)

<table>
<thead>
<tr>
<th>Male sex, n (%)</th>
<th>Patients who consented and engaged (n=11)</th>
<th>Patients who consented and did not engage (n=9)</th>
<th>Patients who did not consent (n=58)</th>
<th>Total (N=78)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 (54.5)</td>
<td>6 (66.7)</td>
<td>31 (53.4)</td>
<td>43 (55.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age, years, median (range)</th>
<th>65 (49.73)</th>
<th>71 (63.87)</th>
<th>73 (50.91)</th>
<th>71 (49.91)</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th>Race, n (%)</th>
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<tbody>
<tr>
<td>White</td>
<td>10 (90.9)</td>
<td>8 (88.9)</td>
<td>54 (93.1)</td>
<td>72 (92.3)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>1 (1.7)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (9.1)</td>
<td>0</td>
<td>0</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Multiple</td>
<td>0</td>
<td>1 (11.1)</td>
<td>0</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>Not reported/Unknown</td>
<td>0</td>
<td>0</td>
<td>3 (5.2)</td>
<td>3 (3.8)</td>
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<thead>
<tr>
<th>Ethnicity, n (%)</th>
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</thead>
<tbody>
<tr>
<td>Not Hispanic</td>
<td>11 (100.0)</td>
<td>9 (100.0)</td>
<td>56 (96.6)</td>
<td>76 (97.4)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0</td>
<td>0</td>
<td>2 (3.4)</td>
<td>2 (2.6)</td>
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<thead>
<tr>
<th>ECOG PS, n (%)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>9 (81.8)</td>
<td>6 (66.7)</td>
<td>31 (53.4)</td>
<td>46 (59.0)</td>
</tr>
<tr>
<td>1</td>
<td>2 (18.2)</td>
<td>3 (33.3)</td>
<td>25 (43.1)</td>
<td>30 (38.5)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2 (3.4)</td>
<td>2 (2.6)</td>
</tr>
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<table>
<thead>
<tr>
<th>Disease type</th>
<th>Patients, n %</th>
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<tbody>
<tr>
<td>CLL</td>
<td>51 (65)</td>
</tr>
<tr>
<td>WM</td>
<td>12 (15)</td>
</tr>
<tr>
<td>SLL</td>
<td>8 (10)</td>
</tr>
<tr>
<td>MZL</td>
<td>4 (5)</td>
</tr>
<tr>
<td>MCL</td>
<td>3 (4)</td>
</tr>
</tbody>
</table>
11 patients (median age=65 years) engaged with the app at least once (Utilization Rate=14%). Questionnaire engagement occurred a median of 2 times (range, 1-17) and a median of 7 times (range, 1-15) for the walk test. 4 patients engaged with the questionnaire and 6 patients engaged in the walk test beyond Week 12. Passive activity was collected for 8 patients beyond Week 12.

### App Utilization Rate

<table>
<thead>
<tr>
<th>Patients, n (%)</th>
<th>Before Week 12</th>
<th>After Week 12</th>
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<tbody>
<tr>
<td>Patients enrolled</td>
<td>78 (100)</td>
<td></td>
</tr>
<tr>
<td>Patients consented</td>
<td>20 (26)</td>
<td></td>
</tr>
<tr>
<td>Any app engagement</td>
<td>11 (14)</td>
<td>11 (14)</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>11 (14)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Walk Test</td>
<td>7 (9)</td>
<td>6 (8)</td>
</tr>
<tr>
<td>Passive Activity</td>
<td>10 (13)</td>
<td>8 (10)</td>
</tr>
</tbody>
</table>

#### Graphs

**Questionnaire Utilization**
- Screening: 5 patients
- Protocol-defined engagement: 6 patients
- Not protocol-defined engagement: 3 patients
- Protocol-defined but no engagement: 1 patient

**Get Up and Walk Test Utilization**
- Week 0: 2 patients
- Week 1: 2 patients
- Week 2: 3 patients
- Week 3: 1 patient
- Week 4: 1 patient
- Week 5: 1 patient
- Week 12: 1 patient

**Passive Activity Tracking Utilization**
- Week 0: 8 patients
- Week 1: 7 patients
- Week 2: 6 patients
- Week 3: 5 patients
- Week 4: 4 patients
- Week 5: 3 patients
- Week 12: 2 patients
Among patients who engaged the HRQoL questionnaire and walk test, compliance rates were 18% and 21%, respectively.

App Compliance Rate

- Get Up and Walk Test: 21%
- Questionnaire: 18%
CONCLUSIONS

• This exploratory analysis showed that a subset of clinical trial patients was willing to participate in the self-administered QoL questionnaire and activity tracker.

• Further comparison of app results and clinical trial findings are ongoing to explore factors affecting utilization and compliance rates.
THANK YOU!

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