TOP LINE DATA FROM PHASE II TRIAL ASSESSING BEMCENTINIB IN HOSPITALISED COVID-19 PATIENTS

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Executive Summary

The trial BGBC020 shows that Bemcentinib has the potential to increase the rate of ventilator free survival in more than 50% of hospitalised COVID-19 patients, addressing the greatest challenge faced by hospitals worldwide fighting the pandemic.

- Top line data from BGBC020, a randomised Phase II clinical study evaluating the efficacy and safety of bemcentinib in hospitalised COVID-19 patients
- Study conducted from October 2020 in 115 patients across sites in South Africa and India
- Ventilator Free Survival 90% in bemcentinib group vs 72% in standard of care
- Subgroup of COVID-19 patients identified with increased disease severity, representing more than 50% of hospitalised patients on the study.
- Analysis of overall survival in the BGBC020 study was combined with UK ACCORD2 study with analogous phase 2 design
- Survival benefit was numerically greater in the bemcentinib treated patients
- Bemcentinib was well tolerated throughout
- BerGenBio continues discussions with international governments and regulators regarding next steps
AXL is targeted by enveloped viruses to enter cells and dampen the viral immune response

Enveloped viruses display phosphatidyserine that is recognized by GAS6, the AXL receptor ligand, that mediates viral entry through "apoptotic mimicry".

Viral-mediated AXL receptor activation dampens type I interferon responses, a key anti-viral defence mechanism for all cells.
Bemcentinib acts on two host pathways
Prevents viral infection and promotes innate immunity

Bemcentinib:
- blocks AXL-dependent viral entry
- enhances anti-viral interferon response
- Mode of action is independent of spike protein (or mutations)
Summary of bemcentinib as a COVID-19 therapy

- Bemcentinib acts on two host pathways
  - Prevents viral infection
  - Promotes innate immunity

- Bemcentinib inhibits viral entry by inhibiting AXL
  - AXL is independent of viral spike protein and should remain effective against current and future variants
  - Ongoing work will confirm viral genome sequencing of clinical trial samples
Study Schematic - BGB020 and ACCORD2 share identical design

COVID positive
N = 120

Informed consent, Screen and Enrolment

Bemcentinib* + SOC

SOC only

SOC, if required

* Bemcentinib treatment up to day 15. Discontinued earlier, if discharged or clinical improvement

Day 1
Day 15
Day 29
Day 60
Day 90

Out-patient or remote

Study Participation

Admission to hospital
Bemcentinib studied in COVID-19 across 3 countries

<table>
<thead>
<tr>
<th>Patient Accrual 3/24</th>
<th>India</th>
<th>South Africa</th>
<th>UK</th>
<th>Total</th>
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<tr>
<td>Bemcentinib</td>
<td>30</td>
<td>28</td>
<td>30</td>
<td>88</td>
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<tr>
<td>SoC</td>
<td>30</td>
<td>27</td>
<td>32</td>
<td>89</td>
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<td><strong>177</strong></td>
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## BGBC020 Enrolment – strata and arm

<table>
<thead>
<tr>
<th>Baseline WHO OCS</th>
<th>Baseline Intent to use steroid</th>
<th>Bemcentinib</th>
<th>SOC</th>
<th>Total</th>
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<tr>
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<td>N/A</td>
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<td>5</td>
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<td>4</td>
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<tr>
<td></td>
<td>Yes</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>58</strong></td>
<td><strong>57</strong></td>
<td><strong>115</strong></td>
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</table>

Baseline intention to treat with steroids - 81 patients (70%); On-study use of steroids - 87 patients (76%)
# Inclusion based on WHO COVID19: 9-point ordinal category scale (OCS)

<table>
<thead>
<tr>
<th>Setting</th>
<th>Severity</th>
<th>Supportive intervention</th>
<th>BGBC020 ACCORD2</th>
<th>Dexamethasone</th>
<th>IL-6 receptor antagonists</th>
<th>Remdesivir</th>
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<tbody>
<tr>
<td>0</td>
<td>Uninfected</td>
<td>no clinical or virological evidence of infection</td>
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<tr>
<td>1</td>
<td>Ambulatory</td>
<td>no limitation of activities</td>
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</tr>
<tr>
<td>2</td>
<td>Ambulatory</td>
<td>limitation of activities</td>
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<tr>
<td>3</td>
<td>mild</td>
<td>no oxygen therapy</td>
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<td>Hospitalised</td>
<td>oxygen by mask or nasal prongs</td>
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<tr>
<td>5</td>
<td>severe</td>
<td>noninvasive ventilation or high-flow oxygen</td>
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<tr>
<td>6</td>
<td>Hospitalised</td>
<td>intubation and mechanical ventilation</td>
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<tr>
<td>7</td>
<td></td>
<td>ventilation and additional organ support --</td>
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<tr>
<td></td>
<td></td>
<td>- vasopressors</td>
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<td>- renal replacement therapy (RRT)</td>
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<tr>
<td></td>
<td></td>
<td>- extracorporeal membrane oxygenation (ECMO)</td>
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</tr>
<tr>
<td>8</td>
<td>Death</td>
<td></td>
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</table>
WHO 9-point scale – graded increase in pulmonary support

- Good health
- Ill health
- Death

- Time after infection
- Time after hospitalisation

0: Good health
1: Time after infection
2: Time after hospitalisation
3: Multigorgan failure I.C.U.
4: Intubation and mechanical ventilation
5: Non-invasive ventilation
6: Oxygen
7: The vast majority of SARS-CoV2 infected patients recover without need for hospital treatment
8: Death

The vast majority of SARS-CoV2 infected patients recover without need for hospital treatment.
Post-hoc exploratory analysis identified subset of patients affected by more severe disease, benefit from bemcentinib

PATIENT Subset: (Grade 4 & 5, CRP>30mg/L)

A. Grades 4 and 5 patients
   Grade 3 patients (not on oxygen)
   • Rarely admitted (not eligible in India)
   • Did not usually progress to require oxygen
   • Shorter stay in hospital (4-5 days)

B. C-reactive protein
   ▪ bemcentinib benefit is greater in patients with higher baseline inflammation
   ▪ CRP is an acute phase blood based biomarker in routine clinical use
   ▪ 30 mg/L threshold identified

VENTILATOR-FREE SURVIVAL (VFS)

GOALS of COVID19 therapy
1. Preventing death
2. Preventing progression to require ventilation
   1. Non-invasive
   2. Intubation and mechanical ventilation

Ventilator Free Survival is an endpoint derived from studies in Acute Respiratory Distress Syndrome
   ▪ Being alive at day 29
   AND
   ▪ not deteriorating to require ventilation

Clinically meaningful endpoint for:
1. Individual Patient health – both acute, and long-term
2. Healthcare system; resource constraints
End Point: Time to deterioration

Deterioration defined as increase from baseline WHO ordinal scale by ≥1 grade (including progression to grade 8 – death)

When evaluating Grade 4 or 5 patients, this endpoint assesses the avoidance of any increased ventilation requirement, this is equivalent to VENTILATOR-FREE SURVIVAL, over 29 days after admission to hospital.
Time to deterioration: BGBC020
all patients (115)
Time to deterioration: BGB020
Grades 4, 5 with CRP>30mg/L (62 Patients)

Ventilator Free Survival

- Defined as the proportion of patients that survived to day 29 day without admission to ICU and the need for ventilator assisted breathing
- A sub-group of patients treated with bemcentinib appeared to be protected from an early deterioration, at day 2 or 3, compared to patients on SOC
- This effect was maintained through 29 days
- In sub-group of patients, ventilator free survival was higher (90%) with bemcentinib treatment compared to SOC only (72%)

For patients who are on oxygen at baseline (grade 4 and 5), this is the proportion who avoid needing any form of ventilation and survive to day 29.
Primary endpoint – time to improvement (WHO 2-point) or discharge

This endpoint, is subject to a broad range of subjective factors, including variation in clinician practice, local epidemic case rates, ensuing demand for bed occupancy in hospital, and resource availability.

Therefore this endpoint may not directly measure the individual patient’s health, or the benefit from bemcentinib.
Primary endpoint – time to improvement

Time to improvement, earliest of either:
1. Time to discharge
2. Time to 2-point improvement on WHO scale from baseline score
3. Time to “fit for discharge”
Primary endpoint: time to improvement or discharge
BGBC020
all patients
Primary endpoint: time to improvement or discharge
BGBC020
Grades 4, 5 with CRP>30mg/L

- The primary endpoint (time to improvement by two WHO grades, from baseline, or time to discharge marginally favoured bemcentinib treatment over SoC

- Difference was not statistically significant
End Point: Survival

Time to mortality event
Survival
**BGBC020 + ACCORD2**
Grades 4,5 with CRP ≥ 30mg/L

- Mortality rates in ACCORD2 SOC treated patients were higher than those in BGBC020 at day 29; (5 of 32 patients (16%) in ACCORD2, versus 3 of 57 (5%) in BGBC020.

- Overall in the combined studies, survival to day 29 was 96.5% (83 of 86 evaluable patients) in bemcentinib arm versus 91.0% (81 of 89) treated with SoC alone.
Summary statements

• Ventilator Free Survival observed to be 90% in bemcentinib treated patients vs 72% in SOC treated patients, in a sub-group of patients with increased disease severity

• Sub-group of patients with increased disease severity (grade 4 & 5) and a blood biomarker for inflammation (CRP>30mg/ml), represented more than 50% of hospitalised patients on the study

• Primary endpoint, although favourable for bemcentinib, did not reach statistical significance

• Survival benefit was numerically greater in the bemcentinib treated patients

• Bemcentinib was well tolerated throughout both studies
Conclusion and Next Steps

- Full scientific analysis of BGBC020 will be combined with the ACCORD2 dataset in a meta-analysis for presentation at a scientific conference and publication in a peer-reviewed journal.

- The totality of data clearly informs a benefit from bemcentinib in treating a substantial subset of hospitalised COVID-19 patients

- Post-hoc data analysis suggests that bemcentinib treatment results in few patients progressing to ICU, the avoidance of ventilator assisted breathing and increased survival

- This data will support ongoing engagement with regulatory agencies, Governments and industry partners.
Questions