Subanalysis from Phase 1 Study of Briquilimab (JSP191), an Anti-CD117 Monoclonal Antibody, in Combination with Low Dose Irradiation and Fludarabine Conditioning, Shows Durable Remissions in Older Adults with Acute Myeloid Leukemia in Complete Remission Undergoing Allogeneic Hematopoietic Cell Transplantation (NCT#04429191)

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Briquilimab (JSP191) is an investigational agent and not approved for any indication.
Conflict of Interest

Muffly - Advisory Boards: Pfizer, Amgen, Jazz, Medexus, CTI Biopharma, Kite; Research Funding: Astellas, Jasper, Adaptive, Kite, BMS; Consulting: Astellas

Lee - Advisory Boards: Kadmon, Kite, Jazz; Research Funding: Incyte; Consulting: Fresenius

Scott - Advisory Boards: BMS, Alexion, Incyte, Taiho

Kwon, Yanagiba, Arulprakasam, Le, Pang - Employment: Jasper

Shizuru – Board of Directors: Jasper

Artz – Consulting: Magenta, Abbvie
Number of Allogeneic HCTs for AML by Recipient Age in the US
Briquilimab Designed to Block CD117 Signaling
Leading to Hematopoietic Stem Cell (HSC) Depletion without Significant Off-Target Toxicities

Briquilimab Blocks SCF Binding to CD117
Empty Bone Marrow Niche
Donor HSC Home to Marrow Niche

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Blockade of CD117 is Synergistic with Low Dose Radiation Leading to Purified Donor HSC Engraftment in Immunocompetent Mouse Model

Donor HSC Engraftment

Radiation only

Anti-CD117 +
Low Dose Radiation

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Chhabra et al. Sci Transl Med 2016; Pang et al. ASH 2019
Study Design

Single-arm, Open Label, in MDS/AML Patients Not Eligible for Myeloablative Conditioning Regimens

Key inclusion criteria:
- MDS or AML
- ≥60 years or HCT-CI ≥3
- HLA matched related or unrelated donor
- Exclude prior HCT

N = 24-40 patients

Experimental arm:
- Briquilimab 0.6 mg/kg
- Flu 30 mg/m² x 3 days
- TBI 200-300 cGy
- HCT

Assessments:

Primary endpoints:
- Safety and tolerability of Briquilimab/TBI/Flu
- Briquilimab PK

Secondary endpoints (follow up to 1 yr):
- Engraftment and donor chimerism
- Relapse-free survival
- GVHD, Non-relapse mortality, and Overall Survival
- MRD clearance

Exploratory endpoints:
- Depletion of HSPCs by briquilimab

**Briquilimab (ISP191) is an investigational agent and not approved for any indication.**
Treatment Schema

Conditioning Regimen

- Real-time PK measurements of briquilimab and modeling were used to determine Flu start date.
- TBI increased from 200 to 300 cGy after first 7 subjects (3 AML from CR) to aid lymphoablation.
- GVHD prophylaxis: tacrolimus, sirolimus, mycophenolate mofetil (Sandmaier et al, Lancet Haematology 2019)

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## Subanalysis of 12 AML Patients with 1-Year Follow-up

### Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients with AML (N=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (range) - year</td>
<td>70 (62-79)</td>
</tr>
<tr>
<td>Sex – no. (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (75%)</td>
</tr>
<tr>
<td>Female</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>Prior AML/MDS Therapy – no. (%)</td>
<td></td>
</tr>
<tr>
<td>Untreated or growth factor supportive care only</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Hypomethylating agent-containing regimens only</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>Anthracycline-based regimens (incl. liposomal formulations) only</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Multiple lines of therapy incl. both hypomethylating agent- and anthracycline-based regimens</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>Donor Type – no. (%)</td>
<td></td>
</tr>
<tr>
<td>Matched related donor</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Matched unrelated donor</td>
<td>11 (92%)</td>
</tr>
<tr>
<td>TBI dose – no. (%)</td>
<td></td>
</tr>
<tr>
<td>200 cGy</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>300 cGy</td>
<td>9 (75%)</td>
</tr>
</tbody>
</table>

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Briquilimab (JSP191) is an investigational agent and not approved for any indication.
Safety and Tolerability

• No significant briquelimab infusion reactions
• No briquelimab-related SAEs
• No primary graft failure

Briquelimab (JSP191) is an investigational agent and not approved for any indication.
Briquilimab Pharmacodynamics: Evaluation of Briquilimab to Deplete HSPCs in Marrow of AML Patients

Marrow aspirates collected at screening and prior to administration of Flu/TBI

Mean HSPC depletion of 67.3 ± 25.9%
(values do not necessarily reflect the nadir of HSPC depletion)

Briquilimab (JSP191) is an investigational agent and not approved for any indication.
Briquilimab/Flu/TBI Conditioning in All Patients Dosed to Date Resulted in Neutropenia Followed by Neutrophil Engraftment

Median time to neutrophil engraftment: 19 days (range: 13-24 days)

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Donor Chimerism in AML Patients

N = 12, complete 1 year follow-up

Briquilimab (JSP191) is an investigational agent and not approved for any indication.
GVHD in AML patients
N = 12, complete 1 year follow-up

Briquilimab (JSP191) is an investigational agent and not approved for any indication.

### Patients with AML (N=12)

#### Acute GVHD (per MAGIC)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Count</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Grade 2-4</td>
<td>3</td>
<td>25%</td>
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<tr>
<td>Grade 2</td>
<td>2</td>
<td>17%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>1</td>
<td>8%</td>
</tr>
<tr>
<td>Grade 4</td>
<td>0</td>
<td>0%</td>
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</table>

#### Chronic GVHD (per NIH Consensus)

<table>
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<tr>
<th>Severity</th>
<th>Count</th>
<th>Percentage</th>
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</thead>
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<td>Mild</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Moderate</td>
<td>4</td>
<td>33%</td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

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Cumulative Incidence of GVHD

- Blue line: Grade 2-4 aGVHD
- Red line: Moderate-Severe cGVHD

Days Post-HCT

Cumulative Incidence of GVHD

- Grade 2-4 aGVHD
- Moderate-Severe cGVHD
Multimodality Measurable Residual Disease (MRD) in AML patients

Cytogenetics, Flow Cytometry, Next Generation Sequencing

<table>
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<tr>
<th>SCRN</th>
<th>TD28</th>
<th>TD56</th>
<th>TD90</th>
<th>TD180</th>
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<tbody>
<tr>
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<td>MRD+</td>
<td>NEG</td>
<td>NEG</td>
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<tr>
<td>MRD+</td>
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<tr>
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<td>NEG</td>
<td>QNS</td>
<td>Relapse</td>
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<tr>
<td>NEG</td>
<td>NEG</td>
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</tbody>
</table>

- MRD clearance in 6 of 9 (67%) at last follow-up
- Median time to MRD negativity: 90 days post-HCT
- 8 of 12 (67%) alive and MRD negative @ 1 yr post-HCT

MRD+ By NGS only
MRD+ By Flow only
MRD+ By Flow and NGS
NEG MRD negative by all assays

* MRD+ for DNMT3A only

= completed study
= off study

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QNS = quantity not sufficient
Outcomes in AML patients

N = 12, complete 1 year follow-up

<table>
<thead>
<tr>
<th>Alive without AML @ 1 yr</th>
<th>8 (67%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive and AML MRD negative @ 1 yr</td>
<td>8 (67%)</td>
</tr>
<tr>
<td>Alive without AML and off immunosuppression @ 1 yr</td>
<td>6 (50%)</td>
</tr>
</tbody>
</table>

Overall Survival

Relapse-Free Survival

Briquilmab (JSP191) is an investigational agent and not approved for any indication.
Summary: Subanalysis of AML Patients (N=12) Enrolled in Phase I Trial with Full 1 Year Follow-up

- 0.6 mg/kg briquilmab demonstrated predictable clearance, allowing safe and effective donor cell infusion 9-14 days after briquilmab
- RFS 67%, OS 75%, NRM 8% @ 1 yr post-HCT, with low rates of GVHD
- 67% alive without evidence of AML MRD @ 1 yr post-HCT
- MRD clearance observed in 6 of 9 patients at last available follow-up, with median time to MRD negativity of 90 days post-HCT
- Briquilmab/Flu/TBI is a novel conditioning regimen that appears safe, well-tolerated, has on target effects on HSPC depletion, permits full donor myeloid chimerism, and results in promising MRD clearance in older AML in CR patients

Briquilmab (JSP191) is an investigational agent and not approved for any indication.
Acknowledgements

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We would also like to thank the participating clinical sites, clinical staff, and collaborators.

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