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## Memorandum

**DATE:** July 6, 2023

**TO:** Matthew Klinker, PhD, Chair  
Upendra Mahat, MD, Clinical Reviewer  
Adriane Fisher, MPH, MBA, RPM

**FROM:** Peter Lenahan, DC, PhD, MPH, Senior Regulatory Reviewer  
Bioresearch Monitoring Branch (BMB)  
Division of Inspections and Surveillance (DIS)  
Office of Compliance and Biologics Quality (OCBQ)

**THROUGH:** Dennis T. Cato, Chief BMB

**THROUGH:** Carrie M. Mampilly, MPH, Director DIS

**SUBJECT:** Bioresearch Monitoring Final Review Memo  
BLA: STN 125706/0  
PRODUCT: Remestemcel-L, Allogeneic Mesenchymal Stem Cells,  
Cultured ex vivo, (b) (4)  
Allogenic Bone Marrow  
SPONSOR: Mesoblast, Inc.

Four Bioresearch Monitoring (BIMO) Clinical Investigator (CI) inspections were performed between June 2020 and August 2020 of the pivotal studies, MSB-GVHD-001 and MSB-GVHD-002 at clinical sites: 301; 302; 304; and 323. In view of this previous inspectional history, the review committee decided that additional BIMO inspections are not warranted for this resubmission.

Should you have any questions or comments about the contents of this memo or any aspect of bioresearch monitoring, please contact me at (973) 331-4947.

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Peter Lenahan, DC, PhD, MPH  
Regulatory Officer

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CBER BIMO Notification