The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2023 – 5316
Date:	November 29, 2023
Product Name:	Darzalex
Therapeutic Area:	Oncology
Product Class:	Targeted Monoclonal Antibody
Condition(s) Studied:	Multiple Myeloma
Protocol Number(s) and Title(s):	**NCT02195479** - A Phase 3, Randomized, Controlled, Open-label Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Subjects With Previously Untreated Multiple Myeloma Who Are Ineligible for High-dose Therapy **NCT02252172** - A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects With Previously Untreated Multiple Myeloma Who Are Ineligible for High Dose Therapy **NCT03412565** - A Multicenter Phase 2 Study to Evaluate Subcutaneous Daratumumab in Combination With Standard Multiple Myeloma Treatment Regimens

Part 2: Data Availability	
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments:	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments:	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes
Comments:	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments:	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments:	

Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes

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Part 4: Proposal Review		
Question:		**Response:**
Summary-level CSR data is appropriate for the proposed analysis.		Yes
Participant-level data is appropriate for the proposed analysis.		Yes
A similar analysis is underway or completed/pending disclosure by Janssen.		Yes
Comments:	A manuscript of the analyzed data that incorporate the 1q21 Gain/Amp FISH is underway. Janssen gave a presentation on some of these data at ASH2022: "Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) in Transplant-ineligible Patients (Pts) With Newly Diagnosed Multiple Myeloma (NDMM): Clinical Assessment of Key Subgroups of the Phase 3 MAIA Study."	