The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2022-5066
Date:	2 December 2022
Product Name:	Ibrutinib
Therapeutic Area:	Oncology
Product Class:	Kinase Inhibitors
Condition(s) Studied:	Waldenström's Macroglobulinemia / Lymphocytic Leukemia / Mantle Cell Lymphoma
Protocol Number(s) and Title(s):	**NCT01722487 - PCYC-1115-CA** - Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor Ibrutinib Versus Chlorambucil in Patients 65 Years or Older With Treatment-naive Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma **NCT01236391 - PCYC-1104-CA** - Multicenter Phase 2 Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Relapsed or Refractory Mantle Cell Lymphoma **NCT01105247 - PCYC-1102-CA** - A Phase 1b/2 Fixed-dose Study of Bruton's Tyrosine Kinase (Btk) Inhibitor, PCI-32765, in Chronic Lymphocytic Leukemia **NCT01578707 - PCYC-1112-CA** - A Randomized, Multicenter, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor Ibrutinib (PCI-32765) Versus Ofatumumab in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma **NCT01611090 - PCI-32765CLL3001** - Randomized, Double-blind, Placebo-controlled Phase 3 Study of Ibrutinib, a Bruton's Tyrosine Kinase (BTK) Inhibitor, in Combination With Bendamustine and Rituximab (BR) in Subjects With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma **NCT02165397 - PCYC-1127-CA** - iNNOVATE Study: A Randomized, Double-Blind, Placebo- Controlled, Phase 3 Study of Ibrutinib or Placebo in Combination With Rituximab in Subjects With Waldenström's Macroglobulinemia **NCT02264574 - PCYC-1130-CA** - A Randomized, Multi-center, Open-label, Phase 3 Study of the Bruton's Tyrosine Kinase Inhibitor Ibrutinib in Combination With Obinutuzumab Versus Chlorambucil in Combination With Obinutuzumab in Subjects With Treatment-naïve Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

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:		

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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
Part 4: Proposal Review	
Question:	**Response:**
Summary-level CSR data is appropriate for the proposed analysis.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	