Protocol PERSPECTIVE (PCYC-1141)
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of the Bruton’s Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination With Rituximab Versus Placebo in Combination With Rituximab in Treatment-Naïve Subjects With Follicular Lymphoma

Study Schema (N=440)
Phase 3 Study conducted in 2 parts

Part 1

| Randomize (N=440) | 3:1 |

ARM A
Ibrutinib (560 mg PO QD continuously) + rituximab weekly x 4 with maintenance

ARM B
Placebo PO QD continuously + rituximab weekly x 4 with maintenance

Part 2

| Randomize 1:1 |

ARM A1
Ibrutinib (560 mg PO QD)

ARM A2
Placebo PO QD

Placebo PO QD

For additional information on this trial, please visit www.clinicaltrials.gov (NCT02947347). The safety and efficacy of the investigational use of this product has not been determined. There is no guarantee that the investigational uses listed will be filed and/or approved for marketing by any regulatory agency.
Disease: **Follicular Lymphoma**
Profile: **Treatment Naïve**
Phase 3 | Recruiting

**Key Eligibility Criteria** (not a complete list of inclusion and exclusion criteria)

**Inclusion Criteria**
- ≥70 years of age OR 60-69 years of age with one or more comorbidities
- Eastern Cooperative Oncology Group (ECOG) performance status score 0-2
- Adequate hematologic, hepatic, and renal function
- Histologically confirmed diagnosis of follicular lymphoma CD20+ (Grade 1, 2, or 3a) Ann Arbor Stage II, III, or IV disease
- Meets one or more Groupe d’Etude des Lymphomes Folliculaires (GELF) criteria

**Exclusion Criteria**
- Transformed lymphoma
- Prior treatment for follicular lymphoma
- CNS lymphoma or leptomeningeal disease
- Currently active, clinically significant cardiovascular disease

**Objectives**

**PRIMARY OUTCOME MEASURE**
- Progression-free survival