U.S. Postmarketing Commitments Table*

Name of Product	NDA Number	Description of Commitment	Date Commitment Given	FDA Projected Completion Date	Commitment Status
IMBRUVICA®	NDA 205552 and NDA210563	Complete and submit the final results of the ongoing randomized, double-blind, placebo-controlled Phase 3 clinical trial (PCI-32765MCL3002) of ibrutinib in combination with bendamustine and rituximab in patients with newly diagnosed mantle cell lymphoma. Enrollment of approximately 520 patients is expected. The primary endpoint is progression-free survival as assessed by investigators. Overall survival is a key secondary endpoint.	13 November 2013	Final Report Submission: 03/2019 Updated Target Date: 12/2021	Released
IMBRUVICA®	NDA 205552 and NDA210563	Submit the complete final report and data from a randomized, Phase 3 trial, comparing ibrutinib in combination with bendamustine and rituximab or rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone versus bendamustine and rituximab or rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone in subjects with previously treated follicular lymphoma or marginal zone lymphoma. At least 50 enrolled subjects need to have a diagnosis of marginal zone lymphoma. The primary endpoint is progression-free survival in the overall intent-to-treat population.	18 January 2017	Final Report Submission: 08/2019 Updated Target Date: 02/2023	Released
IMBRUVICA®	NDA 205552 and NDA 210563	Submit the overall survival analysis and datasets with the final report for clinical trial E1912 titled, "A Randomized Phase III Study of Ibrutinib-Based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia" to provide additional long term efficacy data.	21 April 2020	Final Report Submission: 09/2027	Ongoing

IMBRUVICA®	NDA 205552, NDA210563 and NDA 217003	Conduct analyses to characterize long-term safety of ibrutinib in terms of growth and development in pediatric patients. Patients enrolled in Study PCYC-1146-IM should be evaluated for growth and development milestones annually for at least 5 years from the initiation of ibrutinib. Data should include growth parameters as measured by height and weight, sexual maturation by Tanner stage, performance status, immune reconstitution, adverse events, and patient-reported outcomes measures.	24 August 2022	Final Report Submission: 07/2026	Ongoing

*Chemistry Manufacturing and Controls (CMC) commitments are not included