Bayer announces decision to withdraw Aliqopa® (copanlisib)

- On November 13, 2023 Bayer announced that following discussions with the FDA, it will withdraw the Aliqopa (copanlisib) New Drug Application for adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. A confirmatory clinical trial did not meet the primary endpoint of progression-free survival (PFS) benefit vs. standard immunotherapy.

- Aliqopa was granted accelerated approval by the FDA in September 2017 based on CHRONOS-1, an open-label, single-arm Phase II study. The FDA required clinical benefit to be confirmed through the CHRONOS-4 study.

- In CHRONOS-4, the addition of Aliqopa to standard immunochemotherapy regimens did not meet the primary endpoint of PFS benefit vs. the standard immunochemotherapy control arm in patients with relapsed FL. Bayer intends to publish the results of CHRONOS-4 in a timely manner.

- Bayer is exploring access options for patients currently receiving Aliqopa who have experienced a favorable response to treatment, whose treating physician supports continuing treatment with Aliqopa, and for whom there may be no suitable alternative treatments available.

- Patients currently being treated with Aliqopa should consult their healthcare provider. No new patients should be prescribed Aliqopa. For questions related to ongoing access, contact Bayer Medical Communications at **1-888-842-2937**.