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Product: ADI-PEG 20

Protocol number: POLARIS2013-001

Eudract Number: 2017-004112-19

Phase 1-2 Study of ADI-PEG 20 plus FOLFOX in Subjects with Advanced Gastrointestinal Malignancies Focusing on Hepatocellular Carcinoma

Notification of closure for this study was submitted to UK and Italy regulatory authorities; Although individual patients have been reported to have benefit on the study and the current rate response was in line with the recently approved 2nd line new drugs, to continue the study to achieve regulatory approval will require too many resources and entail too great uncertainty in the final outcome. Results for the phase 2 of this study have been published on ACS Journals. <https://acsjournals.onlinelibrary.wiley.com/doi/abs/10.1002/cncr.33870>. No clinical study report is currently available.

Sincerely yours,

John S. Bomalaski, M.D
Executive Vice-President, Medical Affairs