

08 Aug 2022

Title A phase II study investigating preoperative bintrafusp alfa in operable urothelial carcinoma of the bladder [PEBBLE]
EudraCT 2020-004223-16
Sponsor Queen Mary University of London
CI Prof Thomas Powles

On behalf of the Sponsor, we confirm that the study opened to recruitment in July 2021. Following the recruitment of two patients, the IMP manufacturer and study funder met with the Chief Investigator in October 2021 to discuss key data from their clinical trials portfolio involving bintrafusp alfa.

Following on from these discussion, a request to stop recruitment and terminate the study was submitted to ethics committees and competent authorities in November 2021. At the time of termination there were two patients on treatment (UK=1 and Spain=1). These patients went on to have their cystectomy as per standard of care and the 6 week safety visit. Following this both patients came off study, with the last patient last visit taking place on 18 January 2022.

As only two patients were recruited in the study the Sponsor will not proceed with data analysis. No results are therefore available.

On Behalf of the Sponsor,

Marie-Claire Good
Senior GCP Manager