

To
European Medicines Agency
EudraCT team
Domenico Scarlattiiaan 6
HS Amsterdam Zuid 1083 HS
The Netherlands

Athens, June 10th, 2022

Dear Sir/Madam,

On behalf of the Hellenic Cooperative Oncology Group, we are writing to provide an update on the status of the clinical trial HE 9A/14, entitled **“A study of cabazitaxel treatment in castration resistant bone metastatic prostate cancer patients evaluating the tumor microenvironment” - EudraCT: 2014-004485-21** and the delay in publication of the results.

60 patients entered the trial from 29.10.2015 to 05.07.2019.

Last Subject Last Visit was on 27.12.2019.

Since the beginning of Covid-19 pandemic, we have been facing several issues regarding the analysis of the primary study objective which is the exploration of molecular effects of treatment with Cabazitaxel on the tumor microenvironment of patients in correlation with measures of outcome.

Covid-19 restrictions that were imposed in the US, resulted in significant delays in shipment of the biological samples to MD Anderson Cancer Center where the analysis would be performed under the supervision of Dr Efstathiou who is the Coordinating Investigator of this trial. After several months of waiting for the “green light”, Dr Efstathiou ended her collaboration with MD Anderson Cancer Center. This change significantly affects this part of the analysis and although all other parts for the CSR are available, we have not been able to complete the full analysis yet. In order to avoid providing results solely for the clinical outcomes without the analysis of the translational part which is the primary endpoint, we are currently exploring the option of collaborating with another institution for the processing of the biological samples and we are making every effort to complete the study analysis as per protocol

We remain at your disposal for any further information.

Sincerely,



On behalf of the Sponsor,
Prof. Emer. George Fountzilas
Chairman & Managing Director