

**Title of the Clinical Trial:** oterapy and 6-month androgen deprivation therapy with or without apalutamide in Intermediate and Limited High Risk Localized Prostate Cancer: a phase III study

**EORTC protocol number:** 1531-ROG

**Sponsor:** EORTC  
Avenue E. Mounier 83/11  
1200 Brussels  
Belgium

**EudraCT number:** 2018-000899-15  
**Current protocol:** version 2.0, 25 July 2019

**Concerning:** Premature end of trial.

Dear madam/sir,

In accordance with the European Directive on Clinical Trials, the European Organisation for Research and Treatment of Cancer (EORTC), a non-profit organisation under Belgian law, hereby informs you that the above-mentioned clinical trial ended prematurely on 17 July 2020.

Following the regulatory submission in France, the study was rejected twice by the French Ethics Committees (EC), objecting to the open-label design and the lack of stratification according to the radiotherapy schemes. Given the importance of the contribution French sites would have for this study (approximately 30% of the study accrual target), the significant impact on the study timelines and additional budget due to the French EC's decision and the impact the COVID-19 pandemic had on clinical research, Janssen Pharmaceutica, as the pharmaceutical company providing funding and the study drugs, is no longer able to support additional budget for the EORTC 1531-ROG study. Consequently, EORTC and the 1531 Study Coordinators have decided to close the 1531-ROG study.

No patients were recruited in this trial, therefore no results and no analysis will be available. Please note that all participating Investigators / sites have been informed about this premature end of trial by the sponsor.

Yours sincerely,  
EORTC Headquarters

