CHARITÉ

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Prematurely ended -statement

EudraCT number: 2011-004463-69

Full title of the study: Influence of Lucentis on radiation retinopathy after irradiation of choroidal melanoma.

Sponsor-ID: RadiRet

Sponsor: Charité – Universitätsmedizin Berlin

Study Contact: Prof. Dr. med. Antonia Joussen

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Product: Ranibizumab

Date of the early termination of the trial: 02.12.2016

Statement on discontinuation of the study: The recruitment of the trial RadiRet (phase II, two-arm, randomized, parallel-groups) was terminated after the inclusion of the 31st patient, although initially a recruitment of 60 patients to the trial was planned. The reason for early termination was the lacking recruitment of patients to the study at the clinical study site in Essen (Germany). As the study was only conducted at two clinical study sites (the other clinical study site (Berlin) fully fulfilled its recruitment plan, whilst no patient was recruited in Essen), the sponsor decided, after consultation of the responsible statistician, to terminate inclusion early. All patients in the study at the time of recruitment stop were treated and followed-up according to study protocol. As of 06th December 2016, there were no active patients left in the study. The risk-benefit assessment of the investigational medicinal product was not affected by the early termination of the study.

The obtained data from the trial was analyzed as planned. The intention-to-treat analysis included 31 patients who were randomly assigned to ranibizumab (n=15) or laser treatment (n=16). The abstract was presented at the 2019 ARVO Annual Meeting, held in Vancouver, Canada, April 28 - May 2, 2019.

Julia Koester-Schuster

Clinical Trial Coordinator

ARVO Annual Meeting Abstract | July 2019

Influence of ranibizumab on radiation retinopathy after irradiation of choroidal melanoma (RadiRet) – a randomized controlled trial.

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