

NEWSLETTER DECEMBER 2017

Update about URANUS: Study title: Neo-adj<u>U</u>vant ve<u>R</u>sus <u>A</u>djuva<u>N</u>t chemotherapy in <u>U</u>pper Tract Urothelial Carcinoma: A fea<u>S</u>ibility phase II randomized clinical trial (EUDRACT No: 2016-004017-27; NCT No: NCT02969083)

URANUS study is open to recruitment in Norway and The Netherlands

METC and Medical Agency approval for URANUS has been obtained for Norway and for The Netherlands.

Regulatory approval is expected in the beginning of 2018 for the other countries.

We congratulate the national coordinators in Norway, Dr. Beisland from Haukeland University Hospital in Bergen, and in The Netherlands, Dr. Osanto from the Leiden University Medical Centre, as well as Dr. Van der Heijden from Radboud UMC in Nijmegen, and Dr. Goossens from Alrijne Hospital in Leiderdorp.

Sites with full approval will get Site Initiation Visits by telephone. Following Site Initiation, approved sites will be ready to randomise patients online (https://prod.tenalea.net/euog/DM/).

We are looking forward to centres from Austria, Belgium, France, Germany, Italy, Russia, Slovakia, Spain and Switzerland, receiving their local approval and countersigning the Clinical Trial Site Agreements. The study will be open to recruitment of 200 patients.

Message from the EUOG trial unit

Dear URANUS investigators,

We would like to take this opportunity to thank most sincerely the national coordinators and investigators for all their work and dedication to obtain URANUS regulatory approval for each country. We are pleased that the recruitment can now start in two countries and we would like to encourage all national coordinators and principle investigators in each of the other countries to continue their efforts to obtain the study approval.

Wishing you a very happy and prosperous 2018,

On behalf of the URANUS trial principle investigators and co-investigators and the EUOG Trial Office Team,

Cristina Alvarez Gómez de Segura

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