Overview of trials running in the Benelux

(Belg J Hematol 2010;1:66)

A randomized, double blind, placebo controlled study to assess the efficacy and safety of CNTO 328 (anti IL 6 monoclonal antibody) plus best supportive care compared with best supportive care in subjects with multicentric Castleman's disease

interleukin 6 - monoclonal antibody - multicentric Castleman's disease - phase II - siltuximab

Multicentric Castleman's disease (MCD) is a rare disorder characterized by abnormal noncancerous growths in the lymphatic tissues at multiple sites throughout the body and by systemic manifestations such as fever, night sweats, fatigue, anorexia, and wasting. Also known as giant lymph node hyperplasia, MCD can also be misdiagnosed as malignant lymphoma. There is no currently accepted treatment for MCD. Ortho Biotech Oncology Research & Development, a unit of Centocor Research and Development, Inc. is conducting a pivotal, registration study on MCD. The primary objective is to demonstrate that the investigational medicine CNTO 328 plus best supportive care (BSC) is better than Placebo + BSC in patients with symptomatic MCD. The investigational medicine is a chimeric monoclonal antibody that blocks the function of the cytokine IL-6. The Castleman's Study will be conducted in approximately 25 countries worldwide. As this trial may present a unique opportunity for patients with MCD, you may wish to consider referring your patients with this condition.

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First international Inter-Group Study for Classical Hodgkin's Lymphoma in Children and Adolescents. (EuroNet-PHL-C1)

EUDRACT-2006-000995-33, NCT00433459
(Sponsor: University of Halle, Germany)
childhood - Hodgkin's lymphoma - long-term toxicity - phase III

Satisfactory disease control rates of more than 90% can be achieved in pediatric Hodgkin's lymphoma with established therapeutic modalities. The remaining challenges for further treatment optimization are:
• reduction of acute and long-term toxicity of the chemotherapy and radiotherapy employed.
• reduction of the amount of treatment in those children who are currently over-treated.
Building on the experience of the GPOH-HD study group since 1978, a randomized, controlled, open-label, multicentre phase III study is conducted.
Patients with untreated classical Hodgkin's lymphoma under 18 years of age are eligible. Lymphocyte-predominant Hodgkin's lymphoma are excluded.
The main question for further therapy optimization is a strategy for treatment adapted to response. Results of FDG-PET are formally integrated both into staging and response assessment. In all treatment groups, radiotherapy after completion of chemotherapy will be omitted in patients with adequate response (CR or PR with negative PET) after two cycles of OEPA.
In intermediate and advanced stages (TG-2 & TG-3), COPDAC (with dacarbazine) chemotherapy is randomized versus standard COPP (with procarbazine). This study aims to replace procarbazine by dacarbazine in order to reduce the risk of infertility in males and premature menopause for females.
Relapse treatment is standardized for three relapse groups based on time to failure and initial treatment group.

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