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Reproductive issues in rheumatology

OP0200

CHARACTERISTICS AND OUTCOMES OF PROSPECTIVELY REPORTED PREGNANCIES EXPOSED TO CERTOLIZUMAB PEGOL FROM A SAFETY DATABASE

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Background: Anti-tumour necrosis factor medications (anti-TNFs) are effective in controlling chronic inflammatory diseases, but information about their use and safety in pregnancy is limited. Consequently, anti-TNFs are often discontinued early in gestation. Certolizumab pegol (CZP), an Fc-free, PEGylated anti-TNF approved for treatment of rheumatic diseases and/or Crohn's disease, has no active placental transfer.

[a] Includes 10 sets of twins.

Abstract OP0200 – Figure 1 Overview of pregnancy reports

Objectives: This project provides information on pregnancy outcomes in women receiving CZP, especially those with early pregnancy exposure.

Methods: Prospective and retrospective data on maternal CZP exposure, including timing and duration, outcomes, comorbidities, and major malformations were extracted from the UCB Pharma safety database through 6 March 2017. This analysis was limited to prospective reports to avoid bias associated with retrospective submissions. Numbers of live births, miscarriages, elective abortions, stillbirths, and major congenital malformations were ascertained.

Results: From a total of 1541 maternal CZP-exposed pregnancies, 1137 were reported prospectively, of which 528 pregnancies (including 10 twin pregnancies) had 538 known outcomes: 459 live births (85%), 47 miscarriages (9%), 27 elective abortions (5%), and 5 stillbirths (1%) (figure 1). Of the 459 live births, 8 (2%) cases of major congenital malformations were reported (vesicoureteral reflux, club foot, congenital heart disease, cerebral ventricle dilatation, polydactyly, anal fistula, accessory auricle, and hydronephrosis). Of the 528 prospective pregnancies with known outcomes, 436 (83%) were exposed during the 1 st trimester, when most organogenesis occurs; 201 pregnancies were exposed during the entire pregnancy.

Conclusions: This analysis represents the largest published cohort of pregnant women exposed to an anti-TNF for management of chronic inflammatory diseases. Analysis of pregnancy outcomes does not indicate a malformative effect of CZP compared to the EU general population (2%–3%), nor an increased risk of foetal death. These data are reassuring for women of childbearing age considering treatment with CZP; however, the ongoing collection of post-marketing surveillance data, including the ongoing MotherToBaby study from the Organisation of Teratology Information Specialists, will provide further important information.

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Do we still need biopsies to diagnose Sjögren's and autoimmune myositis?

OP0201

CLINICAL OUTCOMES AND RESPONSE TO ANTI-THROMBOTIC TREATMENT AMONG PATIENTS WITH CONCOMITANT LUPUS NEPHRITIS AND THROMBOTIC MICROANGIOPATHY: A MULTICENTER COHORT STUDY

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Background: In addition to glomerular lesions, renal vascular involvement is an important prognostic marker of lupus nephritis (LN). Among patients with various vascular changes, individuals with thrombotic microangiopathy (TMA) present with severe clinical manifestations and have a high mortality.

Objectives: We sought to assess renal outcomes and response to anti-thrombotic treatments in addition to conventional immunosuppression in patients with biopsy proven LN and TMA.

Methods: Clinical and renal histopathological data for 97 patients with biopsy-proven LN and TMA were retrospectively analysed. Antibody profiles, induction and maintenance therapies for LN, and anti-thrombotic treatments were collected. TMA lesions were classified into acute and chronic (table 1). A complete renal response (CR) was defined as proteinuria <0.5 g/24 hour and normal or near-