**LEMTTRA® (Alemtuzumab) Pregnancy Exposure Registry**

**OBJECTIVE**

- To report the study design and enrolment procedures for the International Alemtuzumab Pregnancy Exposure Registry

**INTRODUCTION**

- Alemtuzumab (LEMTTRA®, Genzyme) is a humanised anti-CD52 monoclonal antibody administered as 2 courses, infused on 5 days at initiation of treatment and on 3 days 12 months later, and approved in over 45 countries for the treatment of patients with relapsing-remitting MS (RRMS), resulting in depletion and subsequent repopulation of circulating T and B lymphocytes.
- Patients demonstrated greater improvements on clinical and MRI outcomes with alemtuzumab compared with SC IFNB-1a in phase 2 and 3 studies of patients with active RRMS.
- Alemtuzumab had durable efficacy over 5 years in a confirmatory, open-label extension study.
- The most frequent adverse events (AEs) with alemtuzumab were infusion-associated reactions; other AEs of interest included autoimmune AEs.
- There are no clinical studies of alemtuzumab in pregnant women; however, because MS is frequently diagnosed in women of childbearing age, it is important to assess the effects of disease-modifying therapy on pregnancy.
- There was no evidence of malformations in animals treated with alemtuzumab during gestation.
- Moreover, cognitive, physical, and sexual development were not affected in murine pups exposed to alemtuzumab at higher doses during lactation.
- Although alemtuzumab is low or undetectable in human serum within approximately 30 days after administration, it is recommended that women of childbearing potential are advised to avoid pregnancy for 1 year after their last alemtuzumab treatment course.
- During the phase 2 and 3 alemtuzumab clinical trials, despite a requirement for contraceptive use, a number of pregnancies were reported:
  - There has been no teratogenicity signal in delivered infants.
  - Spontaneous abortion risk was comparable with rates in treatment-naive MS patients and the general population.

**METHODS**

**Registy Design**

- This is a voluntary, international, prospective, noninterventional, observational, post-authorisation safety study conducted in the following countries:
  - Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Mexico, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, and the UK
  - Additional countries may be added
- National coordinators will liaise with healthcare professionals (HCPs) to collect data on alemtuzumab-exposed pregnancies and coordinate and encourage patient enrolment in the registry (Figure 1)
- UK HCPs wishing to submit information related to alemtuzumab-exposed pregnancies should contact the National Coordinating Centre (NCC; Manchester, UK): Neuroresearch.nurse@srft.nhs.uk
- The registry design is depicted in Figure 2

**RESULTS**

- The study is currently open for enrolment and will continue for approximately 4 years
- As of October 2015, 1 patient has enrolled in the study

**REFERENCES**


**ACKNOWLEDGMENTS AND DISCLOSURES**

This poster was reviewed by A. Nair and Sarah Strickland of Genzyme, a Sanofi company. Editorial support for the poster was provided by Susan M. Kuepp, PhD, and Michelle Jacob, PhD. Evidence Scientific Solutions, and was funded by Genzyme.

**ORCID**

Consultant fees (Bayer Schering, Biogen Idec, Merck Serono, Novartis, Roche, Teva Pharmaceuticals, Sanofi) to employees of Genzyme.

**WIL**: SC, YZ, TF, DHM, and WP: Employees of Genzyme.

**LDMTRA** is a registered trade name of Genzyme, a Sanofi company.

Alemtuzumab is approved in many countries around the world for treatment of attacks with relapsing forms of multiple sclerosis (MS). In the EU, it is approved to treat patients with relapsing-remitting MS with an inadequate response defined by disease-related factors. In the US, the US Food and Drug Administration (FDA) has approved alemtuzumab for the treatment of patients with relapsing-remitting MS who have not responded to at least 2 previous therapies.

**Disclaimer**:

For the purposes of this presentation, the FDA’s advisory committee recommendation is considered the definitive recommendation as it is based on a comprehensive review of the clinical data available. This presentation is intended as an educational tool and does not imply that different opinions are wrong. It is important to consider the potential risks and benefits of the treatment of MS. This material may contain information that is outside of the approved labeling in some countries.