Rapid and Robust B cell Depletion in Preliminary Results of Phase 2 Multicenter Study of Ublituximab, a Novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis.

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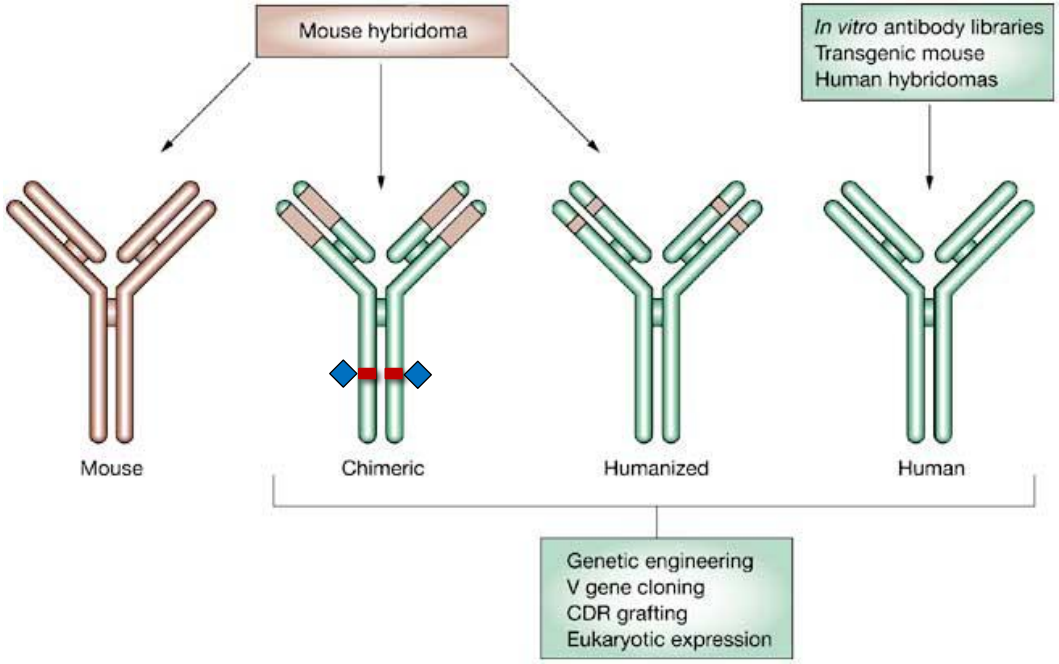
Disclosures

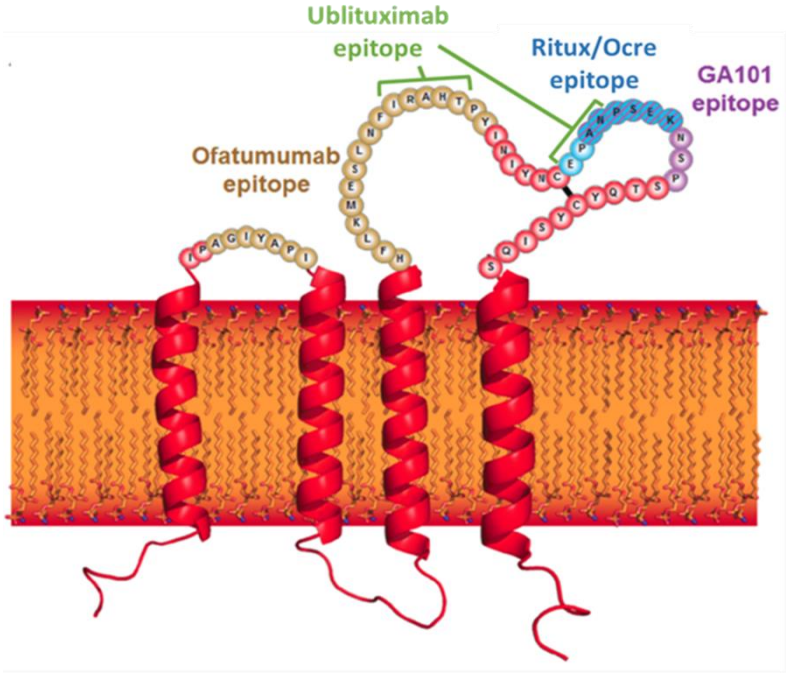
- This clinical trial and immune profile study was funded by TG Therapeutics, New York.

- Dr. Fox has received compensation for research studies, consulting, advisory, and/or speaker's bureau participation with the following: Abbvie, Acorda, Allergan, Bayer, Biogen, Celgene, Chugai, EMD Serono, Genentech Roche, Mallinkrodt, MedDay, Novartis, Sanofi Genzyme, Teva, and TG Therapeutics.

Background

- Ublituximab (TG-1101) is a novel, chimeric monoclonal antibody (mAb) targeting a unique epitope on the CD20 antigen, and glycoengineered to enhance affinity for all variants of FcγRIIIa receptors, thereby demonstrating greater antibody-dependent cellular cytotoxicity (ADCC) activity than rituximab and ofatumumab





CD20 Antibody Epitopes

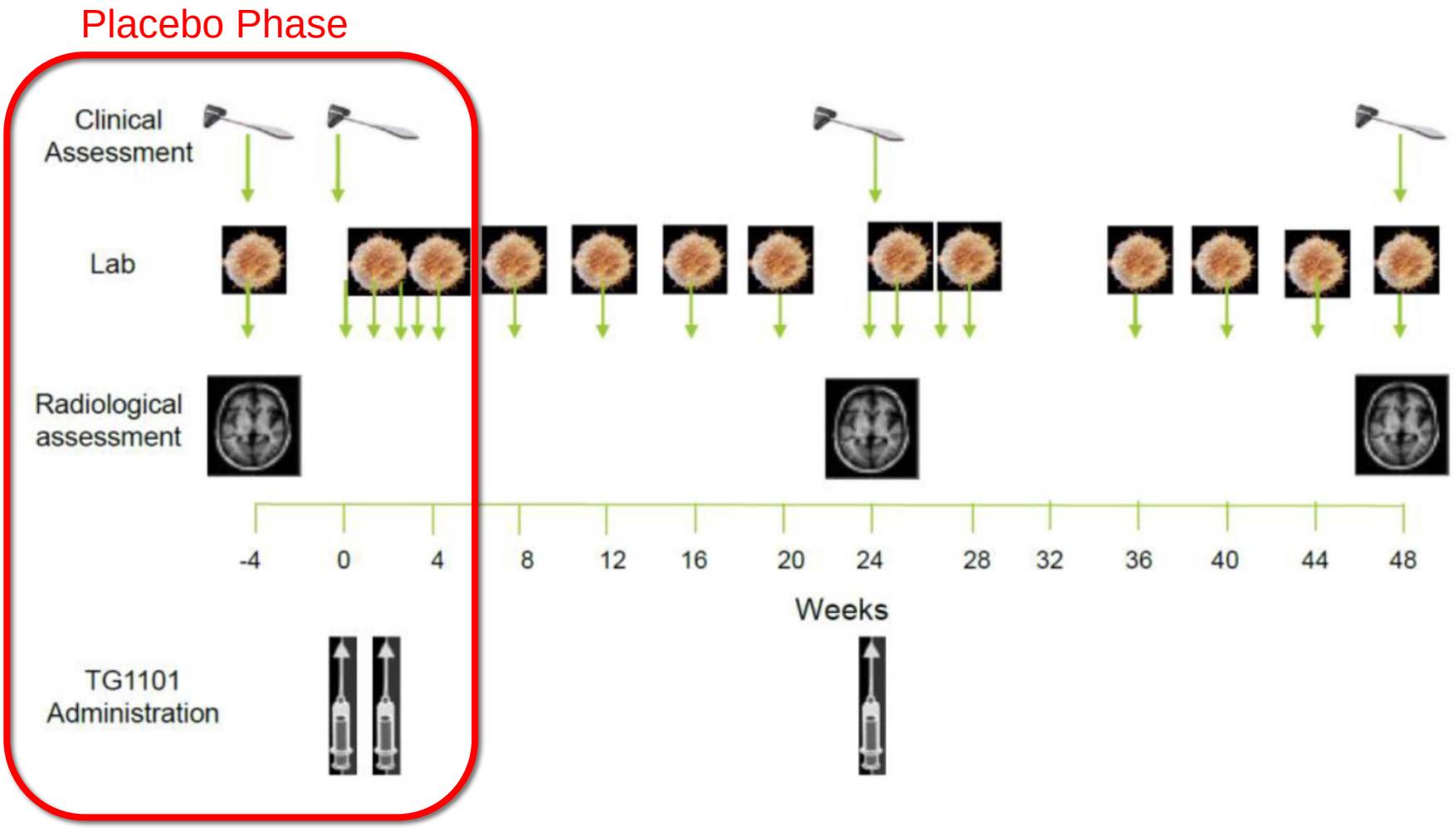
Objective

- TG1101 RMS201 (clinicaltrials.gov NCT02738775) is a randomized, placebo controlled, multi-center study to test the safety and efficacy of ublituximab, at doses markedly less than used in ongoing Phase 3 oncology studies, and at a range of infusion times, with a goal of rapid infusions

- Primary endpoint is the Responders Rate, defined as percent of subjects with ≥95% reduction in peripheral CD19+ B-cells within 2 weeks after the second infusion (day 15)

- The TG1101 RMS201 study in ongoing and will incorporate additional clinical and MRI measures (see Study Design). We report preliminary results of B cell depletion after the second infusion

Study Design

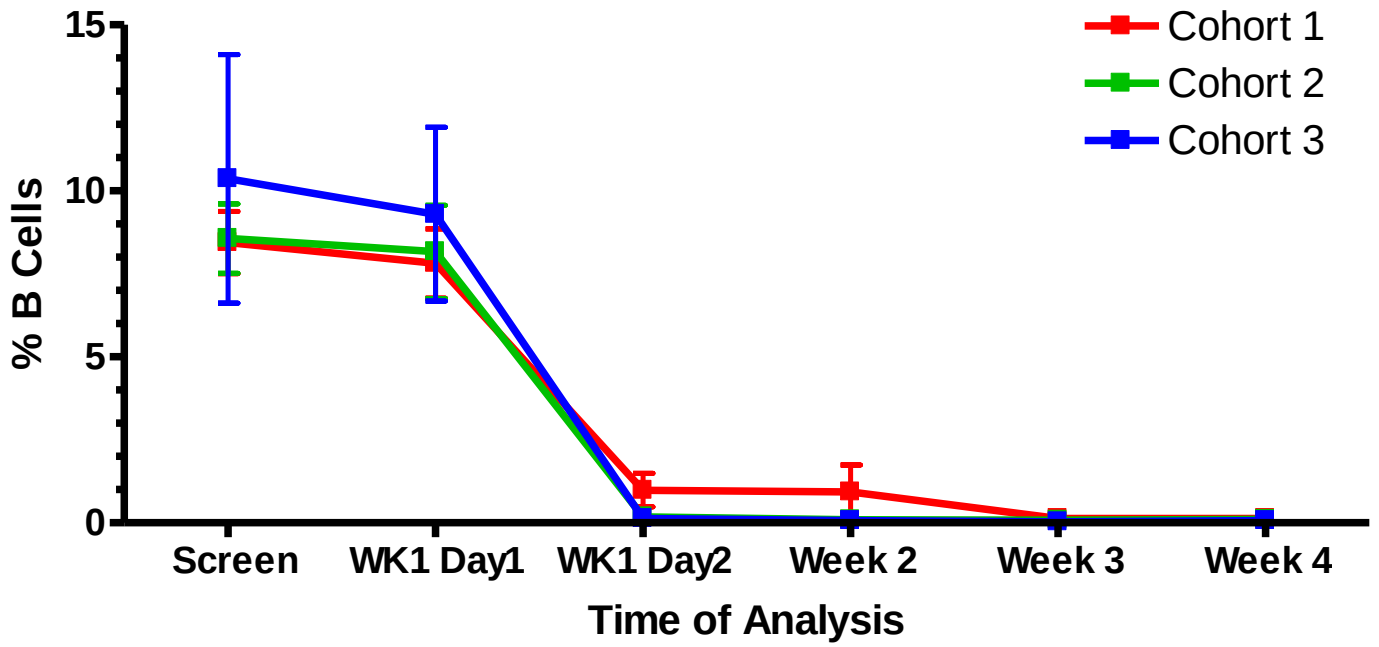


Study Design

Randomization		Treatment Period		
Cohort	**Subjects and treatment**	**Day 1/ infusion time**	**Day 15/ infusion time**	**Week 24/ infusion time**
1	Placebo (n=2)	Placebo / 4h	Placebo / 3h	-
	UTX (n=6)	150 mg / 4h	450 mg / 3h	450 mg / 1.5h
2	Placebo (n=2)	Placebo / 4h	Placebo / 1.5h	-
	UTX (n=6)	150 mg / 4h	450 mg / 1.5h	450 mg / 1h
3	Placebo (n=2)	Placebo / 4h	Placebo / 1h	-
	UTX (n=6)	150 mg / 4h	450 mg / 1h	600 mg / 1h

Three additional cohorts have been added to further reduce infusion times to 1 hr.

B Cell Analysis



*No statistical difference (ANOVA) between cohorts at each time point.
Error bars are mean±SEM.

All patients received the same total dose of 600 mg, only infusion times differed.

Summary

- In patients with relapsing MS, treatment with ublituximab resulted in 99% depletion of B-cells after two infusions
  - This is comparable to previous reports for ocrelizumab[3,4]
- Most commonly reported AEs were infusion related reactions (Grade 1 or 2)
- A decrease in infusion time, as low as one hour for the second infusion, was well tolerated and produced similar levels of B cell depletion
- This one year study of ublituximab in RMS patients is ongoing and clinical and MRI measures will be reported at future congresses

Acknowledgements

Ohio State University, Columbus, OH
Michael K. Racke, MD
Stephanie Scarberry, RN
Yue Liu, MS
Matthew Gormley
Amy Lovett-Racke, PhD

Hope Neurology Multiple Sclerosis Center, Knoxville, TN
Sibyl Wray, MD
Brenda Albertson, CCRP

SC3 Research Group, Pasadena, CA
Richard Shubin, MD
Ngoc Kim Nguyen
Cassie Tran

Associates in Neurology PSC, Lexington, KY
Cary L. Twyman, MD
Laura Sanders, CCRC

Central Texas Neurology Consultants, Round Rock, TX
Edward J. Fox, MD
Lori Mayer, DNP
Koni Lopez

TG Therapeutics, New York, NY
Wendy Su, PhD
James Eubanks, PhD