

Therapeutic Effects of Batoclimab in Chinese Patients with Generalized Myasthenia Gravis: A Double-Blinded, Randomized, Placebo-Controlled Phase II Study

Authors: Chong Yan^{1,9*}; Rui-Sheng Duan^{2*}; Huan Yang^{3*}; Haifeng Li⁴; Zhangyu Zou⁵; Hua Zhang⁶; Hongyu Zhou⁷; Xiao-Li Li²; Hao Zhou³; Lidong Jiao⁴; Jialin Chen⁵; Jian Yin⁶; Qin Du⁷; Michael Lee⁸; Yu Chen⁸; Xiaoxiang Chen⁸; Chongbo Zhao^{1,9};

1. Huashan Rare Disease Center, Department of Neurology, Huashan Hospital, Fudan University, Shanghai, China;

2. Department of Neurology, The First Affiliated Hospital of Shandong First Medical University & Shandong Provincial Qianfoshan Hospital, Jinan, China;

3. Department of Neurology, Xiangya Hospital, Central South University, Changsha, China;

4. Department of Neurology, Xuanwu Hospital, Capital Medical University, Beijing, China;

5. Department of Neurology, Fujian Medical University Union Hospital, Fuzhou, China;

6. Department of Neurology, Beijing Hospital, Beijing, China;

7. Department of Neurology, West China Hospital, Sichuan University, Chengdu, China;

8. Harbour BioMed, Shanghai, China;

9. National Center for Neurological Disorders, Shanghai, China.

* These authors contribute equally to the present studies.

Correspondence: Chongbo Zhao, Department of Neurology, Huashan Hospital, Fudan University, Shanghai, China

E-mail: zhao_chongbo@fudan.edu.cn

Supplemental Materials

Supplemental Table 1 The dose of corticosteroids at baseline

Dose of corticosteroids at base line (Prednisone or equivalent)	Batoclimab 680 mg (N=11)	Batoclimab 340 mg (N=10)	Placebo (N=9)
0 - ≤10 mg	2	2	2
10 - ≤20 mg	4	1	1
20 - ≤40 mg	2	3	4
40 - ≤60 mg	3	0	0
Total	11	6	9

Supplemental Table 2 The dose of immunosuppressants at baseline

Immunosuppressants	Dose	Batoclimab 680 mg (N=11)	Batoclimab 340 mg (N=10)	Placebo (N=9)
Azathioprine	12.5 mg	0	0	1
	50 mg	1	0	0
	100 mg	0	1	0
	150 mg	0	1	0
Tacrolimus	1 mg	0	0	1
	2 mg	0	2	0
	3 mg	5	3	0
	4 mg	2	1	0
	6 mg	0	0	1
Total		8	8	3

Supplemental Table 3 Thymectomy information at baseline

Groups	Subject number	Thymectomy	ICF signature	Interval
Batoclimab	XXX	2011-03-09	2020-11-19	>9 yrs.
680mg	XXX	2012-10	2021-02-24	>8 yrs.
	XXX	2014-01-24	2021-01-06	7 yrs.
Batoclimab	XXX	2018-11-14	2020-08-13	1 yrs.&9 months
340mg	XXX	2012-10	2021-03-24	>8 yrs.
	XXX	2000-08	2021-03-16	>20 yrs.
Placebo	XXX	2016-06	2021-03-05	>4 yrs.
	XXX	2004	2021-03-17	>16 yrs.

Supplemental Table 4 Ethics committee information

Study Site	Ethics Committee	Approval Number
Huashan Hospital, Fudan University	Institutional Ethics Committee for Drugs Clinical Trials of Huashan Hospital, Fudan University	2020-074
The First Affiliated Hospital of Shandong First Medical University	Institutional Ethics Committee for Drugs Clinical Trials of The First Affiliated Hospital of Shandong First Medical University	2020-10
Xiangya Hospital, Central South University	Institutional Ethics Committee of Xiangya Hospital, Central South University	202009223
Xuanwu Hospital, Capital Medical University	Institutional Ethics Committee for Drugs Clinical Trials of Xuanwu Hospital, Capital Medical University	2020-018
Fujian Medical University Union Hospital	Institutional Ethics Committee for Drugs Clinical Trials of Fujian Medical University Union Hospital	2020YW054-01
Beijing Hospital	Institutional Ethics Committee of Beijing Hospital	2020BJYYEC-212-01
West China Hospital, Sichuan University	Institutional Ethics Committee for Drugs Clinical Trials of West China Hospital, Sichuan University	2020-156

Supplemental figure legends

Supplemental Figure 1 Changes of IgM levels

Serum total IgM levels after batoclimab and placebo treatment over the whole study period. Values are mean±standard error, expressed as the concentrations change from baseline.

