

A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of OBI-858 for the Treatment of Moderate to Severe Glabellar Lines

Yu-Hsiu Yen¹ · Tzu-Wen Tsau² · Chih-Hung Lee³ · Hsin-Han Chen⁴ · Chih-Hung Lin⁵ ·
Tim-Mo Chen⁶ · Chi-Ming Pu^{7*}

¹Division of Plastic Surgery, Department of Surgery, Cathay General Hospital, Taipei City, Taiwan.

²Department of Development Team, OBIGEN Pharma, Taipei 115, Taiwan.

³Department of Dermatology, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine, Kaohsiung 833, Taiwan.

⁴Department of Plastic and Reconstructive Surgery, China Medical University Hospital, China Medical University, Taichung, Taiwan.

⁵Department of Plastic and Reconstructive Surgery, Taoyuan Chang Gung Memorial Hospital and Chang Gung University, Taoyuan, Taiwan.

⁶Department of Surgery and Division of Plastic and Reconstructive Surgery, Tri-Service General Hospital, National Defense Medical Center; No.325, Sec.2, Chenggong Rd., Neihu District, Taipei City 114202, Taiwan.

⁷Division of Plastic Surgery, Department of Surgery, Cathay General Hospital, Taipei City, 10630 Taiwan.

School of Medicine, College of Life Science and Medicine, National Tsing Hua University, Hsinchu City, Taiwan.

*Corresponding author

Email: pkman9335@msn.com

Supplementary

Table S1. Participating Institutions, Ethics Committees, and IRB Approval Numbers

Institution / Study Site		Name of Ethics Committee / IRB	IRB Approval/Reference Number*
Chang Gung Memorial Hospital (Master ethics committee)	Linkou	Chang Gung Memorial Hospital Institutional Review Board	202400831A0
	Kaohsiung	Chang Gung Memorial Hospital Institutional Review Board	
Cathay General Hospital		Cathay General Hospital Institutional Review Board	CGH-CS113009
China Medical University Hospital		China Medical University Hospital Research Ethics Comm.	CMUH113-REC1-118
Tri-Service General Hospital		Tri-Service General Hospital Review Board	C202401020

* The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (1964, as revised in 2013).

Table S2. Glabellar Lines Severity Scale at Maximum Frown for Subjects' Assessments

Grade	Severity	Description
0	No wrinkles	Smooth skin
1	Mild wrinkles	Fairly smooth skin
2	Moderate wrinkles	Glabellar lines
3	Severe wrinkles	Deep glabellar lines

Source: Baumann L, Brandt FS, et al., 2009