

Safety and Effectiveness of Glargine 300 U/mL After Switch from Basal Insulins in Patients with Type 1 Diabetes: COMET-T Study

Short Title: Glargine U300 Safety in Patients with Type 1 Diabetes

Stefan Gölz, M.D.¹, Julia K. Mader, M.D.^{2*}, Stefan Bilz, M.D.³, Julia Kenzler, Ph.D.⁴, Thomas Danne, M.D.⁵

Author Affiliations

¹ Amedes MVZ für Diabetologie Esslingen, Esslingen, Germany; E-Mail: goelz@diabetes-esslingen.de

² Division of Endocrinology and Diabetology, Medical University of Graz, Graz, Austria; E-Mail: julia.mader@medunigraz.at

³ Klinik für Endokrinologie, Diabetologie, Osteologie und Stoffwechselerkrankungen, Kantonsspital St. Gallen, St. Gallen, Switzerland; E-Mail: stefan.bilz@kssg.ch

⁴ Established Products General Medicines MCO GSA, Sanofi-Aventis Deutschland GmbH, Berlin, Germany; E-Mail: julia.kenzler@sanofi.com

⁵ Abteilung für Diabetologie, Endokrinologie, Gastroenterologie und Klinische Forschung, Kinder- und Jugendkrankenhaus Auf der Bult, Hannover, Germany; E-Mail: danne@hka.de

*Corresponding author

Prof. Julia K. Mader, M.D.

Division of Endocrinology and Diabetology

Medical University of Graz

Auenbruggerplatz 15, 8036 Graz, Austria;

Email: julia.mader@medunigraz.at

[ORCID ID: 0000-0001-7854-4233](https://orcid.org/0000-0001-7854-4233)

SUPPLEMENTARY MATERIAL

Supplementary Table 1: Details of Ethical Approvals from Centres

Name of institutional review board/Ethics committee	Ethical approval number/Date
Landesärztekammer Baden-Württemberg, Liebknechtstr.	ID: F-2020-106 Approval date: 18.09.2020
33Ethikkommission Ostschweiz (EKOS), Scheibenackerstr. 4, CH-9000 St. Gallen	BASEC-Nr. 2020-01997 Approval date: 26.10.2020
Medizinische Universität Graz Ethikkommission, Auenbruggerplatz 2; A-8036 Graz	32-605 ex 19/20 Approval date: 18.12.2020

Supplementary Table 2: End of the study- Reason (FAS)

Reasons for end of study	Number of patients (n=94)
End of observation period as defined in the observational plan	78 (82.98)
The manufacturer of the CGM/FGM unit was changed	2 (2.13)
Gla-300 was discontinued	3 (3.19)
Loss of contact	2 (2.13)
Other reason	3 (3.29)

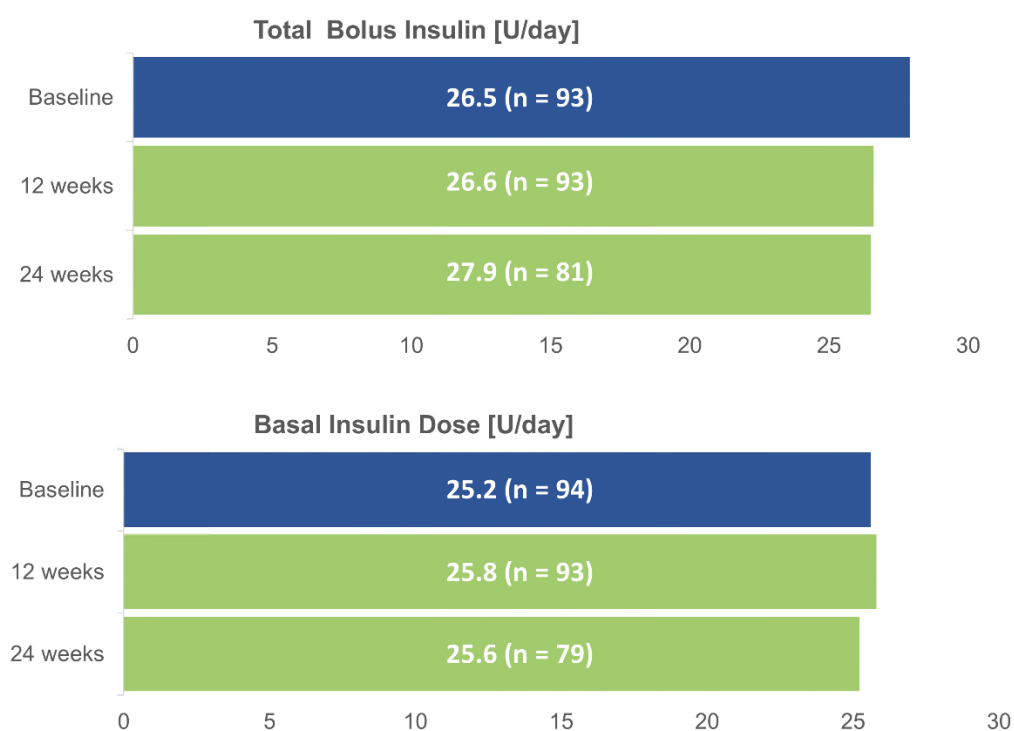
Legends: CGM, continuous glucose monitoring; FAS, full analysis set; FGM, flash glucose monitoring; Gla-300, insulin glargine 300 U/ml

Supplementary Table 3. Mean change in the DTSQ questionnaires at approximately 24 weeks (FAS)

	Baseline		Approx. Week 24		Change from baseline	
	N	Mean±SD	N	Mean±SD	N	Mean±SD
Treatment satisfaction DTSQ Score	93	28.12±6.06	77	29.64±6.84	77	1.64 ±8.09
Diabetes management perceived hyperglycaemia	92	3.60±1.23	76	2.92±1.39	76	-0.63 ±1.45
Diabetes management perceived hypoglycaemia	92	2.17±1.37	76	1.83±1.45	76	-0.34 ±1.47

DTSQ = Diabetes Treatment Satisfaction Questionnaire, FAS = full analysis set, SD = standard deviation

Supplementary Figure 1: Change in Total Bolus Insulin and Basal Insulin dose (FAS)



Legend: FAS, full analysis set