SUPPLEMENTARY MATERIAL

Pharmacokinetics and safety of bilastine 10 mg/day in children aged 2 to <6 years with allergic rhinoconjunctivitis or urticaria: a phase 3 clinical trial

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Table S1. Locations of the BILA–4021 study.

Country	Site name	Site Address	Number of patients
Poland	ALERGO-MED Specjalistyczna Przychodnia Lekarska Sp. z o.o	ul. Polskiego Czerwonego Krzyża 26, 33-100 Tarnów, Poland	6
Slovakia	ALERGO H2B, s.r.o. Ambulancia klinickej imunológie a alergológie	Senný Trh 799/6, 945 01 Komárno, Slovakia	4
Slovakia	Zoll – Med, s.r.o. Ambulancia klinickej imunológie a alergológie	P. Dobšinského 1092, 979 01 Rimavská Sobota, Slovakia	8
Slovakia	DANIMED, s.r.o. Ambulancia klinickej imunológie a alergológie	Námestie hrdinov 11/15, 934 01 Levice, Slovakia	3
Slovakia	ALERGOMEA, s.r.o. Ambulancia klinickej imunológie a alergológie	Ulica mieru 1390/11, 984 01 Lučenec, Slovakia	4
Lithuania	JSC Diagnostic and treatment center for allergic diseases	Seliu str. 64, LT-08109, Vilnius, Lithuania	10
Lithuania	JSC CD8 clinic	Jonavos str. 7, LT-44192, Kaunas, Lithuania	4

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Table S2. Schedule of trial procedures.

	Screening	**Baseline**	**Treatment period**			**Follow-up**
Visit No.	**V1**	**V2**		**V3 (CV)**	**V4 (EoT)/EDV[2]**	**V5**
Days	1 to 7 days before V2	1 to 7 days after V1	1 day after V2	7+3 days after V2	7+3 days after V3 / early discontinuation	7+3 days after V4 EoT / EDV / V3 (CV)[3]
Week				1	2	3
Initiation procedures						
Informed consent	X					
In-/exclusion criteria	X	X				
Demographics	X					
Medical history	X					
Prior/concomitant medication	X	X		X	X	X
Skin prick test/Test for specific IgE	X					
Randomisation to PK sampling groups		X				
Safety and PK						
Physical examination	X	X		X	X	
Height and body weight	X					
Vital signs (body temperature, heart rate)	X	X		X	X	
PK blood sampling				X[4]		
Untoward events (n-TEAEs and TEAEs)	X	X		X	X	X
Treatment medication						
Bilastine dispensing		X		X		
1st bilastine intake			X			
Collection of bilastine (accountability)				X	X	

[1] Only applicable for subjects who did not stop intake of bilastine after V3.
[2] An EDV had to be performed as soon as possible but latest within 7 days in case of early discontinuation during the treatment period.
[3] The follow-up visit had to be performed within 7 + 3 days after V4 (EoT)/EDV or within 7 +3 days after V3 (CV) if bilastine was stopped at V3.
[4] PK samples were obtained at different time-points based on randomisation.
Abbreviations: CV, completion visit; EDV, early discontinuation visit; EoT, end of treatment; PK, pharmacokinetics.

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