Effectiveness of abrocitinib in patients with atopic dermatitis: results of a federated analysis of real-world evidence in the DREAM TO TREAT AD consortium

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Introduction & Objectives:

- DREAM TO TREAT AD (D2T AD) is a pan-European register-based study open in Denmark, Germany, the Netherlands and Belgium, UK and Ireland, evaluating treatment effectiveness of abrocitinib and conventional systemic therapies in atopic dermatitis (AD).

Materials & Methods:

- Data were pre-processed in each register into an analytical dataset with a common structure across all registers. Federated statistical analysis was conducted in the secure DataSHIELD R environment.
- Effectiveness of abrocitinib was described as the average reduction in Eczema Area and Severity Index (EASI) from drug initiation [-42; +7 days window] to week 16 and achieving EASI-50, EASI-75, and EASI-90 at week 16 [+- 42 days].
- Heterogeneity tests between registers were conducted, with P<0.05 indicating heterogeneity.
- Multivariable linear and logistic regression models were run to explain the impact of patient characteristic on EASI.

Results:

- 218 patients received abrocitinib, of which 100 had drug initiation and follow-up EASI available for the analysis.
- EASI at drug initiation and number and types of previous systemic treatments varied between registers.
- At week 16, GY showed the strongest and NL/BE the smallest EASI improvement (Table 1).
- The regression models showed that effectiveness increased with higher EASI at drug initiation, age and female sex, while decreasing with higher number of previous systemic treatments (Table 2).

Table 1. Baseline characteristics and EASI changes at 16 weeks in patients receiving abrocitinib in D2T AD

Variable	TREAT Germany (GY)	ASTAR UK (UK)	SCRATCH Denmark (DK)	TREAT-NL/BE (NL/BE)	P-value for hetero-geneity
Number of patients	**44**	**24**	**12**	**20**	
Age at treatment initiation	38.0	30.1	39.4	33.0	P=0.127
% of females	34	46	42	30	P=0.685
EASI at treatment initiation	18.1	23.4	17.6	18.1	P=0.366
Patients received any systemic therapy in the past, %	55	96	100	95	P<0.001
Number of previous systemic treatments, mean	1.0	3.3	3.5	2.2	P<0.001
Patients received conventional systemic therapy in the past, %	41	83	92	90	P<0.001
Patients received biologic therapy in the past, %	30	92	50	45	P<0.001
Patients received JAKi therapy in the past, %	14	25	83	15	P<0.001
Mean EASI difference between drug initiation and week 16	-14.4	-12.5	-11.1	-5.7	P=0.121
Mean EASI improvement at week 16, %	71	53	56	12	P=0.034
% EASI improvement per month at week 16	24	15	17	4	P=0.002
Patients achieving EASI-50 at week 16, %	82	62	58	45	P=0.023
Patients achieving EASI-75 at week 16, %	68	50	58	30	P=0.035
Patients achieving EASI-90 at week 16, %	43	33	42	20	P=0.303

Table 2. Regressions to explain the impact of baseline characteristics on EASI outcomes at week 16.

Outcome	For each previous treatment	EASI (10 units)	Age (10 years)	Female
Per month(1):	-1.44 (P=0.002)	0.61 (P<0.001)	0.04 (P=0.808)	4.79 (P=0.008)
EASI-50(2):	0.83 (P<0.001)	1.65 (P<0.001)	1.07 (P=0.047)	1.70 (P<0.001)
EASI-75(2):	0.89 (P=0.057)	1.36 (P<0.001)	1.10 (P=0.007)	1.59 (P<0.001)
EASI-90(2):	0.90 (P=0.061)	1.25 (P<0.001)	1.13 (P<0.001)	1.77 (P<0.001)

(1) Linear regression model to explain the percentage of EASI reduction per month, the coefficients are % reduction of EASI. (2) Logistic regression models for achieving the binary EASI outcomes (the coefficients are OR).

Conclusion:

- Using a novel federated analysis approach, we estimated the effectiveness of abrocitinib in a real-world setting in four European registers.
- The differences in effectiveness between countries are likely due to differences in healthcare settings and patient characteristics.
- Further analyses will focus on comparing the long-term effectiveness of systemic medications.