An Interim Analysis of a Prospective Observational Study of Upadacitinib in Patients with Atopic Dermatitis with Prurigo Nodules

Hiroyuki Murota[1], Teppei Hagino[2], Hidetoshi Takahashi[3], Shintaro Takeoka[4], Sei-ichiro Motegi[5], Motoi Takenaka[1], Takeshi Ishido[6], Hiroyuki Hozawa[6], and Yayoi Tada[7]

[1]Nagasaki University Department of Dermatology, [2]Nippon Medical School, Chiba Hokusou Hospital Department of Dermatology, [3]Takagi Dermatological Clinic, [4]Takeoka Dermatological Clinic, [5]Gunma University Department of Dermatology, [6]AbbVie GK, [7]Teikyo University Department of Dermatology

OBJECTIVE

To assess the efficacy of upadacitinib in patients with moderate-to-severe atopic dermatitis with prurigo nodules in clinical practice

CONCLUSIONS

Our study suggested that upadacitinib, an oral Janus kinase inhibitor, has a high level of efficacy and safety in patients with moderate-to-severe atopic dermatitis with prurigo nodules (n=120)

For the primary endpoint of WP-NRS, an improvement of at least 4 points was observed in 64.3% of patients at Week 4

At Week 12, palpable prurigo nodules (IGA-CNPG) and pruriginous lesions with excoriations or crusts (IGA-CNPG activity) had cleared or almost cleared in 67.0% and 72.5% of patients, respectively

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SYNOPSIS

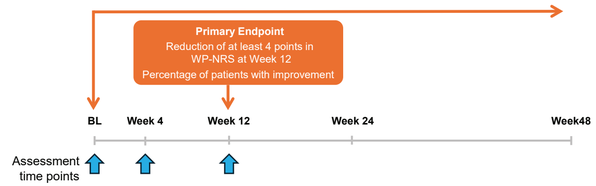
- Pruriginous atopic dermatitis (AD) is one of the most refractory phenotypes of AD and is characterized by multiple, widespread prurigo nodularis; patients with pruriginous AD experience intense, persistent pruritus
- The efficacy and safety of multiple targeted immune modulators (TIMs), such as dupilumab and nemolizumab, have been confirmed in patients with prurigo nodularis, but data evaluating the efficacy of TIMs in patients with pruriginous AD are limited, and no specific prospective study has been reported
- This multicenter prospective observational study (ADMIRE) assesses the efficacy and safety of upadacitinib, an oral Janus kinase-1 inhibitor, in moderate-to-severe AD patients with prurigo nodularis in a real-world setting

METHODS

- **Study Design:** Non-interventional, multicenter, prospective, observational study conducted in Japan
- **Population:** Moderate-to-severe AD patients with prurigo nodules
- **Enrollment period:** December 2022 to November 2023
- **Data cutoff:** April 2024
- **Number of enrolled patients:** 120 (number of patients to obtain a 95% confidence interval within ±9%, assuming an improvement in Worst Pruritus Numerical Rating Scale [WP-NRS] of at least 4 points in 60% of patients)

Figure 1. Study Design

Follow-up of 48 weeks in patients who started UPA according to the package insert at the physician's discretion in routine clinical practice



UPA, upadacitinib; WP-NRS, Worst Pruritus Numeric Rating Scale

RESULTS

Table 1. Patient Characteristics

Items	Number of patients	%	Mean	SD
Age	120	-	33.1	17.6
Male	68	56.7	-	-
Height (cm)	117	-	162.2	9.3
Body weight (kg)	115	-	63.4	15.4
Had prior systemic therapy for atopic dermatitis[a]	48	40.0	-	-
Prior therapy for atopic dermatitis (name of drug and/or therapy)[b]				
Dupilumab	14	11.7	-	-
Nemolizumab	2	1.7	-	-
Baricitinib	10	8.3	-	-
Abrocitinib	4	3.3	-	-
Cyclosporine	16	13.3	-	-
Oral steroids	13	10.8	-	-
UV light therapy	13	10.8	-	-
Biological products, JAK inhibitors and immunosuppressants other than those listed above	1	0.8	-	-
Had concomitant medications for atopic dermatitis	107	89.2	-	-

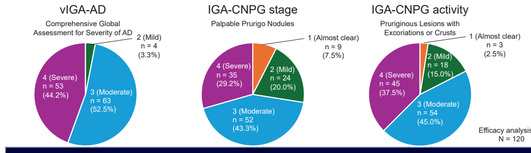
[a]Prior systemic therapy: biological products, oral JAK inhibitors, oral immunosuppressants, oral steroids, UV light therapy; [b]Multiple drugs/therapies applicable in same patient; JAK, Janus Kinase; SD, Standard Deviation.

Table 2. Baseline Prurigo Lesions to be Evaluated and Patient-Reported Outcomes

Prurigo lesions to be evaluated	Number of patients	Number of prurigo lesions in representative area		
		Mean	SD	Median (Q1, Q3)
Total evaluated prurigo lesions	120	25.8	39.0	14.0 (6.0, 32.0)
Physician assessments				
EASI	120	26.4	9.4	26.2 (20.1, 31.6)
BSA (%)	120	46.2	18.2	44.0 (30.0, 60.0)
Patient-reported outcomes				
WP-NRS	119	7.2	1.9	7.0 (6.0, 9.0)
Skin Pain NRS	116	5.7	2.6	6.0 (4.0, 8.0)
DLQI	87	12.1	6.5	12.0 (7.0, 16.0)

BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; Q, Quartile; SD, Standard Deviation; WP-NRS, Worst Pruritus Numerical Rating Scale.

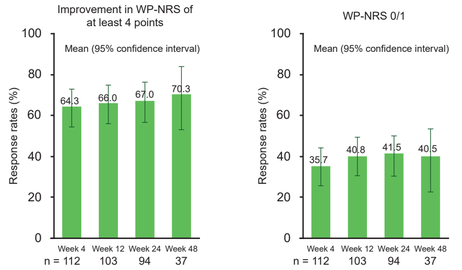
Figure 2. Physician Assessment at Baseline

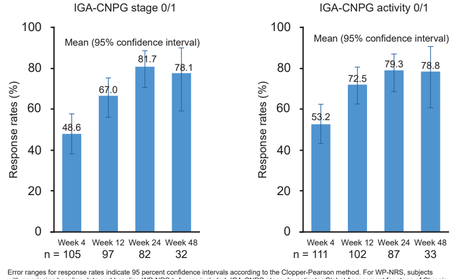


Endpoint	Score	Skin findings
IGA-CNPG stage		
	0 (Clear)	No palpable prurigo nodules (0)
	1 (Almost clear)	Rare palpable prurigo nodules (approximately 1-5)
	2 (Mild)	Few palpable prurigo nodules (approximately 6-19)
	3 (Moderate)	Many palpable prurigo nodules (approximately 20-100)
	4 (Severe)	Abundant palpable prurigo nodules (> = 100)
IGA-CNPG activity		
	0 (Clear)	No pruriginous lesions have excoriations or crusts
	1 (Almost clear)	Very small proportion of pruriginous lesions have excoriations or crusts (up to approximately 10% of all pruriginous lesions)
	2 (Mild)	Minority of pruriginous lesions have excoriations or crusts (approximately 11-25% of all pruriginous lesions)
	3 (Moderate)	Many pruriginous lesions have excoriations or crusts (approximately 26-75% of all pruriginous lesions)
	4 (Severe)	Majority of pruriginous lesions have excoriations or crusts (approximately 76-100% of all pruriginous lesions)

AD, Atopic Dermatitis; IGA-CNPG activity, Investigator Global Assessment for signs of activity in Chronic Nodular Prurigo; IGA-CNPG stage, Investigator Global Assessment for stage of Chronic Nodular Prurigo; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis.

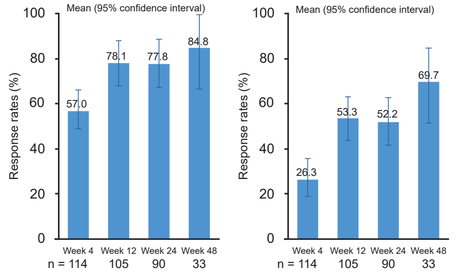
Figure 3. Rapid Improvement of Prurigo Nodules from Week 4 of Upadacitinib Treatment





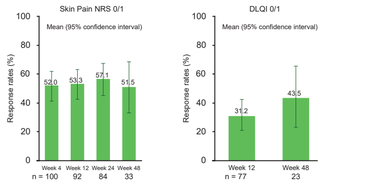
Error ranges for response rates indicate 95 percent confidence intervals according to the Clopper-Pearson method. For WP-NRS, subjects with no missing baseline data and baseline WP-NRS ≥ 4 were included. IGA-CNPG stage, Investigator Global Assessment for stage of Chronic Nodular Prurigo; WP-NRS, Worst Pruritus Numerical Rating Scale.

Figure 4. Achievement of EASI 75 and EASI 90 by Week 48



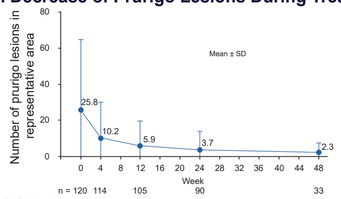
Error ranges for response rates indicate 95 percent confidence intervals according to the Clopper-Pearson method. EASI, Eczema Area and Severity Index; OC, Observed Cases.

Figure 5. Achievement of Skin Pain NRS 0/1 and DLQI 0/1 by Week 48



Error ranges for response rates indicate 95 percent confidence intervals according to the Clopper-Pearson method. DLQI, Dermatology Life Quality Index; OC, Observed Cases, NRS, Numerical Rating Scale.

Figure 6. Decrease of Prurigo Lesions During Treatment



OC, Observed Cases; SD, Standard Deviation.

Table 3. Adverse Events

PT (Preferred Term) reported in ≥ 2 patients	N = 120	
	Number of events	N (%)
Folliculitis	5	5 (4.2)
Gastroenteritis	2	2 (1.7)
Herpes simplex	3	2 (1.7)
Herpes zoster	4	4 (3.3)
Influenza	11	10 (8.3)
Nasopharyngitis	11	9 (7.5)
Otitis externa	2	2 (1.7)
Paronychia	2	2 (1.7)
Tonsillitis	3	1 (0.8)
Oral herpes	2	2 (1.7)
COVID-19	7	7 (5.8)
Skin papilloma	2	2 (1.7)
Abdominal discomfort	5	3 (2.5)
Acne	24	24 (20.0)
Urticaria	2	2 (1.7)
AESI (Adverse Events of Special Interest)		
Serious infection	2	2 (1.7)
Opportunistic infection (excluding tuberculosis and herpes zoster)	0	0
Herpes zoster	4	4 (3.3)
Active tuberculosis	0	0
Malignant tumor	0	0
Hepatic dysfunction	4	4 (3.3)
Gastrointestinal perforation	0	0
Anaemia	2	2 (1.7)
Neutropenia	0	0
Lymphopenia	0	0
Creatine phosphokinase (CPK) increased	0	0
Renal impairment	0	0
Adjudicated cardiovascular events (MACE)	0	0
Adjudicated venous thromboembolism	0	0