Efficacy and Safety of Ruxolitinib Cream for the Treatment of Moderate to Severe Chronic Hand Eczema: 32-Week Data From a Randomized, Phase 2 Study

Presented at the
Fall Clinical Dermatology Conference
Las Vegas, NV, USA • October 23–26, 2025

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Objective

- To investigate the efficacy and safety of 1.5% ruxolitinib cream BID applied as needed through Week 32 in the open-label extension period of a phase 2 study (NCT05906628)

Conclusions

- **In patients with nonatopic CHE, 1.5% ruxolitinib cream BID substantially improved clinical signs, symptoms, and quality of life vs vehicle in a 16-week, double-blind continuous treatment period, with improvements sustained throughout a 16-week OLE with as-needed BID treatment**
- **Patients who crossed over from vehicle to 1.5% ruxolitinib cream during the OLE achieved comparable levels of improvement to those initially randomized to ruxolitinib cream**
- **Ruxolitinib cream was generally well tolerated throughout the 32-week study, consistent with its established safety profile[7,8]**
- **These findings support the use of ruxolitinib cream as a potential treatment option for the management of nonatopic CHE**

Abbreviations

AD, atopic dermatitis; BID, twice daily; CHE, chronic hand eczema; DBVC, double-blind vehicle-controlled; DLQI, Dermatology Life Quality Index; EoS, end of study; HECSI, Hand Eczema Severity Index; HECSI-75/90, ≥75%/≥90% improvement from baseline in HECSI score; IGA, Investigator's Global Assessment; IGA-CHE-TS, IGA-CHE treatment success (score of 0 or 1 with ≥2-grade improvement from baseline); JAK, Janus kinase; NRS, numerical rating scale; NRS2, ≥2-point improvement from baseline in NRS score; NRS4, ≥4-point improvement from baseline in NRS score; OLE, open-label extension; PGIC, Patient Global Impression of Change; STAT, signal transducer and activator of transcription; TEAE, treatment-emergent adverse event.

Disclosures

LFSG has served as an investigator, advisor, and/or speaker for AbbVie, Arcutis, Bristol Myers Squibb, Dermavant, Eli Lilly, Incyte Corporation, Ortho Dermatologics, Pfizer, Regeneron, and Sanofi. PH is an employee of Incyte Biosciences International Sàrl and a shareholder of Incyte Corporation. YK and HN are employees and shareholders of Incyte Corporation. HLS has served as an investigator for AbbVie, Bristol Myers Squibb, Dermavant, Lilly, Incyte Corporation, and Sanofi.

Acknowledgments

The authors thank the patients and their families, the investigators, and the site personnel who participated in this study. The authors also acknowledge M. Celeste Ferreira-Cornwell, PhD, Qian Li, PhD, and Michelle Miller, MA, for their contributions to the study. This study was funded by Incyte Corporation (Wilmington, DE, USA). Medical writing support was provided by Jessica Brandwein, PhD, from Citrus Health Group, Inc. (Chicago, IL, USA) and was funded by Incyte Corporation.

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Introduction

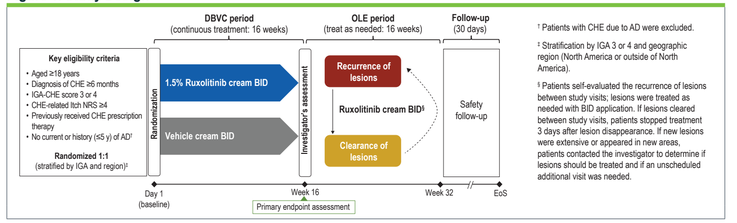
- CHE (hand eczema that persists for >3 months or recurs ≥2 times per year) is a common inflammatory disorder associated with pruritus, burning, pain, stinging, sleep disturbances, and/or mood disturbances[1,2]
  - CHE negatively affects quality of life, performance of daily activities, and work productivity
- The pathophysiology of hand eczema is mediated by multiple cytokines acting through the JAK-STAT signaling pathway[3,4]
- Ruxolitinib (selective JAK1/JAK2 inhibitor)[5] cream BID demonstrated significant efficacy vs vehicle and was well tolerated in patients with moderate to severe nonatopic CHE during the 16-week, double-blind treatment period in a phase 2 study[6]

Methods

Patients and Study Design

- Eligible patients were randomized 1:1 to apply 1.5% ruxolitinib cream or vehicle BID to all areas affected at baseline for 16 weeks (DBVC period; **Figure 1**)
- Patients then applied 1.5% ruxolitinib cream BID on an as-needed basis for an additional 16 weeks in an OLE

Figure 1. Study Design



† Patients with CHE due to AD were excluded.

‡ Stratification by IGA 3 or 4 and geographic region (North America or outside of North America).

§ Patients self-evaluated the recurrence of lesions between study visits; lesions were treated as needed with BID application. If lesions cleared between study visits, patients stopped treatment 3 days after lesion disappearance. If new lesions were extensive or appeared in new areas, patients contacted the investigator to determine if lesions should be treated and if an unscheduled additional visit was needed.

Results

Patients

- Patients (N=186) had a median (range) age of 50 (18–80) years, 59.7% were female, and 90.3% were White
  - Baseline IGA-CHE score was 3 (moderate) in 72.6% of patients, and median (range) baseline Itch NRS and Skin Pain NRS scores were 6.6 (2.1–10) and 6.3 (0.6–10), respectively
  - Mean (95% CI) baseline DLQI scores were 11.8 (10.6–13.1) for the vehicle group and 13.2 (11.9–14.5) for the ruxolitinib cream group
  - Overall, several CHE types were represented, including irritant contact dermatitis (27.4%), allergic contact dermatitis (16.1%), vesicular (pompholyx; 15.1%), and hyperkeratotic eczema (14.0%)
- Of patients initially randomized to ruxolitinib cream (n=94) or vehicle (n=92), 84 (89.4%) and 77 (83.7%) entered the OLE period, respectively

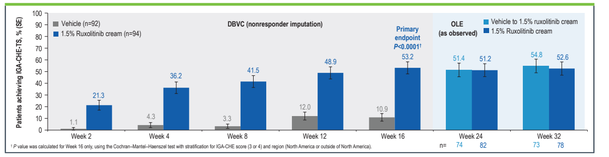
Efficacy

- Significantly more patients who applied ruxolitinib cream vs vehicle achieved IGA-CHE-TS at Week 16 (primary endpoint) and Itch NRS4 at Weeks 4 and 16 (key secondary endpoints)[6]
  - Numerical improvement in Itch NRS4 was observed by Day 2, with statistically significant improvement by Day 7 (key secondary endpoint)
- Patients who continued applying ruxolitinib cream as needed in the OLE maintained the improvements seen at Week 16 in IGA-CHE-TS (**Figure 2**), Itch NRS4 (**Figure 3**), HECSI-75 (**Figure 4**), HECSI-90 (**Figure 5**), DLQI score (**Figure 6**), and Skin Pain NRS2 (**Figure 7**)
  - Patients who crossed over from vehicle to open-label ruxolitinib cream at Week 16 demonstrated rapid improvement in signs and symptoms of CHE, and by Week 24 had responses comparable to those in patients initially randomized to ruxolitinib cream, with improvements maintained at Week 32
- A similar result was observed in the proportion of patients applying 1.5% ruxolitinib cream who reported a PGIC score of 1 or 2 (very much or much improved; Week 16, 88.8% vs 35.1% [vehicle]; Week 32, 86.1% vs 86.6% [crossover from vehicle])

Safety

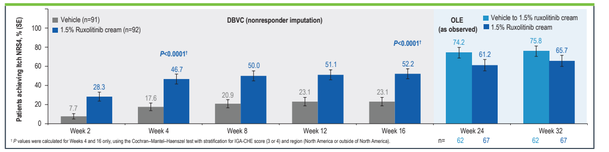
- Ruxolitinib cream was well tolerated in the OLE, consistent with the DBVC period (**Table 1**)
- In the OLE, the only treatment-related TEAE was grade 1 application site pain
- No grade ≥3 or serious TEAEs were considered related to treatment

Figure 2. Proportion of Patients Achieving IGA-CHE-TS



† *P* value was calculated for Week 16 only, using the Cochran–Mantel–Haenszel test with stratification for IGA-CHE score (3 or 4) and region (North America or outside of North America).

Figure 3. Proportion of Patients Achieving Itch NRS4



† *P* values were calculated for Weeks 4 and 16 only, using the Cochran–Mantel–Haenszel test with stratification for IGA-CHE score (3 or 4) and region (North America or outside of North America).

Figure 4. Proportion of Patients Achieving HECSI-75

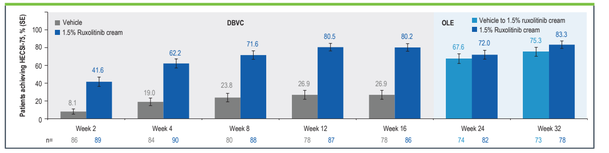


Figure 5. Proportion of Patients Achieving HECSI-90

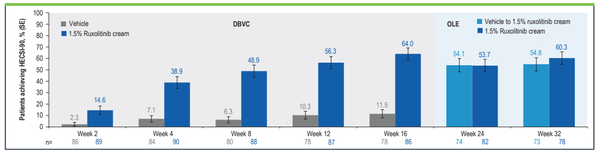


Figure 6. Change From Baseline in DLQI

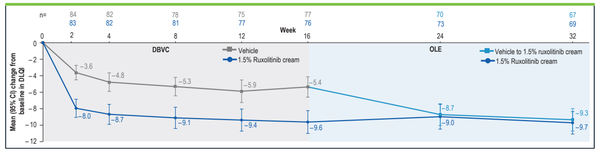


Figure 7. Proportion of Patients Achieving Skin Pain NRS2

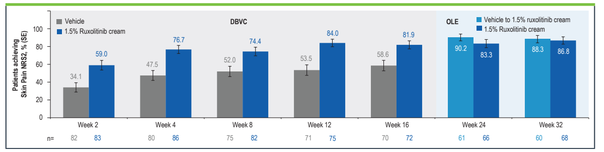


Table 1. TEAEs During the Study

	DBVC		OLE
n (%)	Vehicle (n=92)	1.5% Ruxolitinib cream (n=94)	1.5% Ruxolitinib cream (n=161)
Patients with TEAE	29 (31.5)	36 (38.3)	35 (21.7)
Most common TEAEs*			
Nasopharyngitis	9 (9.8)	7 (7.4)	3 (1.9)
Upper respiratory tract infection	3 (3.3)	4 (4.3)	3 (1.9)
Patients with treatment-related TEAE	3 (3.3)	6 (6.4)	1 (0.6)†
Patients with grade ≥3 TEAE‡	1 (1.1)	2 (2.1)	2 (1.2)‡
Patients with serious TEAE§	1 (1.1)	2 (2.1)	3 (1.9)§
Patients with fatal TEAE	0	0	1 (0.6)¶
Patients with TEAE leading to dose reduction/interruption	0	0	0
Patients with TEAE leading to discontinuation of study drug	0	0	1 (0.6)¶

* Reported in ≥3% patients treated with ruxolitinib cream in either the DBVC period or OLE.

† Application site pain (grade 1; nonserious; resolved).

‡ Grade ≥3 TEAEs were cardiac arrest¶ and osteoarthritis (n=1 each; none considered related to treatment).

§ Serious TEAEs were brain neoplasm (later determined to be nonneoplastic lesion), cardiac arrest,¶ and osteoarthritis (n=1 each; none considered related to treatment).

¶ Fatal TEAE of cardiac arrest in patient with cardiovascular risk factors. This event led to discontinuation of study drug and was not considered related to treatment.