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Efficacy and Safety of Ruxolitinib Cream in Patients With Hidradenitis Suppurativa (Hurley Stage I and II): Results From a Randomized, Double-Blind, Vehicle-Controlled Phase 2 Study

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Presenting Author Disclosures

- MJP has received consulting fees from AbbVie, Alumis, Eli Lilly, Incyte Corporation, Janssen, Novartis, Pfizer, Prometheus Laboratories, Sanofi, Sonoma Biotherapeutics, Trifecta Clinical, and UCB
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Background

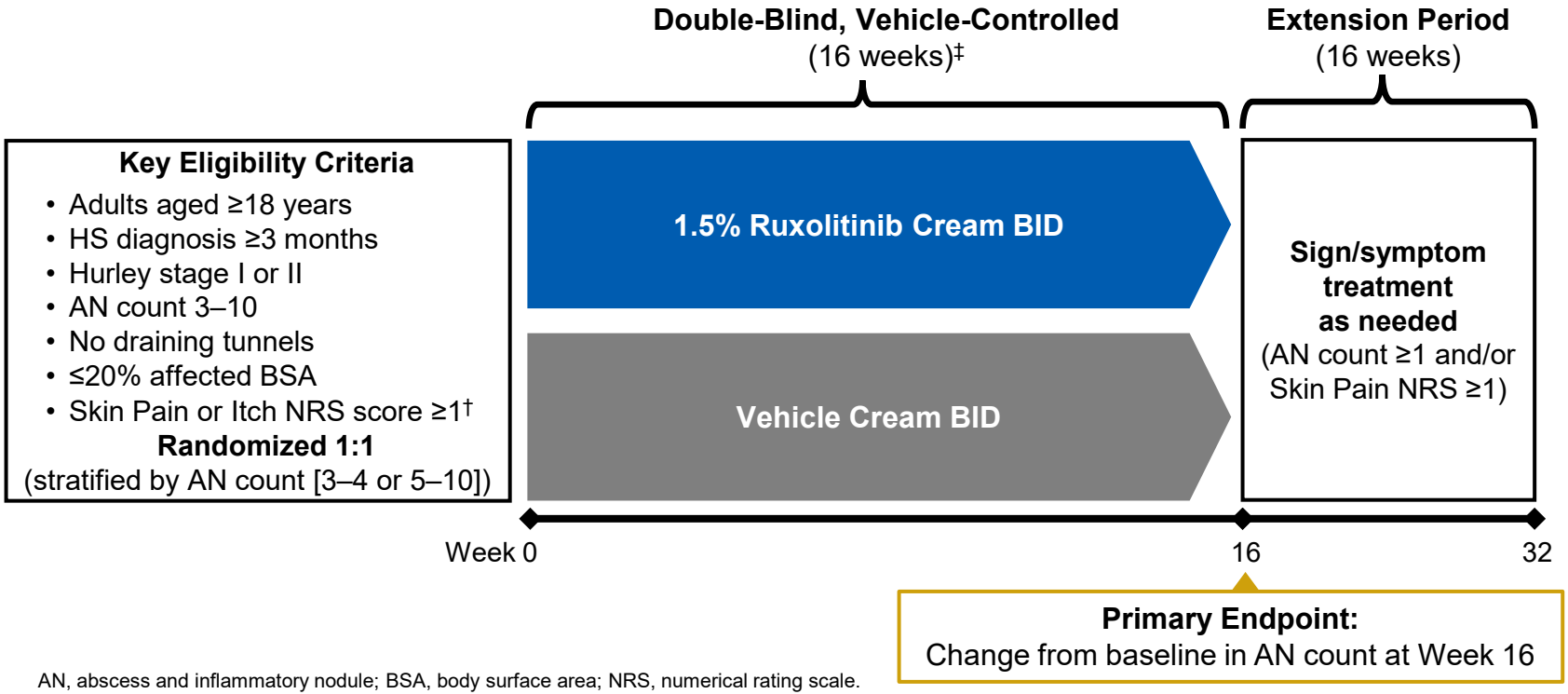
- HS is a chronic, recurring inflammatory skin disease that is associated with painful inflammatory nodules and abscesses[1]
  - May progress to draining tunnels, ulcerations, malodorous discharge, and permanent scarring
- There is no currently approved therapy for milder HS, and standard treatments are often inadequate[1]
- Ruxolitinib (selective JAK1/JAK2 inhibitor)[2] cream has demonstrated efficacy in other inflammatory and autoimmune skin diseases[3,4]

- **Objective:** To assess the efficacy and safety of 1.5% ruxolitinib cream BID for the treatment of HS during 16 weeks of treatment

BID, twice daily; HS, hidradenitis suppurativa; JAK, Janus kinase.

1. Sabat R, et al. *Nat Rev.* 2020;6(1):18. 2. Quintás-Cardama A, et al. *Blood.* 2010;115(15):3109-3117. 3. Papp K, et al. *J Am Acad Dermatol.* 2021;85(4):863-872.
4. Rosmarin D, et al. *N Engl J Med.* 2022;387(16):1445-1455. 5. Jemec GBE, et al. *N Engl J Med.* 2012;366(2):158-164.

Study Design



AN, abscess and inflammatory nodule; BSA, body surface area; NRS, numerical rating scale.
ClinicalTrials.gov: NCT05635838.
† Baseline and study visit scores calculated as the average of the 7 prior daily scores.
‡ Treatment was applied directly to each AN (including ~1 cm of the surrounding area) identified at baseline as well as new lesions identified postbaseline after consultation with the investigator. Rescue treatment was not permitted.

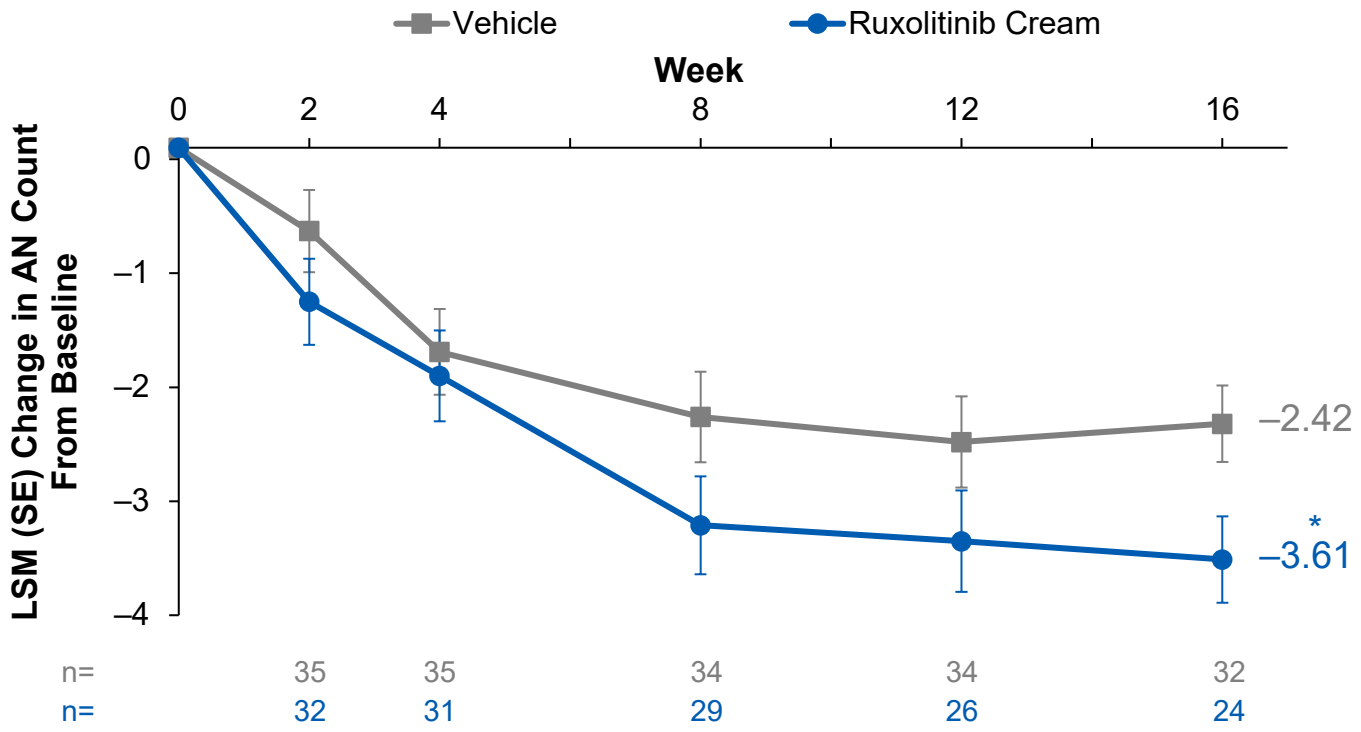
Patient Demographics and Baseline Clinical Characteristics

Characteristic	Vehicle (n=35)	1.5% Ruxolitinib Cream (n=34)
Age, median (range), y	29.0 (18–54)	29.0 (19–59)
Female, n (%)	33 (94.3)	29 (85.3)
Race, n (%)		
White	12 (34.3)	19 (55.9)
Black	18 (51.4)	11 (32.4)
Asian	2 (5.7)	0
Other	3 (8.6)	3 (8.8)
BMI, mean (SD), kg/m^2	33.1 (6.7)	36.7 (9.5)
Relevant comorbidities, n (%)		
Anxiety	10 (28.6)	7 (20.6)
Depression	9 (25.7)	7 (20.6)
Disease duration, median (range), y	6.3 (0.4–20.1)	4.2 (0.4–38.1)

Characteristic	Vehicle (n=35)	1.5% Ruxolitinib Cream (n=34)
Hurley stage, n (%)		
I	18 (51.4)	17 (50.0)
II	17 (48.6)	17 (50.0)
AN count, mean (SD)	5.3 (1.8)	5.6 (1.8)
Abscesses	0.7 (1.3)	0.6 (1.3)
Inflammatory nodules	4.6 (2.1)	4.9 (2.0)
Itch NRS score, mean (SD)	4.1 (2.8)	4.0 (2.6)
Skin Pain NRS score, mean (SD)	4.2 (2.4)	4.4 (2.4)
Prior HS therapy, n (%)	21 (60.0)	21 (61.8)
Biologics	2 (5.7)	0
Prior surgical treatment, n (%)	9 (25.7)	6 (17.6)

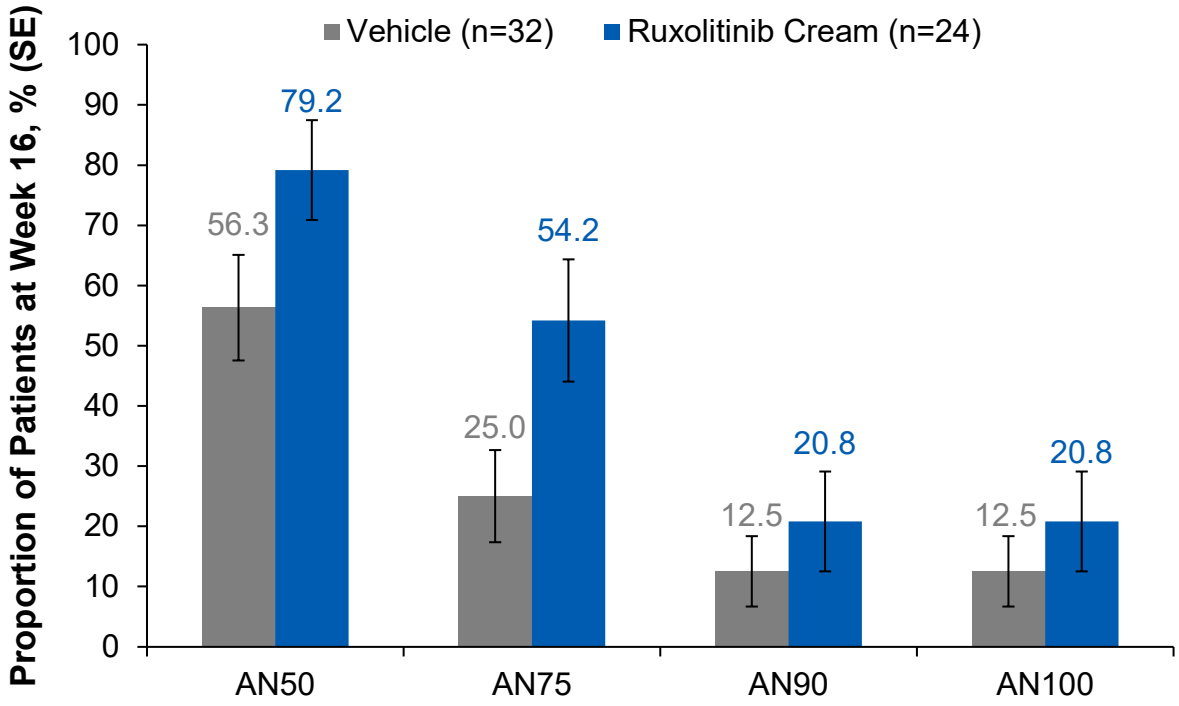
BMI, body mass index.

Change From Baseline in AN Count Through Week 16 (Primary Endpoint)



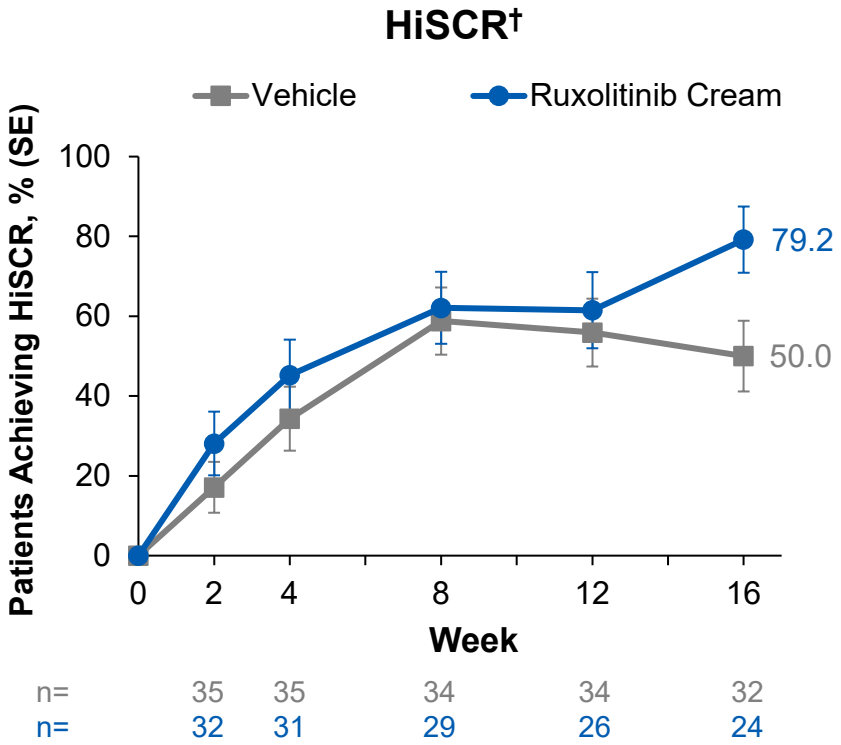
LSM, least squares mean.
* *P*<0.05 vs vehicle calculated from mixed model for repeated measures with fixed effect of treatment group, stratification factor, visit, and visit by treatment interaction.

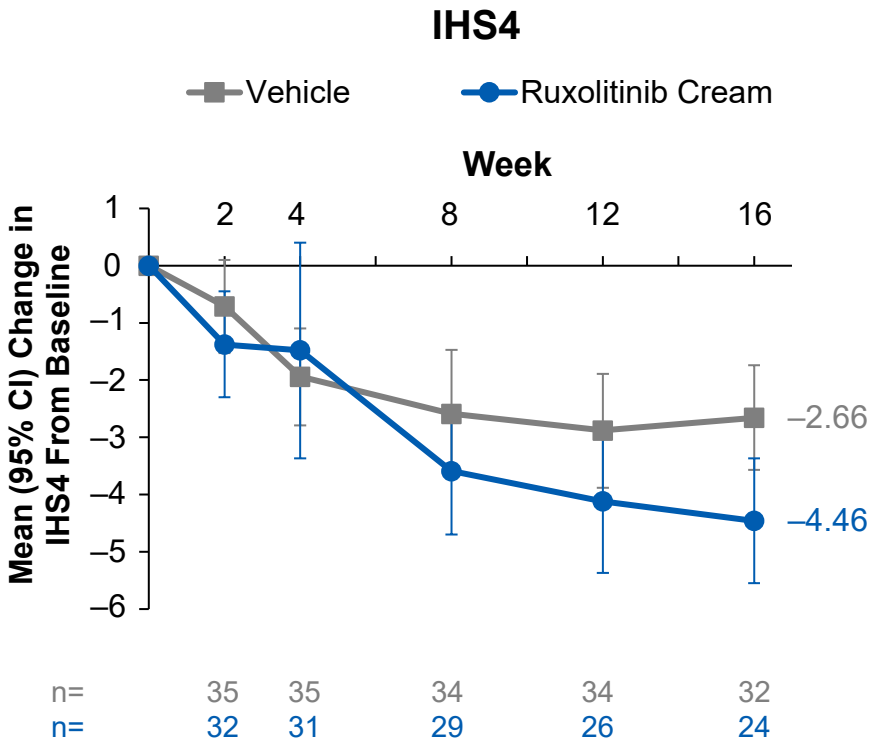
Proportion of Patients Achieving AN50, AN75, AN90, and AN100 at Week 16



AN50/75/90/100, ≥50%/≥75%/≥90%/100% reduction in AN count vs baseline.

Patients Achieving HiSCR and Change in IHS4 Score From Baseline Through Week 16

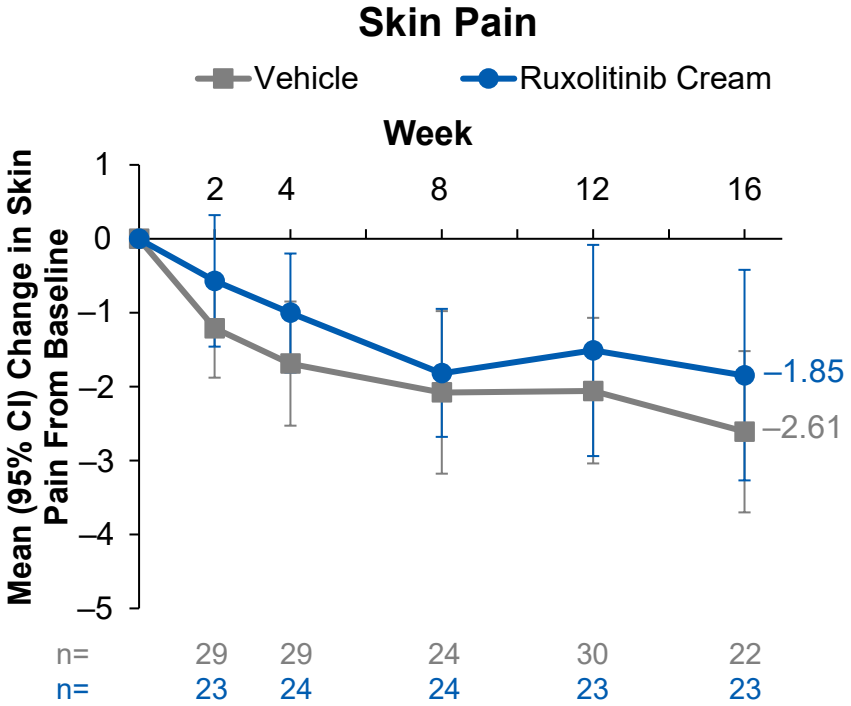


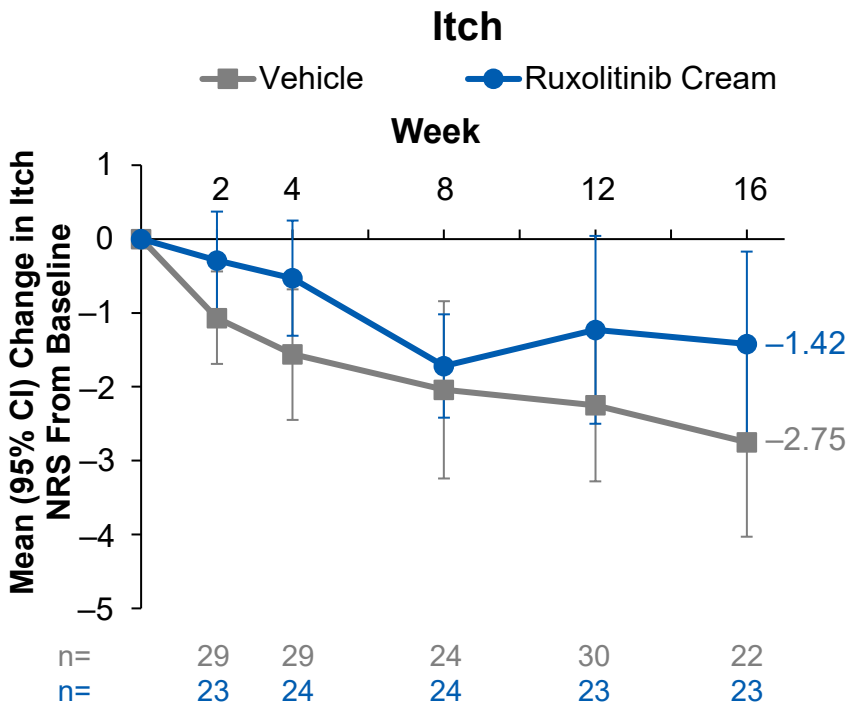


HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4, International Hidradenitis Suppurativa Severity Score System.
† ≥50% reduction in AN count and no increase in abscess or draining fistula count from baseline.

Change From Baseline in Skin Pain and Itch NRS Score Through Week 16

- Skin Pain and Itch NRS scores were moderate at baseline† and improved similarly in both groups during the study





† Mean (SD) Skin Pain NRS score at baseline: vehicle, 4.2 (2.4); ruxolitinib cream, 4.4 (2.4). Mean (SD) Itch NRS score at baseline: vehicle, 4.1 (2.8); ruxolitinib cream, 4.0 (2.6).

Safety at Week 16

- Ruxolitinib cream was generally well tolerated over 16 weeks
- No serious TEAEs were reported among patients who applied ruxolitinib cream

n (%)	Vehicle (n=35)	1.5% Ruxolitinib Cream (n=34)
Patients with TEAE	15 (42.9)	13 (38.2)
Most common TEAEs†		
COVID-19	0	2 (5.9)
Nasopharyngitis	0	2 (5.9)
Nausea	2 (5.7)	0
Patients with treatment-related TEAE‡	4 (11.4)	4 (11.8)
Patients with application site reactions	1 (2.9)	1 (2.9)
Patients with serious TEAE	1 (2.9)	0
Patients with grade ≥3 TEAE	2 (5.7)	0
Patients with TEAE leading to discontinuation	0	2 (5.9)§

TEAE, treatment-emergent adverse event.
† Occurring in ≥2 patients in either treatment group.
‡ No treatment-related TEAE occurred in >1 patient.
§ Contact dermatitis (n=1, related to treatment); hidradenitis (n=1, unrelated to treatment).

Conclusions

- Twice-daily 1.5% ruxolitinib cream was effective in patients with milder HS
  - Patients who applied ruxolitinib cream achieved a significantly greater reduction in AN count from baseline at Week 16 vs vehicle (primary endpoint)
  - More patients who applied ruxolitinib cream vs vehicle achieved
    - AN count reduction thresholds (≥50%, ≥75%, ≥90%, or 100%)
    - HiSCR
    - Greater IHS4 improvements
- Ruxolitinib cream was generally well tolerated in patients with milder HS
- Modifications to traditionally accepted clinical endpoints may be needed in studies of patients with milder HS

Thank You

- We thank the study investigators, patients, and their families for their participation in this study

- For questions, please contact Dr Martina J. Porter (mporter3@bidmc.harvard.edu)

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