The Second-generation Janus Kinase 1 Selective Inhibitor Atinvicitinib: A Safe and Effective Once-daily Treatment for Pruritus in Dogs with Allergic Dermatitis

Faris Jirjis[1]; Vanessa Domann[1]; Lindsey Overbey[1]; Qi Cao[2]; Matthew Stock[1]; and Inka Kuhlmann[3]
[1]Merck & Co., Inc., Rahway, NJ, USA;
[2]MSD Animal Health, Boxmeer, The Netherlands;
[3]MSD Animal Health Innovation, Zur Propstei, Schwabenheim 55270, Germany

Introduction

- Allergic dermatitis is a common cause of pruritus in dogs
- A randomized, blinded, placebo-controlled clinical trial was conducted in dogs with allergic dermatitis to confirm the safety and effectiveness of atinvicitinib tablets (NUMELVI®) in dogs

Materials and methods

Study population

- Client-owned dogs (≥6 months old, weighing ≥2 kg) with allergic dermatitis and a pruritus visual analogue scale (PVAS) score ≥6 were enrolled at 26 US veterinary practices

Study design

- 289 dogs were randomized 1:1 to receive atinvicitinib (0.8–1.2 mg/kg) or placebo once daily for 28 days

Assessments

- **Safety:** Monitored via adverse events and clinical pathology (hematology, clinical chemistry, urinalysis)
- **Efficacy:** Owner-assessed PVAS recorded daily from days 0 to 7
- **Primary endpoint:** ≥50% reduction in PVAS from baseline on at least 5 out of 7 days compared to placebo. Secondary measures of success included daily PVAS compared to baseline, Dermatitis Visual Analog Scale (DVAS) score on days 7 and 28 compared to baseline, and the percentage of cases with a reduction in PVAS at each assessment
- **Statistics:** A generalized linear mixed model with a logit link was used for PVAS percentage PVAS reduction, and Wilcoxon's rank sum test for change in centimeters

Results

Table 1. Signalment and demographics of dogs at enrollment

Variable	Atinvicitinib (N=145)	Placebo (N=144)
Mean age (years, range)	5.81 (0.66–15.08)	6.31 (0.95–14.66)
Mean weight (kg, range)	20.0 (3.00–54.70)	22.5 (2.50–58.20)
Mean owner PVAS score (range)	7.4 (6.0–9.7)	7.6 (6.0–10.0)
Mean veterinarian Dermatitis VAS score (range)	4.8 (0.0–9.7)	5.2 (0.3–9.0)

- Mixed breeds (n=137) and 60 pure breeds (n=152) were included; most common pure breeds were American pit bull terrier (n=13), golden retriever (n=12), and Labrador retriever (n=11)

Safety

- Atinvicitinib was well tolerated with no notable changes or trends in hematology, clinical chemistry, and urinalysis
- Decreases in mean eosinophil, neutrophil, monocyte, and total white blood cell counts remained within the reference ranges, indicating reduced allergy-mediated inflammation without immunosuppression[1]

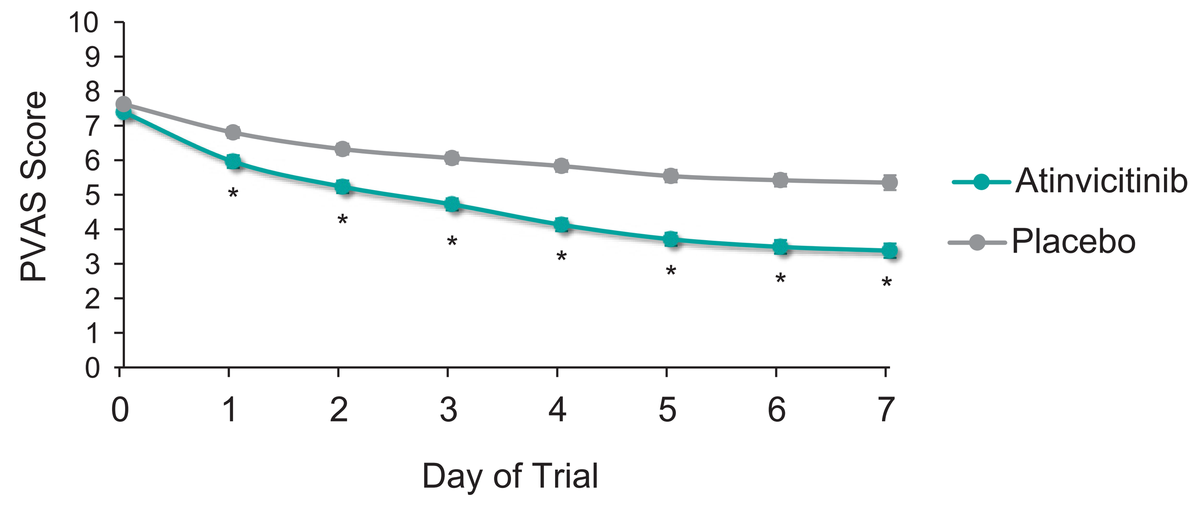
Common adverse reactions[1]	Atinvicitinib	Placebo
Vomiting	2.1%	1.4%
Diarrhea	2.1%	4.9%
Anorexia (reduced appetite)	0.7%	2.1%
Lethargy	2.8%	1.4%

- These signs, for which a relationship to treatment could not be ruled out, were typically mild and transient and did not require veterinary intervention or additional treatment
- No papilloma or skin masses were reported

Efficacy

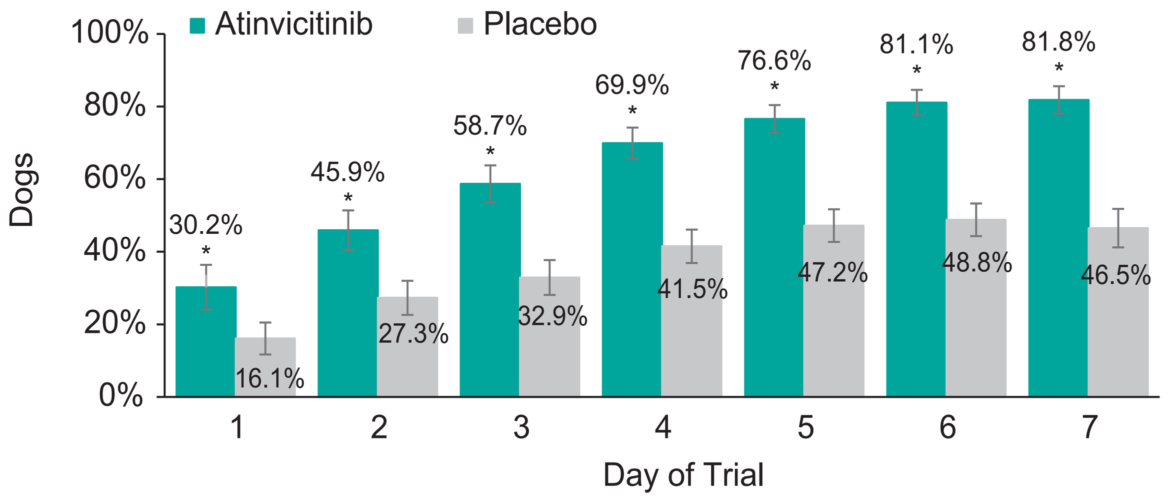
Significantly more atinvicitinib-treated (24.2%, 31/128) than placebo-treated (8.7%, 11/126) dogs had ≥50% reduction in PVAS on at least 5 of 7 days (P=0.0109) (**Figures 1 and 2**).

Figure 1. Rapid reduction in pruritus from the first dose



Pruritus improved with mean owner PVAS scores significantly lower in dogs in the atinvicitinib group* on each of the 7 days, compared to placebo.

Figure 2. Substantial reduction in itch from the first dose

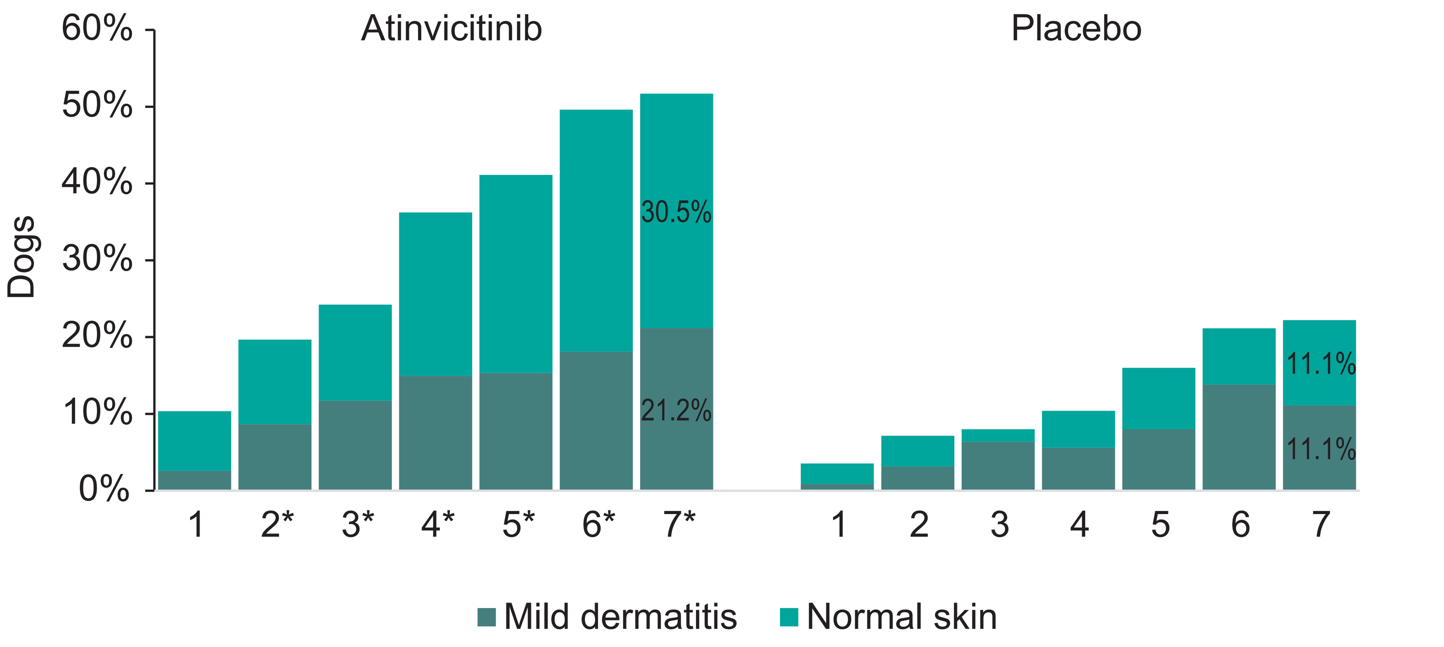


At least a 2-cm reduction in PVAS was observed in significantly more atinvicitinib-treated than placebo-treated dogs from days 1 to 7*.

By day 7 (**Figure 3**)

- 30.5% of the dogs had PVAS <2 cm, corresponding to normal skin
- 51.7% of the dogs had PVAS <3.6 cm, consistent with mild dermatitis

Figure 3. Rapid and clinically relevant improvement in PVAS scores corresponding to thresholds for normal skin (<2 cm) and mild dermatitis (<3.6 cm)



Reduction in PVAS thresholds corresponding to normal skin (<2 cm) and mild dermatitis (<3.6 cm) was observed in significantly more dogs treated with atinvicitinib from days 2 to 7*, compared to placebo. This was reached after two doses for mild dermatitis (P=0.0139) and after three doses for normal skin (P=0.0111).

Veterinary DVAS scores decreased by 51% on average in the atinvicitinib group by day 7 and were significantly lower than placebo (P<0.0001).

Discussion

- The high selectivity of atinvicitinib for JAK1 likely contributes to a reduction in allergy-mediated inflammation without immuno-suppression, as supported by stable hematologic parameters remaining within reference ranges[1]
- Clinically meaningful reductions in PVAS to thresholds indicating normal skin (<2 cm) or mild dermatitis (<3.6 cm) may better reflect treatment success than relative changes from baseline[2]
- The primary efficacy endpoint confirmed rapid and sustained pruritus reduction from the first dose through day 7, supported by consistent improvements in secondary measures

Conclusion

Once-daily atinvicitinib at 0.8–1.2 mg/kg is a safe, well-tolerated, and effective treatment for pruritus and clinical signs in dogs with allergic dermatitis aged 6 months and older under field conditions

References

1. European Medicines Agency. Summary of Product Characteristics and Public Assessment Report. Numelvi tablets for dogs. 2025 Union Product Database: https://medicines.health.europa.eu/ veterinary/
2. Olivry T, Bensignor E, Favrot C, Griffin CE, Hill PB, Mueller RS, Plant JD, Williams HC; International Committee of Allergic Diseases of Animals (ICADA). Development of a core outcome set for therapeutic clinical trials enrolling dogs with atopic dermatitis (COSCAD'18). *BMC Vet Res.* 2018;14(1):238.

Presented at European Veterinary Dermatology Congress; Bilbao, Spain; 11-13 September 2025.

35th

EUROPEAN VETERINARY DERMATOLOGY CONGRESS

ORGANIZED BY ESVD-ECVD-ISVD

BILBAO - SPAIN

11-13 SEPTEMBER 2025

PROCEEDINGS BOOK

EUSKALDUNA CONFERENCE CENTRE

SHORT COMMUNICATIONS

The second-generation Janus kinase 1 selective inhibitor atinvicitinib is a safe and effective once-daily treatment for pruritus in dogs with allergic dermatitis

M. Stock[1]
F. Jirjis[1], V. Domann[1], L. Overbey[1], Q. Cao[2], I. Kuhlmann[3]

[1] Merck & Co., Inc., Rahway, New Jersey, United States
[2] MSD Animal Health, Boxmeer, Netherlands
[3] MSD Animal Health Innovation, Schwabenheim an der Selz, Germany

Allergic dermatitis commonly causes pruritus in dogs. A randomized, blinded, placebo-controlled clinical trial was conducted in dogs with allergic dermatitis to confirm the safety and effectiveness of atinvicitinib tablets in dogs. Client-owned dogs (≥6 months old, weighing ≥2 kg, n=289) with allergic dermatitis and a pruritus visual analog scale (PVAS) score ≥6 were enrolled at 26 US veterinary practices. Dogs were randomly assigned (1:1) to treatment with atinvicitinib at 1.0 (0.8-1.2) mg/kg (A) or placebo once daily for up to 28 days. Safety was assessed on adverse events and clinical pathology. Efficacy was assessed using daily (D0-7) owner pruritus visual analog scale scores (PVAS). A generalized linear mixed model for binomials using a logit link was used for PVAS analysis. Atinvicitinib was well tolerated. There were no notable changes or trends in red cell parameters, clinical chemistry and urinalysis. In atinvicitinib-treated dogs, mean eosinophil, neutrophil, monocyte, and total white blood cell counts decreased but remained in reference intervals, indicating a reduction in allergy-mediated inflammation. The most common adverse reactions (atinvicitinib/placebo) were mild and transient vomiting (2.1%/1.4%) or diarrhea (2.1%/4.9%), with reduced appetite (0.7%/2.1%) and lethargy (2.8%/1.4%). Papilloma and skin masses were not reported. Significantly more atinvicitinib- than placebo-treated dogs had a 50% reduction in PVAS on at least 5/7 days ($P=0.0109$). By D7, 81.8±3.8% (least square mean±SEM) atinvicitinib- and 46.5±5.3% placebo-treated dogs had a ≥2 cm reduction in PVAS ($P<0.0001$). Atinvicitinib 1.0 (0.8-1.2) mg/kg once daily was safe and effective for the control of pruritus in dogs with allergic dermatitis.

Source of funding:
MSD Animal Health

Conflict of interest:
Authors are employed by MSD Animal Health