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MEDIA & INVESTOR RELEASE

Novartis data presentations at AAAAI and AAD underscore commitment to advancing treatment of hidradenitis suppurativa (HS) and chronic spontaneous urticaria (CSU)

- *Two-year efficacy and safety data analyses from Phase III SUNSHINE and SUNRISE trials of continuous Cosentyx® (secukinumab) treatment in HS to be presented*

- *New analyses of 52-week data from Phase III REMIX pivotal trials of investigational remibrutinib, demonstrating impact in key clinical outcomes for patients with CSU also to be presented*

- *Regulatory submissions for remibrutinib as a treatment for CSU on track for filing in 1H 2025*

Basel, February 28, 2025 – Novartis announced today it will present data from 17 abstracts, including investigator-initiated trials, across its immunology portfolio at the 2025 American Academy of Allergy Asthma and Immunology (AAAAI) and World Allergy Organization (WAO) Joint Congress and the 2025 American Academy of Dermatology (AAD) Annual Meeting.

Data presented at the congresses include long-term urticaria control, sleep, and activity analyses from the Phase III REMIX-1 and REMIX-2 studies evaluating investigational remibrutinib for the treatment of chronic spontaneous urticaria (CSU). Additionally, long-term data from the Cosentyx® (secukinumab) Phase III SUNSHINE and SUNRISE trials in patients with hidradenitis suppurativa (HS) and patient-reported outcomes from a Phase II trial evaluating remibrutinib in HS will be presented.

“Conditions like CSU and HS are more than just skin deep, often having a profound impact on patients' daily lives and activities," said Angelika Jahreis, Global Head, Development, Immunology, Novartis. "These data at AAAAI and AAD highlight our continued commitment to reimagine medicine and address treatment gaps for people with immune-mediated diseases. We are particularly excited about the potential for remibrutinib as a novel oral treatment for patients with CSU who remain symptomatic on antihistamines.”

These CSU data will support regulatory submissions in the first half of 2025. In addition to CSU, remibrutinib is being investigated in other immune-mediated conditions, including chronic inducible urticaria (CIndU), HS, and food allergy.

Key abstracts accepted by AAAAI include:

Abstract Title	Abstract Number/ Presentation Details
Remibrutinib	
The Impact of Remibrutinib on Urticaria Control in Patients with Chronic Spontaneous Urticaria: Long-term Results from the REMIX-1/-2 Phase 3 Trials	Abstract #598 Oral Presentation Saturday, March 1 2:35 – 2:45 PM PST
Remibrutinib Treatment Has No Clinical Impact on Mean Blood Cell Counts in Patients With Chronic Spontaneous Urticaria: Pooled Safety Analysis From REMIX-1 and REMIX-2 Studies	Abstract #592 Poster Presentation Sunday, March 2 9:45 – 10:45 AM PST

Key abstracts accepted by AAD include:

Abstract Title	Abstract Number/ Presentation Details
Remibrutinib	
Effect of Remibrutinib on Sleep and Daily Activities in Patients With Chronic Spontaneous Urticaria (CSU) up to Week 52 in the REMIX-1/-2 studies	Abstract #62278 e-Poster with Oral Presentation Friday, March 7 4:55 – 5:00 PM EST
Improvements in Itch and Hive Symptoms With Remibrutinib as Early as Week 1 in Patients With Chronic Spontaneous Urticaria (CSU) in REMIX-1/-2	Abstract #P62280 e-Poster Presentation
Effects of Remibrutinib Treatment on Ambulatory Blood Pressure in Adult Patients With Chronic Spontaneous Urticaria (CSU)	Abstract #62284 e-Poster Presentation
Remibrutinib in patients with moderate to severe hidradenitis suppurativa: Patient reported outcomes from a randomized, phase 2, double-blind, placebo-controlled platform study	Abstract #62279 e-Poster Presentation
Cosentyx	
The impact of continuous secukinumab treatment between weeks 52–104 on draining tunnels in patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE extension trial	Abstract #63334 e-Poster Presentation
The impact of continuous secukinumab treatment between weeks 52–104 on HiSCR75, HiSCR90, and	Abstract #62149 e-Poster Presentation

HiSCR100 in patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE extension trial	
Efficacy of secukinumab uptitration from every 4 weeks to every 2 weeks dosing between weeks 52-104 in week 52 HiSCR non-responder patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE extension trial	Abstract #63451 e-Poster Presentation
The impact of continuous secukinumab treatment through week 104 on efficacy outcomes in patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE core and extension trials	Abstract #64857 e-Poster Presentation
The impact of continuous secukinumab treatment through week 104 on patient reported outcomes in patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE core and extension trials	Abstract #64674 e-Poster Presentation

Product Information
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