UNION THERAPEUTICS

Revolutionizing standard of care in immunology

An introduction to orismilast in hidradenitis suppurativa

December 2024

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Introduction to orismilast

Ole, HS patient

UNION's orismilast aims to change standard of care in Hidradenitis Suppurativa (HS)

Significant opportunity in Hidradenitis Suppurativa (HS) for a safe oral with fast pain relief

- HS affects at least 2m people across the US and EU5 and the HS market is expected to grow to around $4bn by 2034
- Large unmet medical need insufficiently addressed by currently available MoAs with medium efficacy on lesions, limited impact on pain reduction and no benefits for associated cardiovascular comorbidities

Orismilast is a next-generation, oral, high potency, selective PDE4 B/D inhibitor

- PDE4-inhibition **commercially and clinically validated** by successfully marketed drugs
- Next-generation, **higher potency** on multiple inflammatory pathways driven by sub-type selectivity
- PDE4-inhibition associated with metabolic benefits clinically translating to weight reduction

Orismilast potential in HS and beyond

- **First-in-class** opportunity in **hidradenitis suppurativa** with much needed new mode-of-action - **early stage data** indicates potential to have **efficacy on par with or better than existing treatment options**
- **First-in-class** opportunity as **safe oral in atopic dermatitis** with **fast onset on itch**
- **Broad potential across other immunological indications**, leveraging broad MoA coupled with well-established safety profile

IP protection expected to protect orismilast **into 2040s**

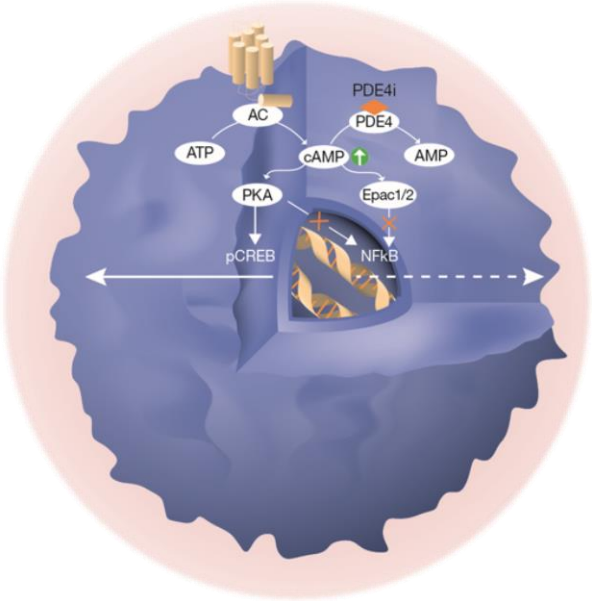
Led by **team with significant clinical development expertise** and more than 15 FDA/EMA approvals, and a scalable, immunology-focused search and development business model

Note: PDE4 = phosphodiesterase type-4. [A] Based on cross-trial comparison of studies to date

PDE4 B/D subtypes are central mediators of inflammation, constituting a promising target for broad cytokine inhibition and therapeutic application within immunology

PDE4 inhibition increases intracellular cAMP

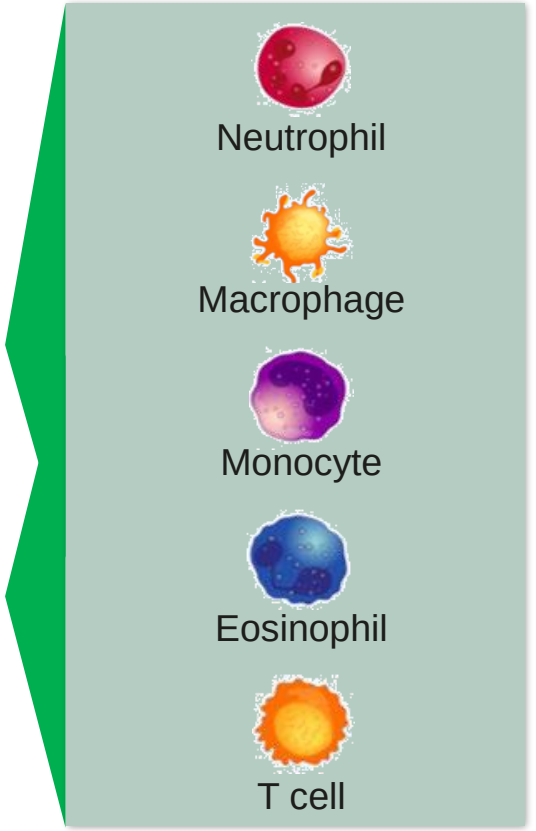
- Increased production of anti-inflammatory mediators by activation of the pCREB pathway
- Reduced production of pro-inflammatory cytokines through inhibition of NFkB pathways



Four PDE4 subtypes are identified

PDE4
- PDE4A
- PDE4B
- PDE4C
- PDE4D

PDE4 B/D subtypes are driving inflammation



Notes: cAMP = Cyclic adenosine monophosphate. pCREB = phosphorylated cAMP response element-binding protein. NFkB = Nuclear factor kappa-light-chain-enhancer of activated B cells.
Sources: Silverberg et al. (2023); Blauvelt et al. (2023)

Orismilast demonstrates potent and selective inhibition of PDE4 B/D subtypes resulting in up to 100x higher potency than Otezla on key cytokines

Orismilast is different from pan-PDE4 inhibitors due to its higher potency on B/D subtypes…

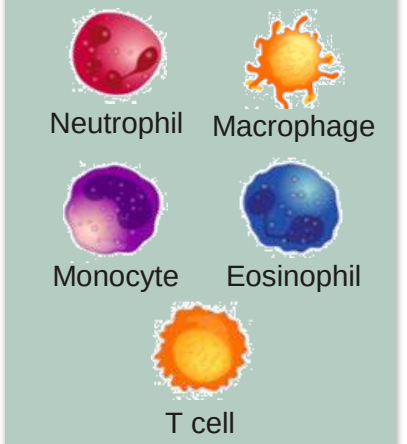
… which are the subtypes mainly found in immune cells…

… enabling suppression of key inflammatory cytokines and inhibition of T_h1, T_h2 and T_h17^B pathways

Drug inhibition of PDE4 subtypes[1]
In vitro IC_{50} values[A] (nM, biochemical assay, low value = high potency)

Subtype	Otezla (apremilast)	ORISMILAST	ORISMILAST vs Otezla (apremilast)
PDE4A	87	26	x3
PDE4B	92	8	x12
PDE4C	244	104	X2
PDE4D	51	7	x7

PDE4B and **D** are the subtypes mainly expressed in immune cells



Inhibition of key cytokines[1]
In vitro IC_{50} values[A] (nM, whole blood, low value = high potency)

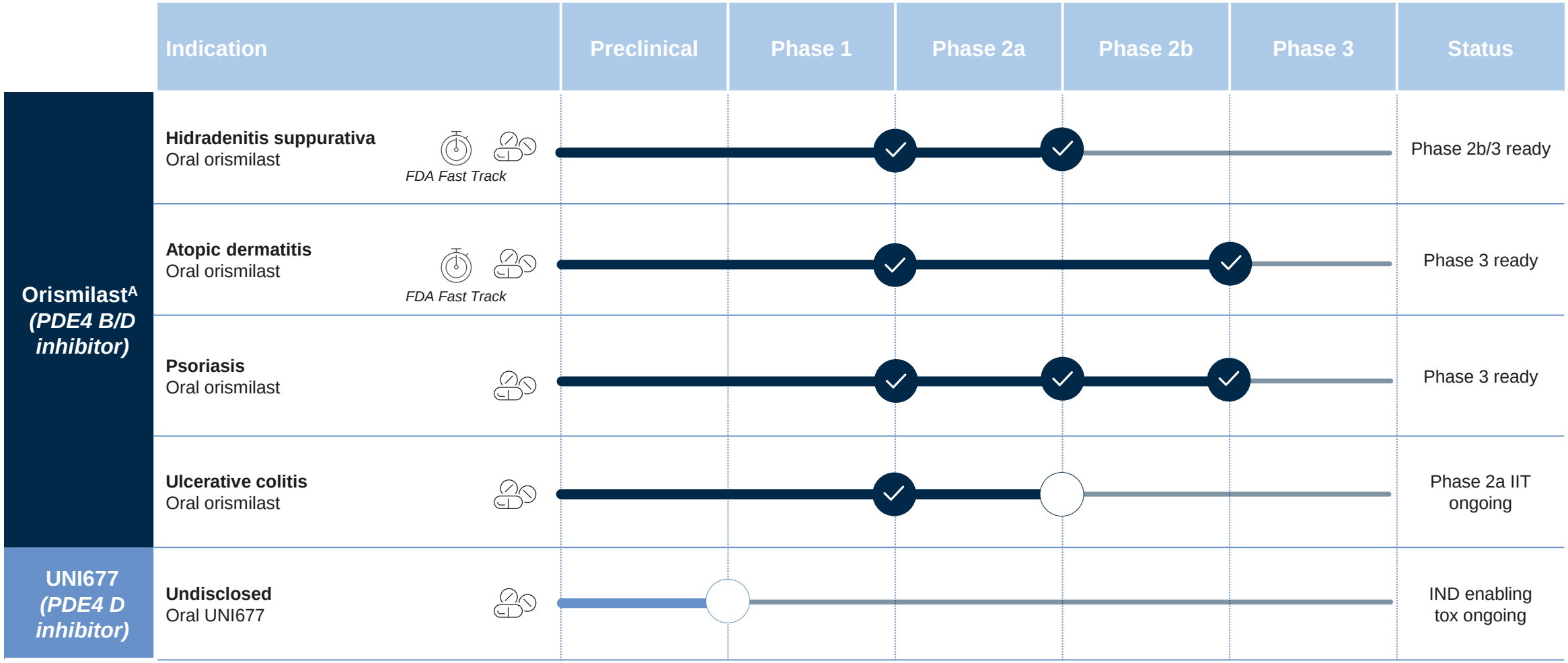
Pathway (relevant diseases)	Cytokine	Otezla (apremilast)	ORISMILAST	ORISMILAST vs Otezla (apremilast)
T_h1, T_h17 (PsO, HS, UC)	TNFα	432	30	x14
	IFNγ	275	3	x92
T_h2 (AD)	IL-4	1 160	~20[C]	x58
	IL-13	880	8	x110

Orismilast is more potent on PDE4-B and PDE4-D subtypes, which are directly related to inflammation[2]

Orismilast inhibits key inflammatory cytokines up to 100x more potently than Otezla

Notes: [A] Average across measured isoforms; [B] Shown in PBMC assays, [C] Estimated IC50 based on 4-point curve
Sources: [1] Silverberg et al. (2023) and UNION data (unpublished); [2] Contreras S., et al. (2017).

UNION is advancing a late-stage clinical pipeline targeting indications with major unmet needs for safe, oral treatments

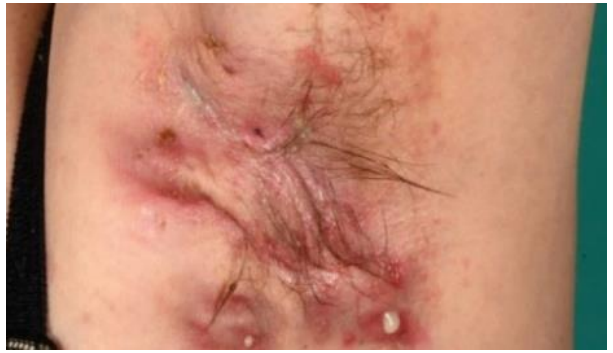


Notes: IIT = Investigator initiated trial; IND = investigational new drug. [A] Innovent Biologics has exclusive rights to orismilast and an option on topical orismilast for China, Hong Kong, Taiwan and Macau; UNION retains remaining worldwide rights.

UNION is initially prioritizing orismilast development in HS and AD with first-in-class safe oral positioning

Hidradenitis suppurativa

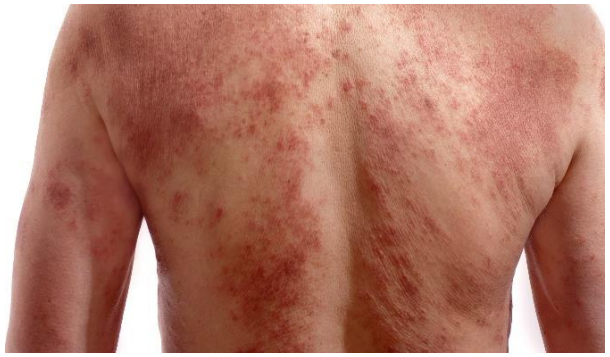
2.1m patients with moderate-severe HS[B]



- **Limited treatment options**
- **No effective oral** available[D]
- Desire for safe, **biologic sparing** option

Atopic dermatitis

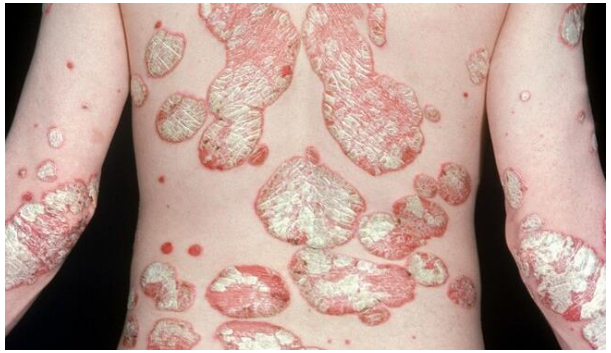
17.4m patients with moderate-severe AD[A]



- **No safe oral** treatments available[C]
- **High non-responder rates** with existing Rx
- **Lack of convenience** with injectables

Psoriasis

8.3m patients with moderate-severe psoriasis[A]



- Need for simple, **efficacious orals** without safety concerns

ORISMILAST *objectives*

First-in-class oral HS treatment with broad inflammatory effects and potential to reduce need for biologics and surgery

First-in-class safe oral AD treatment alternative with broad inflammatory effects and potential 1st line use

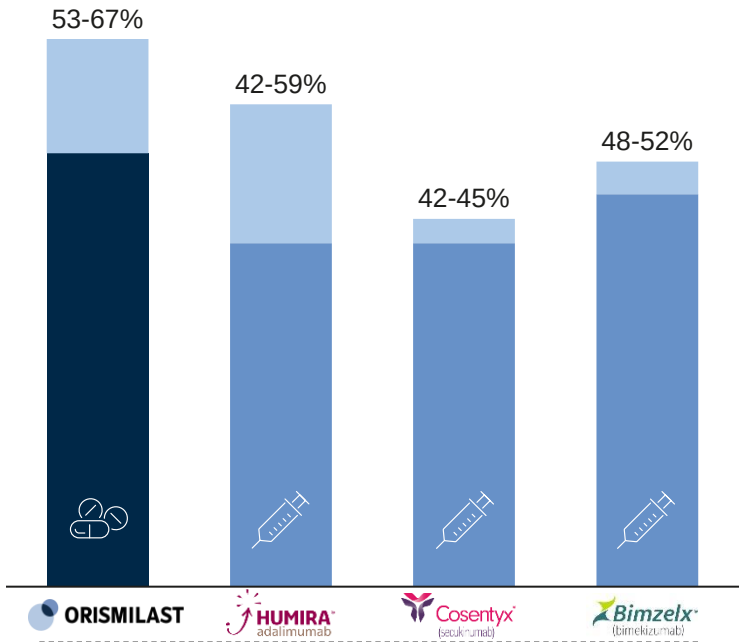
Best-in-class oral psoriasis treatment with higher potency and selectivity driving better efficacy

Notes: [A] Diagnosed patient numbers incl. US, EU5, and Japan, [B] Prevalent patient numbers incl. US and EU5 based on meta-analysis by Phan et al (2020). [C] Two JAKs are approved for oral treatment but carry boxed warnings for increased risk of serious heart-related events, cancer, blood clots and death; [D] Only biologics are approved for HS.
Sources: EvaluatePharma (November 2024)

Compelling efficacy profile of orismilast established across indications tested so far

HS: Orismilast Ph2a IIT data compares favorably to biologics

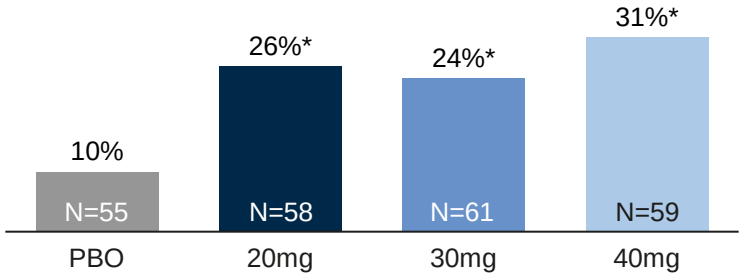
HiSCR50 scores, wk 16



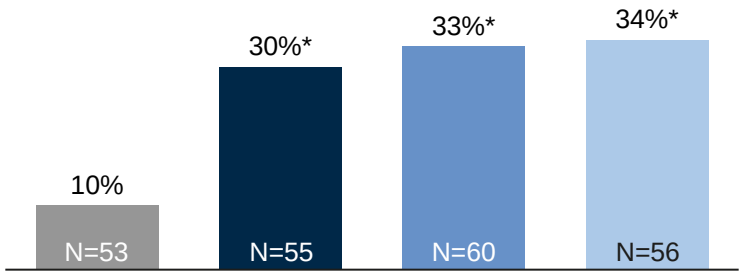
10-40mg BID	40 mg QW	300mg Q2W	320mg Q2W
Ph2a[B]	Ph3[C]	Ph3	Ph3
n=20	n=307/326	n=541/543	n=505/509

Atopic dermatitis: Orismilast Ph2b study demonstrating effect on lesions as well as fast onset of itch reduction

IGA0/1, wk 16 (MI)



Peak pruritus, ≥4-point reduction in NRS, wk 2 (MI)



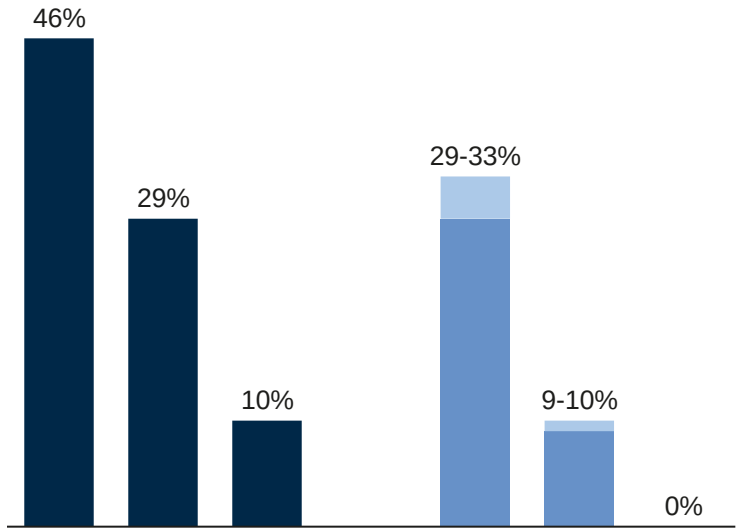
ORISMILAST

Ph2b

n=233

Psoriasis: Orismilast Ph2b study demonstrating a higher and deeper response than previously observed for Otezla

PASI75, PASI90 and PASI100 scores, wk 16,
20/30 mg[A] BID (NRI) for orismilast
30 mg BID (LOCF) for Otezla



ORISMILAST | Otezla (apremilast)

Ph2b	Ph3
n=202	n=844/411

Notes: MI = multiple imputation; NRI = non-responder imputation; LOCF = Last observation carried forward; IIT = Investigator initiated trial; A) Weight-based dosing regimen (n=48); B) Orismilast range based on completers (n=9) and a modified LOCF (subjects with >2 weeks of treatment, n=17); C) Data at W12 for Humira.

Sources: Orismilast study reports OSIRIS , ADESOS, IASOS; Otezla Ph3 studies ESTEEM-1, ESTEEM-2; Sotyktu Ph3 studies POETYK-1, POETYK-2; Cosentyx Ph3 studies SUNSHINE, SUNRISE; Humira Ph3 studies PIONEER-1/2 and Frew JW., et al. (2019); Bimekizumab Ph3 studies BE HEARD-1/2 (AAD, 2023)

Well-established safety and tolerability profile of PDE4-class confirmed in >500 patients to date (across Ph1 and Ph2 studies)

Safety profile confirmed with very few SAEs across larger, controlled Ph2b studies

Pooled safety data across Ph2b trials in AD and psoriasis

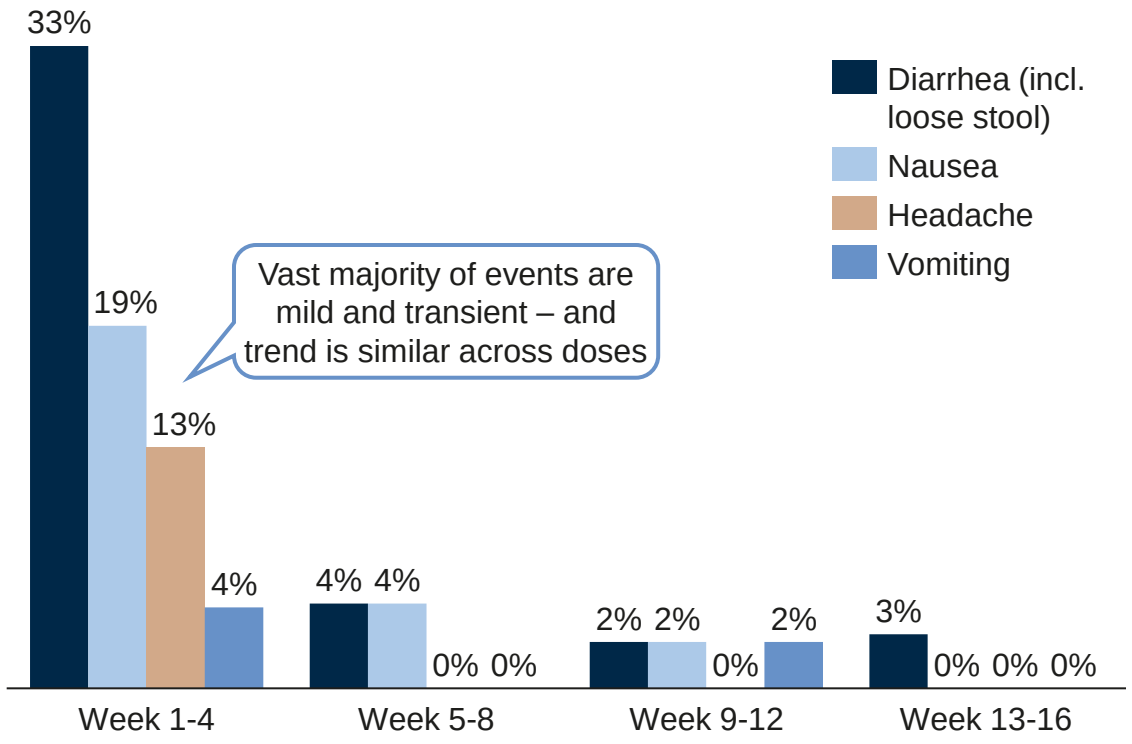
Category	Placebo (N=106)	Orismilast (all) (N=329)
Deaths	0	0
Treatment emergent neoplasms (benign or malignant)	0	0
Treatment emergent serious adverse events	0	4

Only one possible related SAE (from Ph2b in AD): ‘Vasovagal syndrome, pre-syncope and mild hypokalaemia’

System-organ class	*Preferred term*	Placebo	Orismilast (all)
Infections and infestations	All	18%	16%
Psychiatric disorders	All	8%	8%
	Depression	4%	4%

Tolerability profile comparable to that of other marketed PDE4s – mild and transient GI events

Share of patients with event onset in period (20mg orismilast example from Pso Ph2b)



Sources: Orismilast Ph2b study ADESOS; Orismilast Ph2b study IASOS

PDE4-inhibition for hidradenitis suppurativa

Ole, HS patient

Current HS treatment space leaves high unmet need for novel MoAs to address lesions as well as improve core symptom of pain – and ideally also benefit CV comorbidities

Only 2 MoAs approved for HS – significant unmet need persists for novel MoAs

Moderate HS

Severe HS

Antibiotics (off-label)

No oral options exist beyond antibiotics (with limited efficacy)

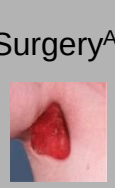
HUMIRA® adalimumab

Cosentyx® (secukinumab)

Bimzelx

Only 2 different MoAs currently approved for HS!

Surgery[A]



1 Need for novel MoAs, incl. orals

*Heterogeneous nature of disease underlines **need for broad set of tools** to treat; existing biologic treatments are **not very efficacious** and currently **no oral treatments** are available*

2 Improvement of QoL and Pain management

***Need for better pain management** illustrated by this being the most critical symptom to patients affecting their life quality; and current treatments not treating it well*

3 Need for safe MoAs with CV benefits

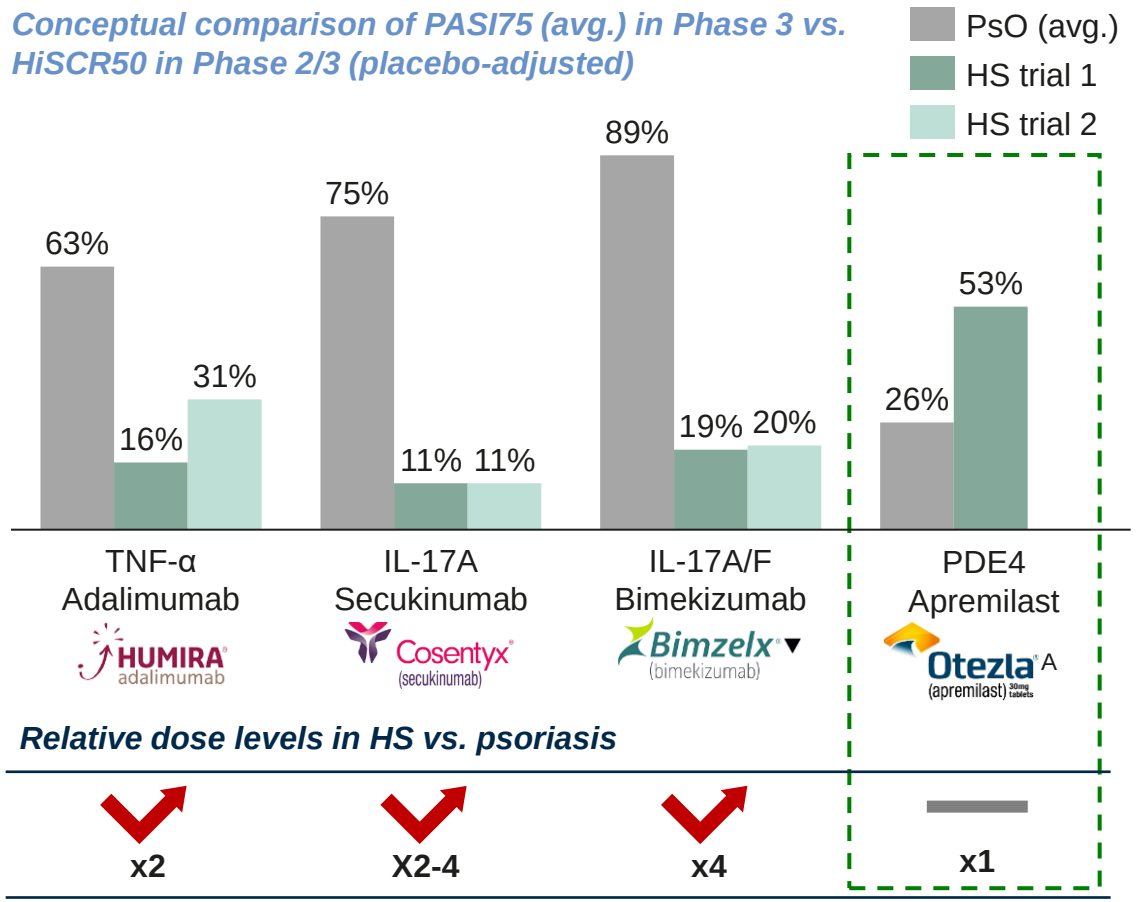
*50-70% of **HS patients suffer from metabolic syndrome** and therefore need treatment with medicines deemed **safe** for this "at-risk" population*

Notes: Humira also available as biosimilar adalimumab. [A] Smaller procedures like drainage and incision also conducted in certain cases with mild-moderate patients.

1 Broad MoA of PDE4-inhibition a good fit with HS; narrow single-cytokine inhibitors have needed 2-4x dosing to obtain substantial efficacy

Single cytokine inhibition seems less effective in HS vs Pso – PDE4 B/D could have significant effect

Conceptual comparison of PASI75 (avg.) in Phase 3 vs. HiSCR50 in Phase 2/3 (placebo-adjusted)



PDE4B/D inhibition is associated with suppression of key HS-related cytokines

Inhibition of cytokines involved in HS by PDE4 inhibition vs marketed competitors

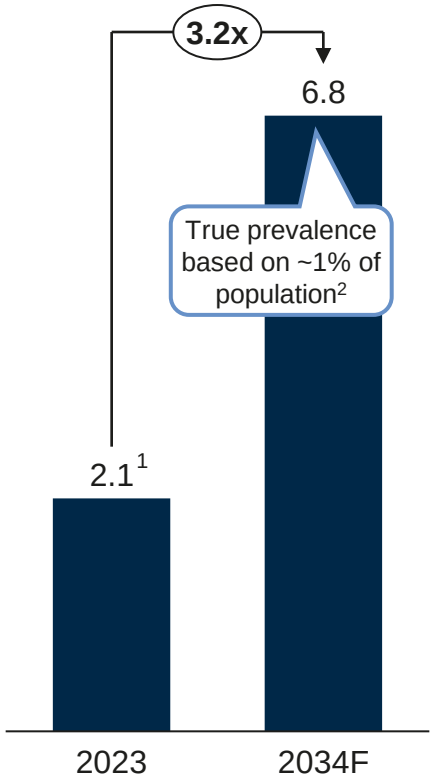
Key cytokines	ORISMILAST	HUMIRA adalimumab	Cosentyx (secukinumab)	Bimzelx (bimekizumab)
TNF-α	✓	✓ ✓	–	–
IFN-γ	✓	–	–	–
IL-1β	✓	(✓)	–	–
IL-6	✓	(✓)	–	–
IL-8	✓	(✓)	–	–
IL-17	✓	–	✓ ✓	✓ ✓
IL-23	✓	–	–	–
TGF-β	✓	–	–	–

Notes: [A] Apremilast (Otezla) not approved for treatment of HS.
Sources: Dalamaga M., et al. (2020); Au BT., et al. (1998); Vossen ARJV, et al. (2018); Humira SmPC; Otezla SmPC; Daxas SmPC; Vossen ARJV., et al. (2019); Rumberger BE., et al. (2020); Kim J., et al. (2018); FDA- and EMA-issued product labels and Ph2/3-Ph3 publications.

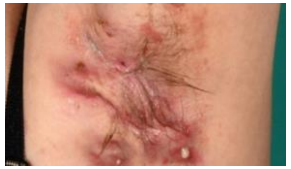
2 HS severely impacts life quality especially due to pain symptoms and affects at least ~2m people across the US and EU5 countries

HS patient count expected to more than double over next decade

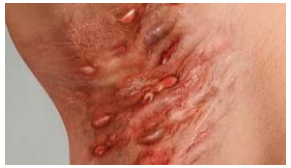
Number of moderate-severe HS patients across US & Europe (m)



Example of moderate HS
(est. 42% of total)[3]

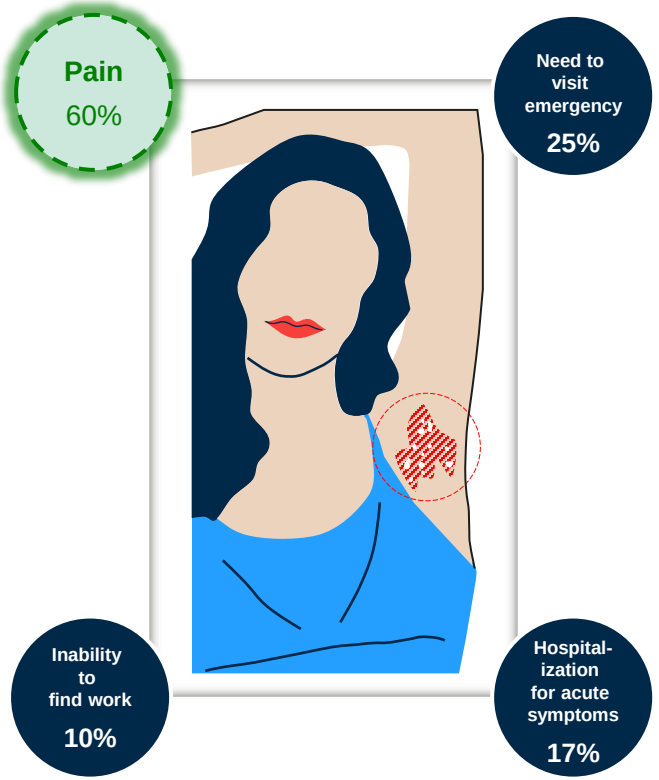


Example of severe HS
(est. 22% of total)[3]



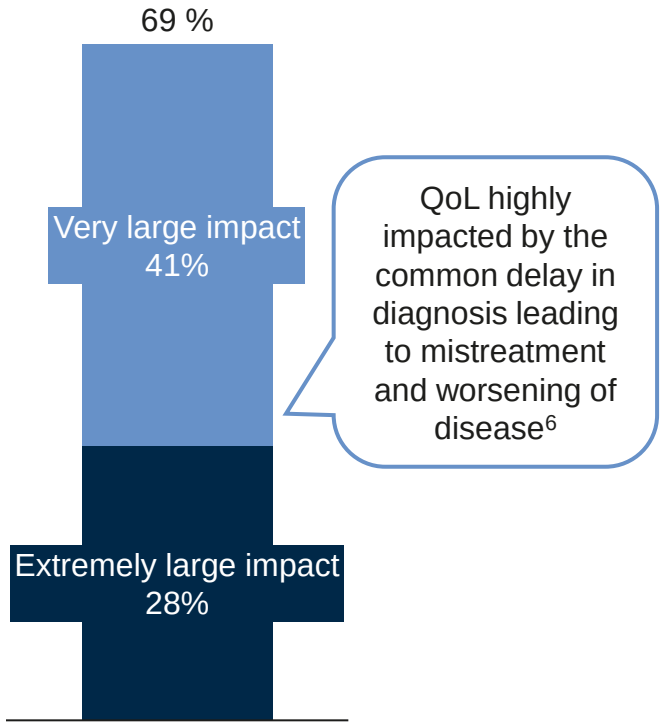
Pain relief is critical to patients with HS

HS patients deem pain to be the most problematic symptom (by share of resp.)[4]



HS is a stigmatized disease with high impact on Quality of Life (QoL)

Share of HS patients with very large / extremely large impact on QoL[5]



Sources: [1] Prevalent patient numbers incl. US and EU5 based on meta-analysis by Phan et al (2020). [2] Jfri et al (2021); Phan et al (2020); Delaney et al (2018); Ingram et al (2018); Theut Riis et al (2019). [3] Spherix HS whitepaper (Nov 2024). [4] [1] Garg, et al., (2020). [5] HS Uncovered: Results from a global survey revealing patient perspective in hidradenitis suppurativa. EADV 2023. Berlin. [6] Kokolakis et al (2020)

3 Beneficial metabolic effect of PDE4B/D inhibition is an important differentiator from biologics and JAKs in HS

PDE4s target metabolic pathways similarly to GLP1s

- PDE4-inhibition directly impacts energy sensors and metabolism in metabolic cell types
- Most important isoform is PDE4-D5 for metabolic effects, where orismilast has 18 times the potency for PDE4-D5, compared to apremilast
- Non-clinical cell assay indicates that, at Ph3 dosing, orismilast stimulates metabolic cells similarly to oral semaglutide (Rybelsus) 14 mg daily

HS patients are commonly overweight and have CV disease

- **68.7% of HS patients in the US are obese** (vs. 29.8% in the background population)[2]
- Danish HS patients have nearly **4 times higher odds ratio** for metabolic syndrome[3]
- HS patients in a Danish cohort study (n=5964) had **double the risk of CV-associated death**[4]
- In conclusion, many HS patients will likely not be able to use JAKs* due to increased risk of major cardiovascular events and thrombosis

Clinically orismilast and other PDE4s have impacted weight

- Apremilast has clear CV benefits in recent publication at EADV 2024[1]
- Consistent weight loss observations in clinical trials with orismilast
  - **Mean weight loss in the HS pts. completing 16 weeks treatment with orismilast was 4.8 kg**
  - Weight loss on par with oral semaglutide (Rybelsus) 14 mg daily

Note: *) The JAK class is still in development for HS with no marketed drugs to date. Boxed warning is included for all approved oral JAKs in dermatogological indications.

Souces: [1] Treichel et al., EADV Amsterdam (2024); [2] Balgobind et al.(2020); [3] Miller et al. (2014); [4] Egeberg et al. (2016)

Orismilast in hidradenitis suppurativa

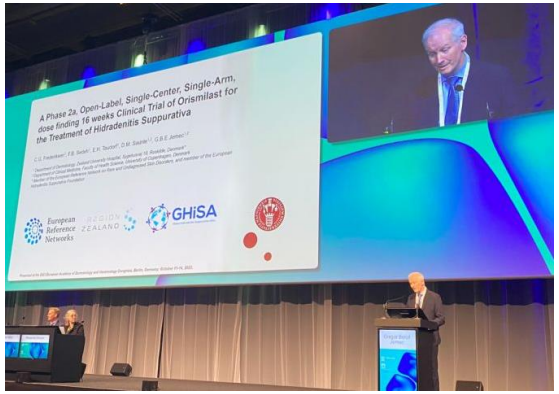
Ole, HS patient

The OSIRIS study was sponsored by global KOL Professor Gregor Jemec to generate clinical proof-of-concept with orismilast in HS

OSIRIS was an exploratory, open-label, single-center, single-armed trial

Objectives

- To explore safety and efficacy of oral orismilast in the treatment of HS
- To explore tolerability of the proposed dosing regimen in patients with HS



Prof. Gregor Jemec

PhD, MD, Lead investigator of the OSIRIS study

Most cited KOL in the HS field

Eligibility

- Diagnosis of mild, moderate and severe HS
  - Abscesses and nodules (AN) count ≥2
  - Draining fistula count ≤30
- Age 18+
- Any prior treatment was allowed

Design

Orismilast tablet
10-40 mg BID, N=20

Follow up

16 weeks (Titration[A])

14 weeks

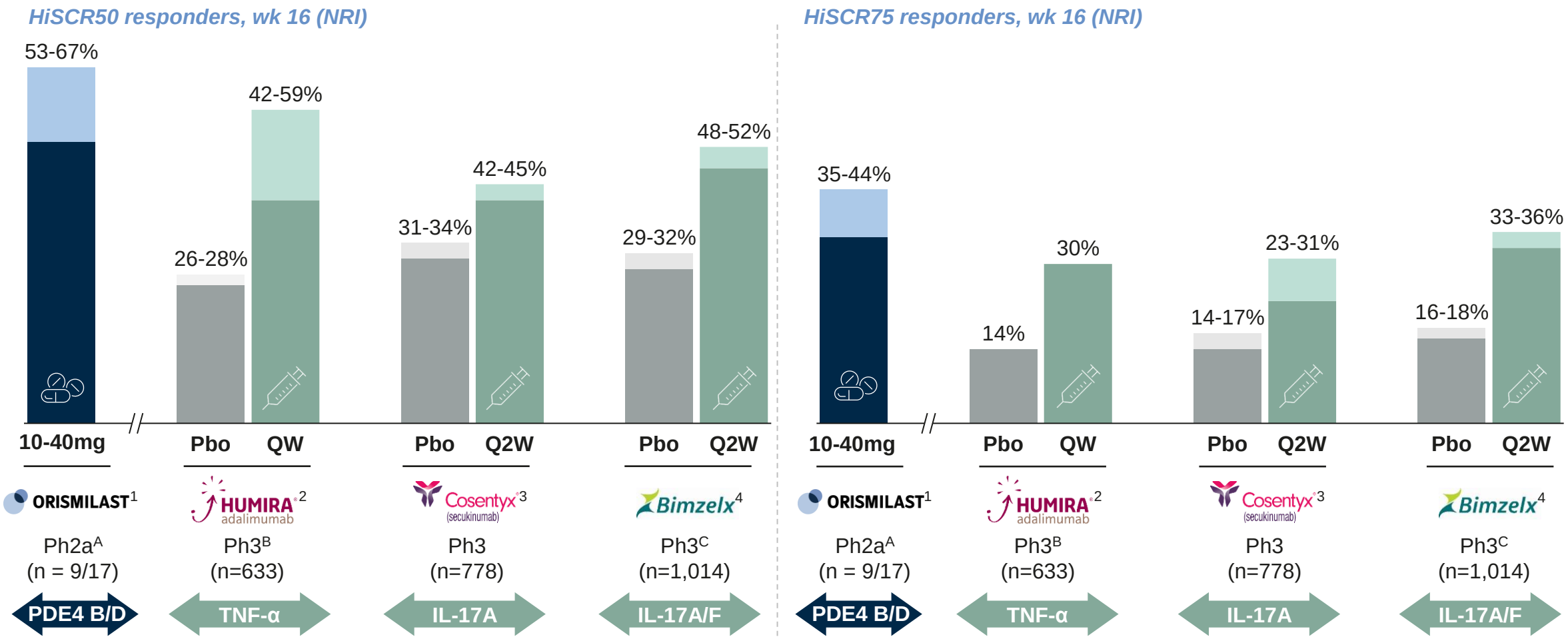
Key endpoints

Efficacy (at week 16)
- Change in AN and lesion count
- Share achieving HiSCR50/75 at week 16
- Change in global pain and QoL

Safety and tolerability
- Occurrence of treatment emergent adverse events (TEAE)

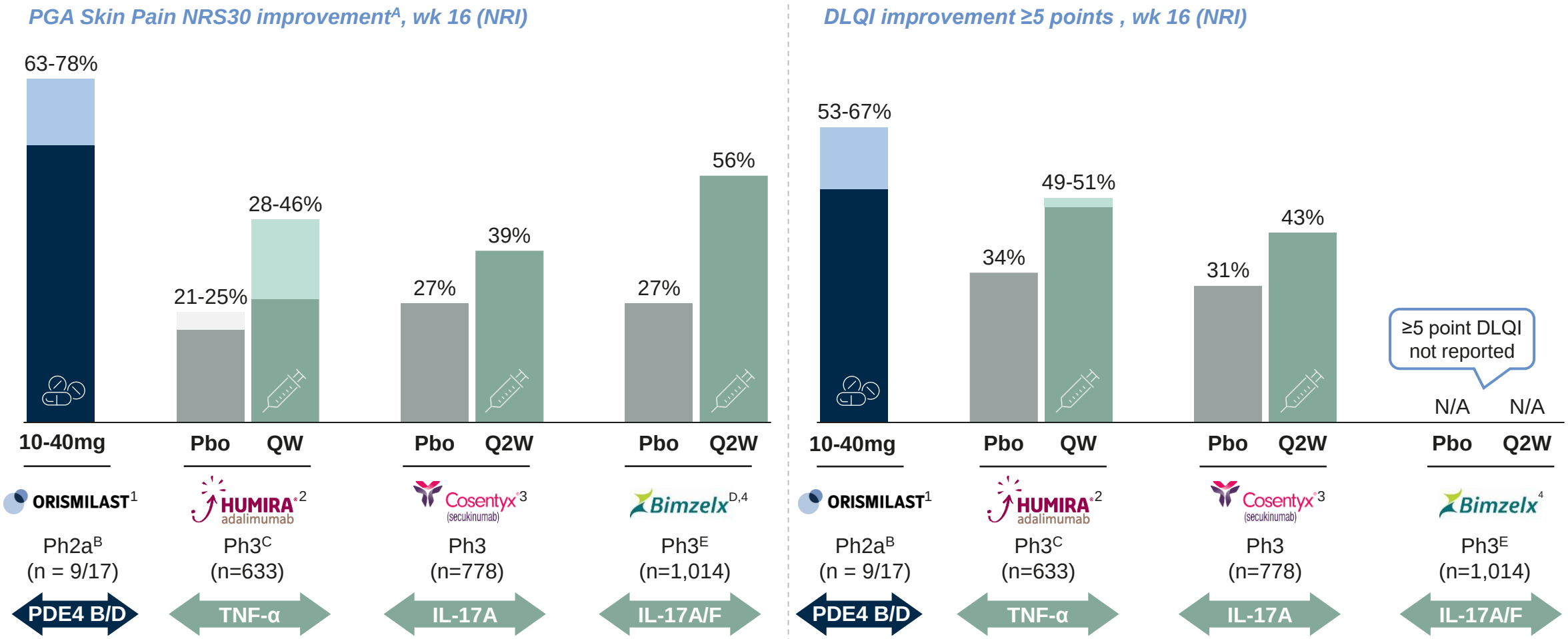
Notes: [A] Orismilast was initially titrated from 10 mg BID to 40 mg BID during the first 17 days, but later more flexibility was allowed in titration.
Sources: Orismilast IIT, PoC study OSIRIS (NCT04982432).

Indirect comparison between orismilast data and results for marketed HS drugs shows promising efficacy on lesions…



Notes: [A] Orismilast range based on completers (n=9) and a modified LOCF (subjects with >2 weeks of treatment (n=17). [B] Week 12 data. [C] mNRI for bimekizumab.
Sources: [1]Orismilast IIT, PoC study OSIRIS (completed from Frederiksen et al (2023), mLOCF not published) [2] Kimball et al (2016) [3] Kimball et al (2023) [4] Kimball et al (2024)

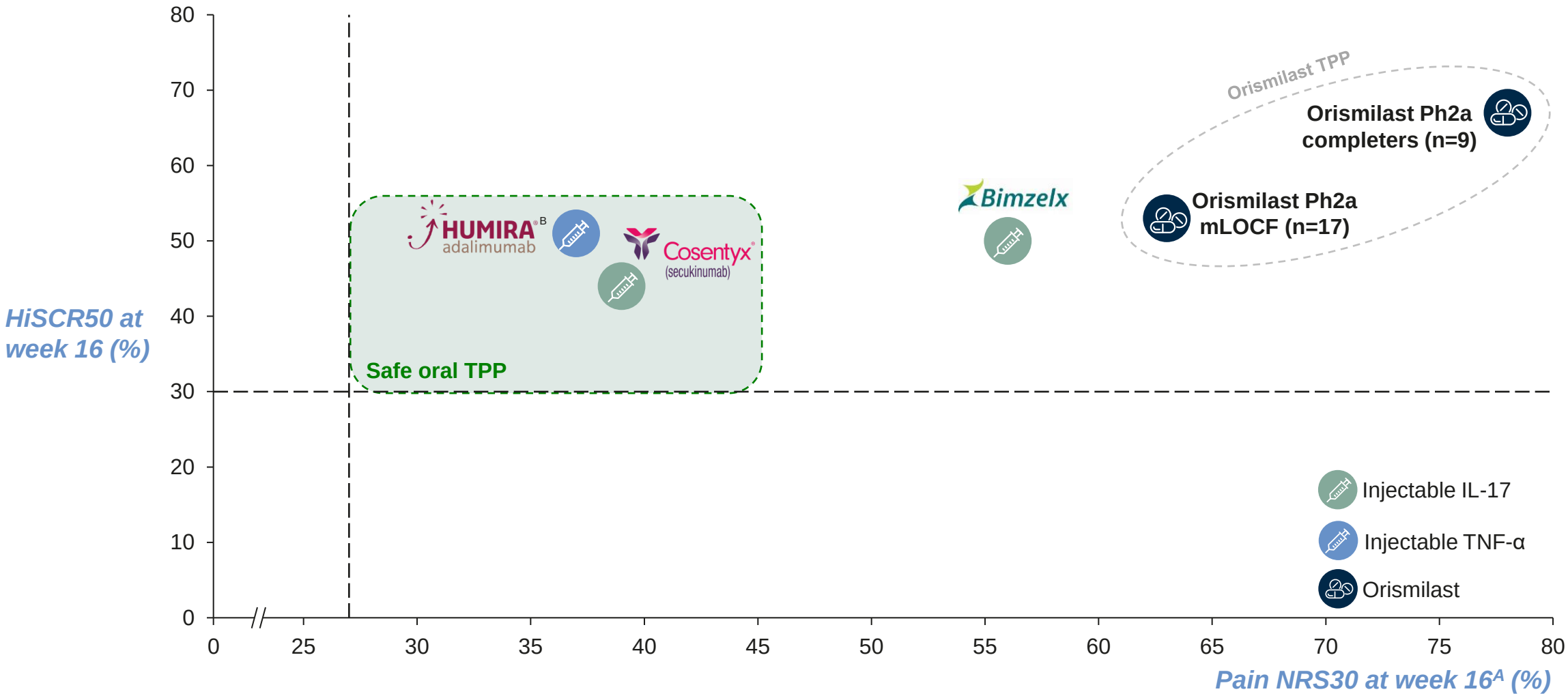
As well as on pain and life quality – key symptoms affecting the lives of HS patients



Notes: Baseline severity of kin Pain NRS score ≥3; Cosentyx (na.), Humira (DLQI score of ≥5); [A] Criteria vary slightly across trials. Humira requires 1-unit pain reduction, Cosentyx a 2-unit pain reduction. [B] Orismilast range based on completers (n=9) and a modified LOCF (subjects with >2 weeks of treatment (n=17). [C] Week 12 data. [D] Worst skin pain measured by HSSDD (HS Symptom Daily Diary) instead of skin pain NRS. ≥30% improvement and ≥1-point reduction. [E] mNRI for bimekizumab.

Sources: [1] Orismilast IIT, PoC study OSIRIS (not published) [2] Kimball et al (2016) [3] Kimball et al (2023) [4] Orenstein et al. (poster: Bimekizumab impact on pain moderate to severe hidradenitis suppurativa: Week 16 results from BE HEARD I&II, SHSA 2023 – mNRI)

Orismilast shows promising potential based on OSIRIS Ph2a data – comparable to best-performing biologics in development



Notes: Patient's Global Asssessment used for pain imputations across trials except Bimzelx, where Hidradenitis Suppurativa Symptom Daily Diary (HSSDD), a similar score, is used. [A] Pain NRS30 refers to share of patients achieving ≥30% and ≥1 point reduction in pain among those with NRS score ≥3 at baseline. [B] Week 12 data for Humira, week 16 for other compounds.
Sources: Ph3 publications (NRI except Cosentyx is MI and Bimzelx is mNRI); Orismilast Ph2a study (OSIRIS); HS TPP market research (Sermo, N=51, February 2024)

Next steps: UNION aims to further develop orismilast for HS in a Ph2b program designed to have upside potential as one of the pivotal trials

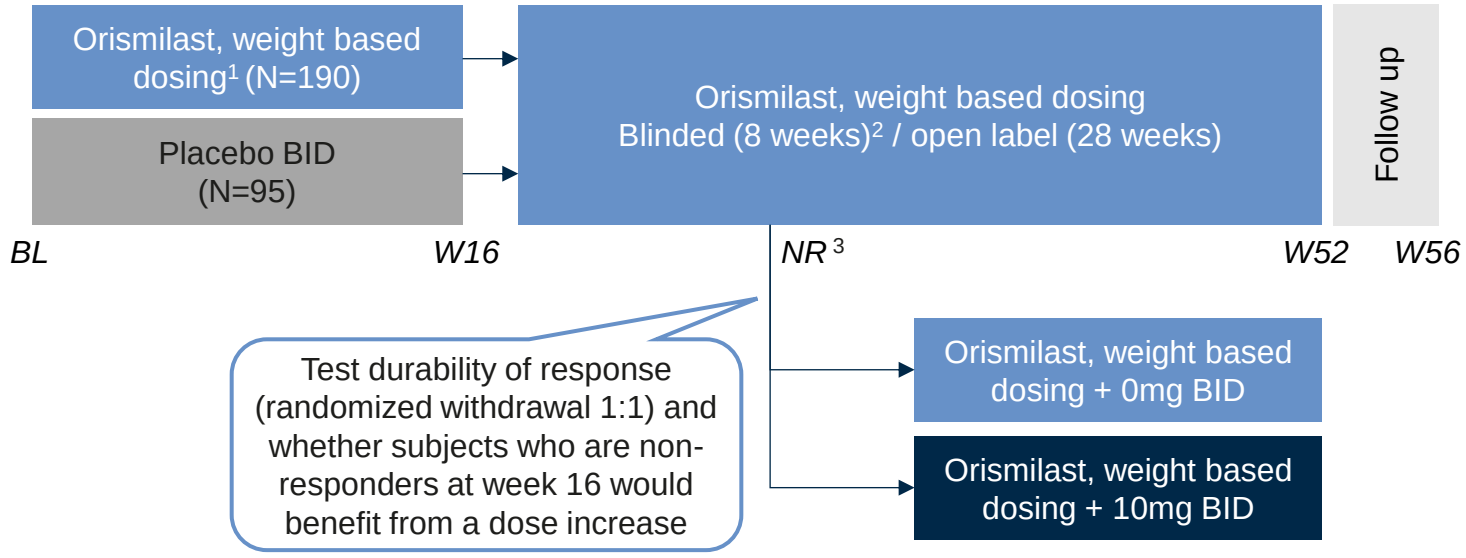
HS Phase 2b randomized, double-blinded trial

Key eligibility criteria

- HS lesions in at least 2 distinct anatomic areas
- Total AN count ≥6 at both the Screening and Baseline visits
- Cannot have >20 draining tunnels (fistulas) at either the screening or baseline visit

Phase 2b

Randomisation (2:1)



Key Objectives

- Efficacy of orismilast compared to placebo at Week 16
- Long-term efficacy and safety of twice-daily oral orismilast up to Week 52
- Efficacy of orismilast on metabolic comorbidities

Key Endpoints

- Achieving HiSCR50 at Week 16
- Change in number of draining fistulas from baseline Week 16
- Reduction in skin pain
- Reduction in body weight and HbA1c

Notes: BID = twice daily; BL = baseline; HiSCR = Hidradenitis Suppurativa Clinical Response; NR: Non-response. [1] Orismilast weight-based dosing: 10mg (<60kg), 20mg (≥60 to <100kg) or 30mg (≥100kg). Dose titration with once-daily dosing for the first 2 weeks and highest dose from Week 8 for participants ≥100kg. [2] Titration of participants coming from the initial 16 weeks placebo treatment to maintain trial integrity. [3] Response defined as HiSCR50 achieved without prohibited medication.

Thank you for your attention

UNION THERAPEUTICS