



## CONTROLLING INFLAMMATION

R&D Event:  
Vilobelimab and Hidradenitis  
Suppurativa

February 3, 2022



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# AGENDA

INTRODUCTION & OVERVIEW

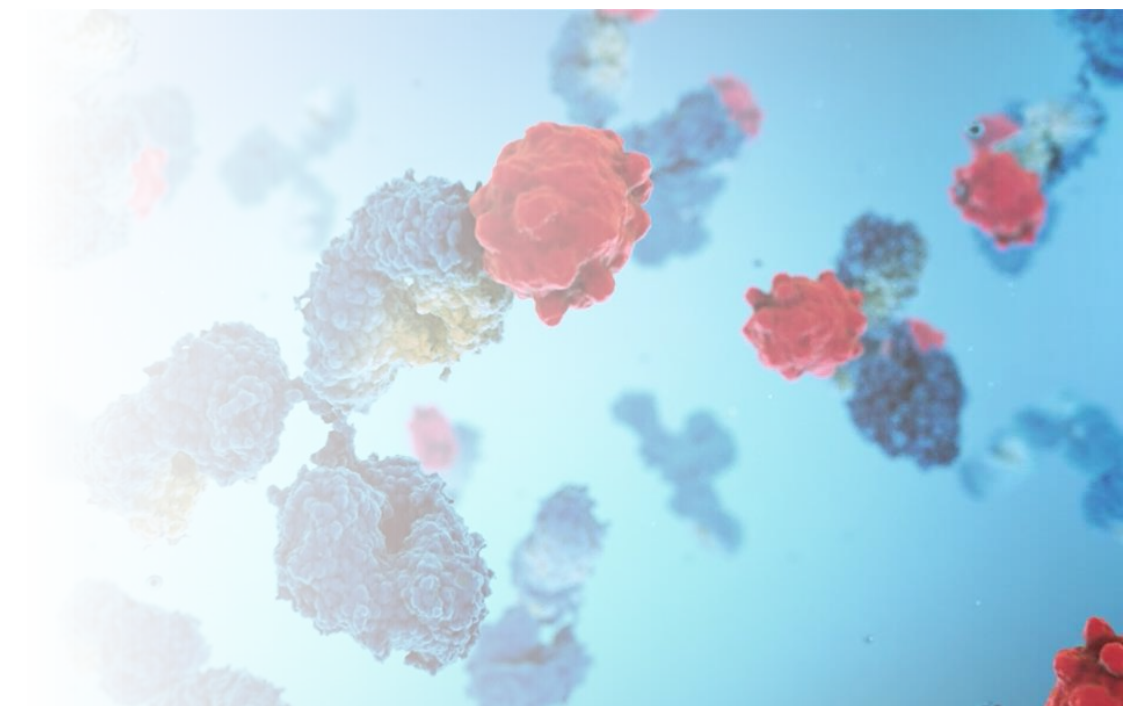
HIDRADENITIS SUPPURATIVA (HS)

VILOBELIMAB OVERVIEW AND MODE OF ACTION

SHINE STUDY RESULTS & LEARNINGS

NEW ENDPOINT m-HiSCR & PHASE III DEVELOPMENT

Q&A



# Speakers



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University of North Carolina School of Medicine, Chapel Hill, NC



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Chief Executive Officer, InflaRx



**JORDAN ZWICK**

Chief Strategy Officer, InflaRx



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Chief Clinical Development Officer, InflaRx



**HODA TAWFIK, PH.D.**

Senior Program Director Dermatology, InflaRx



**Lead product candidate entering pivotal testing, focus on immuno-dermatology**

### Clinical Efficacy and Clean Safety Profile Enabling Vilobelimab to Advance in Multiple Indications

- **Hidradenitis Suppurativa (HS):** Initiated **pivotal Phase III study in Q1 2022** based on supportive FDA feedback
- **Severe COVID-19:** Phase III trial enrollment completed; **topline data expected in Q1 2022**
- **Pyoderma Gangraenosum (PG):** Positive Phase IIa data – to seek regulatory advice on next steps for pivotal program
- **Cutaneous squamous cell carcinoma (cSCC):** Phase II study ongoing
- **ANCA-associated vasculitis (AAV):** Positive Phase II data enabling further development

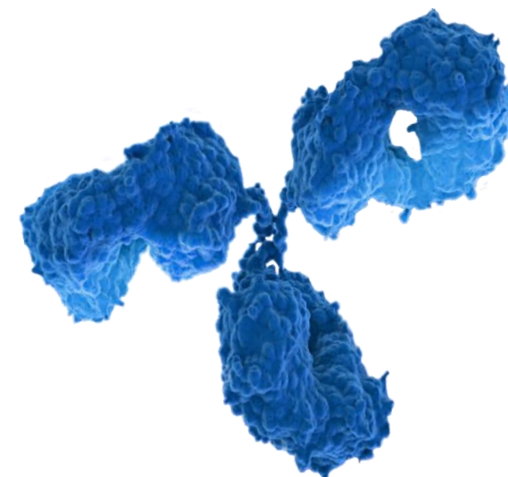
### Proprietary Anti-C5a Technology with Strong Patent Coverage

- Patent protection until end of 2030 / 2035 with extension








### New Program INF904: Oral C5aR Inhibitor to Enter Clinic in H2 2022

- Promising activity and clean safety profile in pre-clinical models
- Best-in-class potential
- US patent issued in October 2021

### Strong Cash Balance of €120.6 Million to Drive Programs Forward



# Pipeline with Multiple Opportunities

	FRANCHISE	INDICATIONS	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	UPDATE
<b>Vilobelimab (IFX-1)</b> <i>C5a Inhibitor</i>	Immunodermatology	Hidradenitis Suppurativa (HS)					<ul style="list-style-type: none"> <li>Phase IIb completed</li> <li>Pivotal trial initiated with new primary endpoint</li> </ul>
		Pyoderma Gangraenosum (PG)					<ul style="list-style-type: none"> <li>Positive Phase IIa open label results</li> </ul>
	Life-threatening Inflammatory Diseases	Severe COVID-19					<ul style="list-style-type: none"> <li>Phase II/III study: Phase II results published; Phase III fully enrolled, topline data expected Q1 2022</li> </ul>
		ANCA-Associated Vasculitis (AAV)					<ul style="list-style-type: none"> <li>Phase II: Positive data in both the US and EU trials</li> </ul>
	Oncology	Cutaneous Squamous Cell Carcinoma (cSCC)					<ul style="list-style-type: none"> <li>Phase II trial: First patient dosed in June 2021</li> </ul>
<b>IFX-2</b> <i>C5a Inhibitor</i>	Undisclosed Chronic Inflammatory and Autoimmune Diseases						<ul style="list-style-type: none"> <li>Developing for optimized use for other chronic inflammatory indications</li> </ul>
<b>INF904</b> <i>Oral C5aR Inhibitor</i>							<ul style="list-style-type: none"> <li>First-in-human study to be initiated in H2 2022</li> </ul>

A photograph of a modern building at night, featuring large glass windows and balconies. The interior lights are on, and the building's structure is visible against the dark sky.

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DISCOVERY

COMPLEMENT

# Hidradenitis Suppurativa (HS)

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Disease Overview & Patient Quality of Life – Dr. Christopher Sayed



# Hidradenitis Suppurativa (HS)

Debilitating neutrophil-driven inflammatory skin condition with high unmet need

## Diagnostic Criteria

- Classic lesions: abscesses, nodules, tunnels
- Predilection for intertriginous sites: axillae, groin, buttocks, inframammary
- Recurrent for years

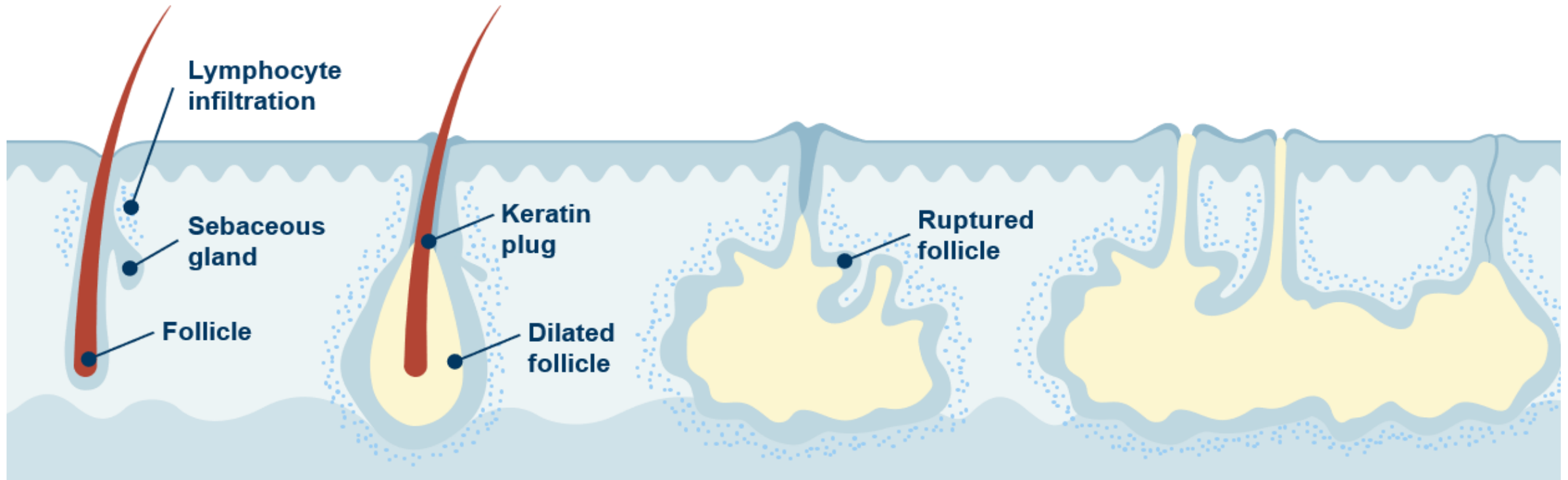
## Clinical Features

- Draining tunnels leading to considerable scarring and functional disability
- Abscesses and nodules are acutely painful
- Can result in physical disability and disfiguring scarring
- Prevalence in the US and Europe is likely 0.7-1.2%
- Likely > 200,000 moderate to severe HS patients in US





# HS Progression



**1.** Perifollicular inflammation

**2.** Hyperkeratinization of follicular epithelium with occlusion and dilation of the follicle

**3.** Follicular rupture and release of intrafollicular debris into the dermis with increased inflammation

**4.** Formation of tunnels (sinus tracts and fistulas) filled with debris and/or fluid that connect to the surface of the skin and to the base of other ruptured follicles

Adapted from: Saunte DML, Jemec GBE. JAMA. 2017;318(20):2019-2032

# Hurley Staging



## Stage I

Single / multiple abscesses  
but no sinus tracts or  
scarring



## Stage II

Single or multiple separated,  
recurrent abscesses with  
tract formation and scarring



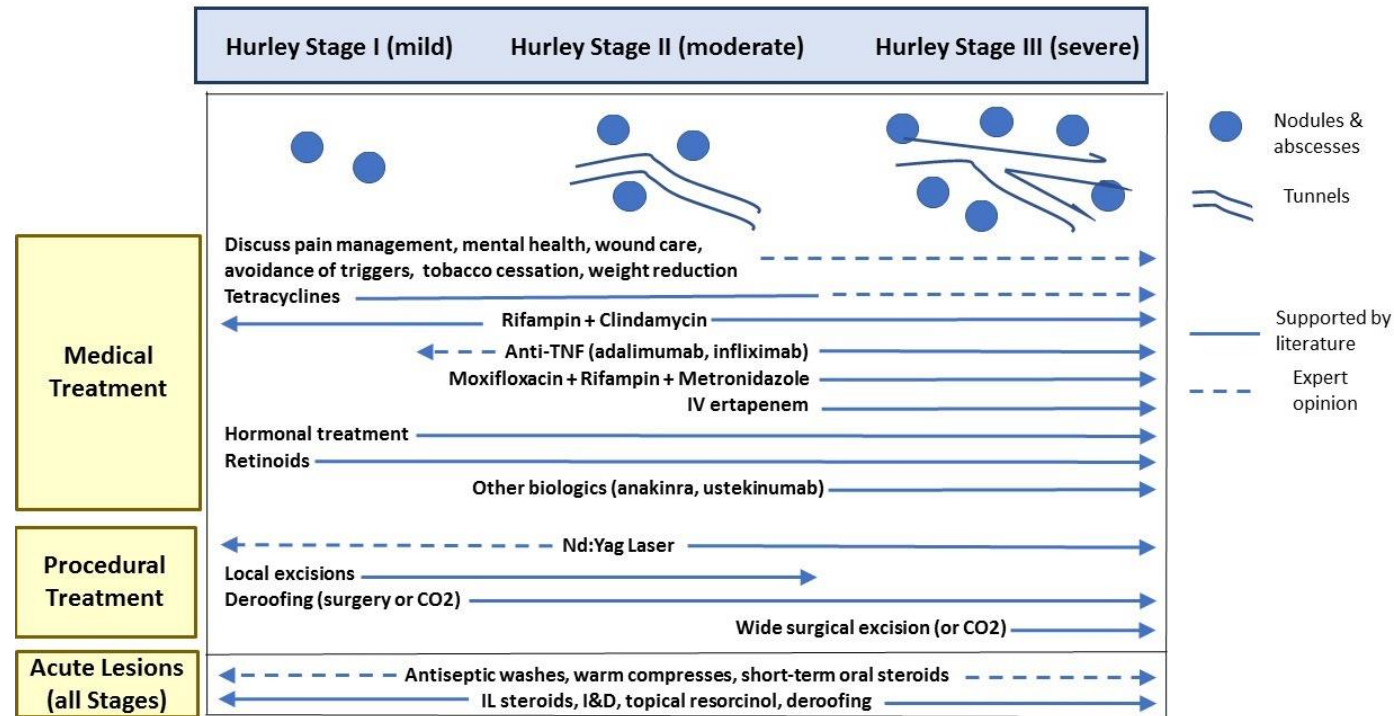
## Stage III

Multiple interconnected  
tracts and abscesses  
involving an entire anatomic  
region

# Current Treatment

## Adalimumab (Humira) is the only FDA-approved treatment:

- 50% of patients achieving response measure by HiSCR50 at week 12 of treatment
- The delta in response rate between placebo and active group was only about 25 – 30%
- 50% of the responders lose response over the first year of treatment



Alikhan A, Sayed C, et al. J Am Acad Dermatol. 2019 Jul;81(1):76-90.  
doi: 10.1016/j.jaad.2019.02.067. Epub 2019 Mar 11., PMID: 30872156.



# Hidradenitis Suppurativa

The disease is characterized by 3 inflammatory skin lesions (the matrix for all physician rated scores developed) most frequently present in the groin areas, genitals, the buttock and the armpits:

1. **Inflammatory Nodules (N)** = most frequent lesion, least impact on QoL (pain, discomfort)
2. **Abscesses (A)** = less frequent lesion, higher impact on QoL (pain, pus + smell when opening)
3. **Draining tunnels (DT)** = most severe lesion, highest impact on QoL (pain, constant pus + smell)

HS is considered a life-destroying disease with the highest impact on quality of life (QoL) amongst chronic skin diseases.

Treatment: There is only 1 drug approved Humira® (adalimumab) but this drug leaves the majority of patients with no long-term treatment benefit: There is an immense medical need.

# Impact of Lesion Type on Patient's Daily Life

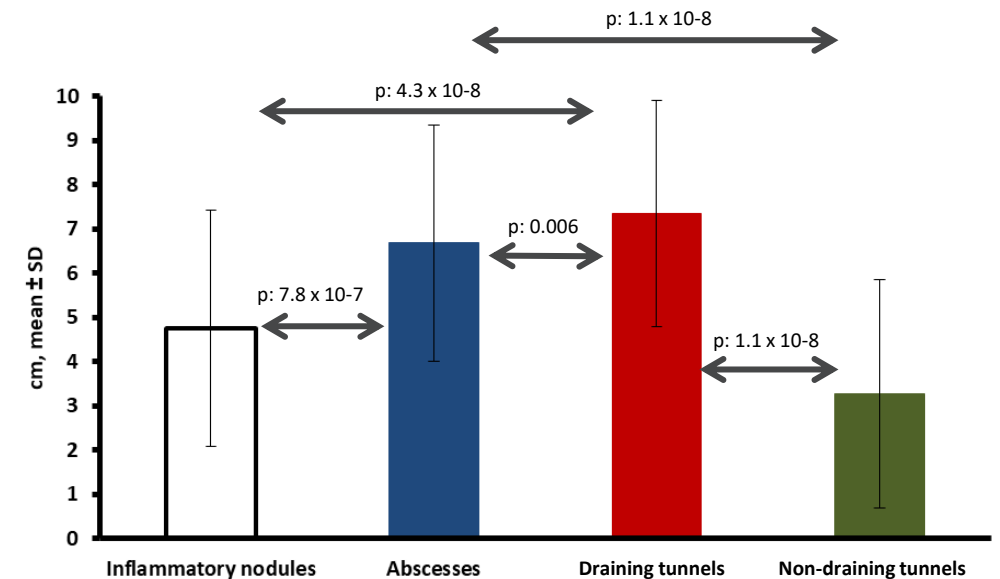
## New study on patient's global impression on impact of inflammatory lesions as well as non-dT

### Recent work\* with patient questionnaire:

- 73 patients who experienced all three inflammatory lesions in their history, rated lesions on a visual analogue scale with 0 being no impact of disease and 10 being the worst negative impact on their lives
- dTs are the inflammatory lesions with highest perceived negative impact on patient's life and persist months-years
- Non-dTs have a minor impact similar to scar

### Former studies\*\* reported that:

- Drainage was the most frequent symptom (71.8%) reported by patients as impacting quality of life (n = 1299 patients)
- Other important frequent symptoms were moderate to severe pain (61.4%), fatigue (61.0%), and odor (53.8%)



## Patients see draining tunnels as the lesion most negatively impacting their lives

\* Mouktaroudi et al, Impact of Individual Lesions of Hidradenitis Suppurativa in the Quality of life, EHSF 2021

\*\* Thorlacius et al. 2018 & Global Voice Study, Garg et. al. 2020

# HS Impact

- Typical onset in teens/20s
- Devastating impact on social and intimate relationships
- Physical disability can negatively impact school and work performance and attendance

➤ **Linked to job loss and lower socioeconomic status**

➤ **Linked to high rates of depression, anxiety, and increased risk of suicide**

Matusiak, L. (2020). "Profound consequences of hidradenitis suppurativa: a review." Br J Dermatol 183(6): e171-e177.

Yao, Y., et al. (2020). "Work productivity and activity impairment in patients with hidradenitis suppurativa: a cross-sectional study." Int J Dermatol 59(3): 333-340.

Bailey, A. M. J., et al. (2021). "Hidradenitis suppurativa and socioeconomic status." Int J Dermatol 60(12): e502-e504

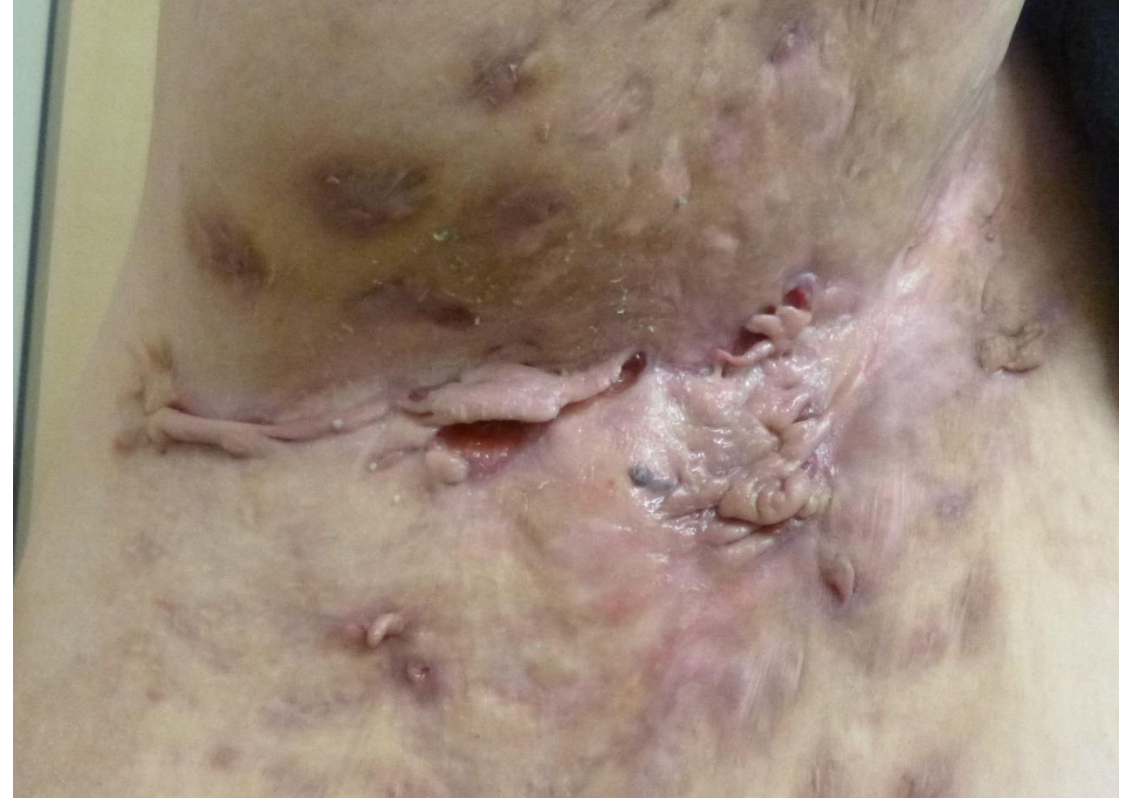


## Impact of Treatment\*



\* Based on HS standard of care treatment

## Impact of Treatment\*



\* Based on HS standard of care treatment

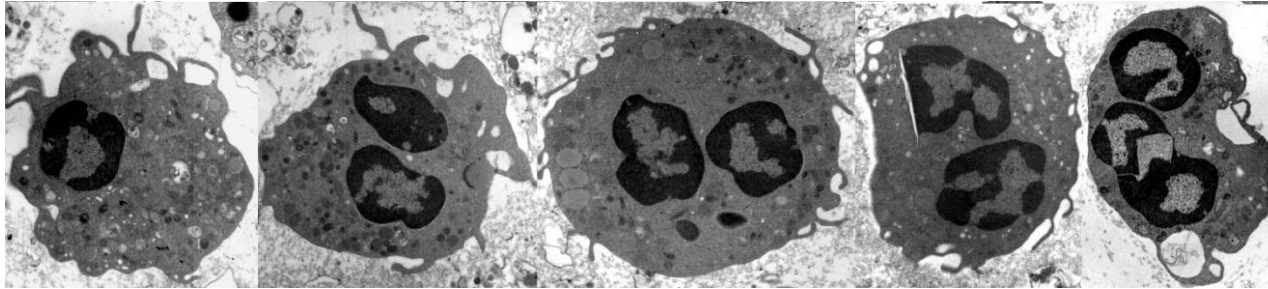


# Neutrophil Activation by C5a

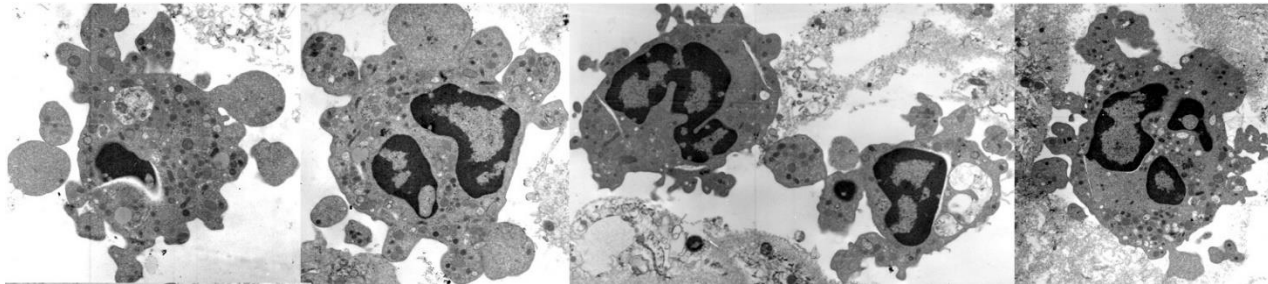


## NEUTROPHILS (4,600X ENLARGED)

control



+ C5a



Data Source: Prof. Peter Ward, University of Michigan

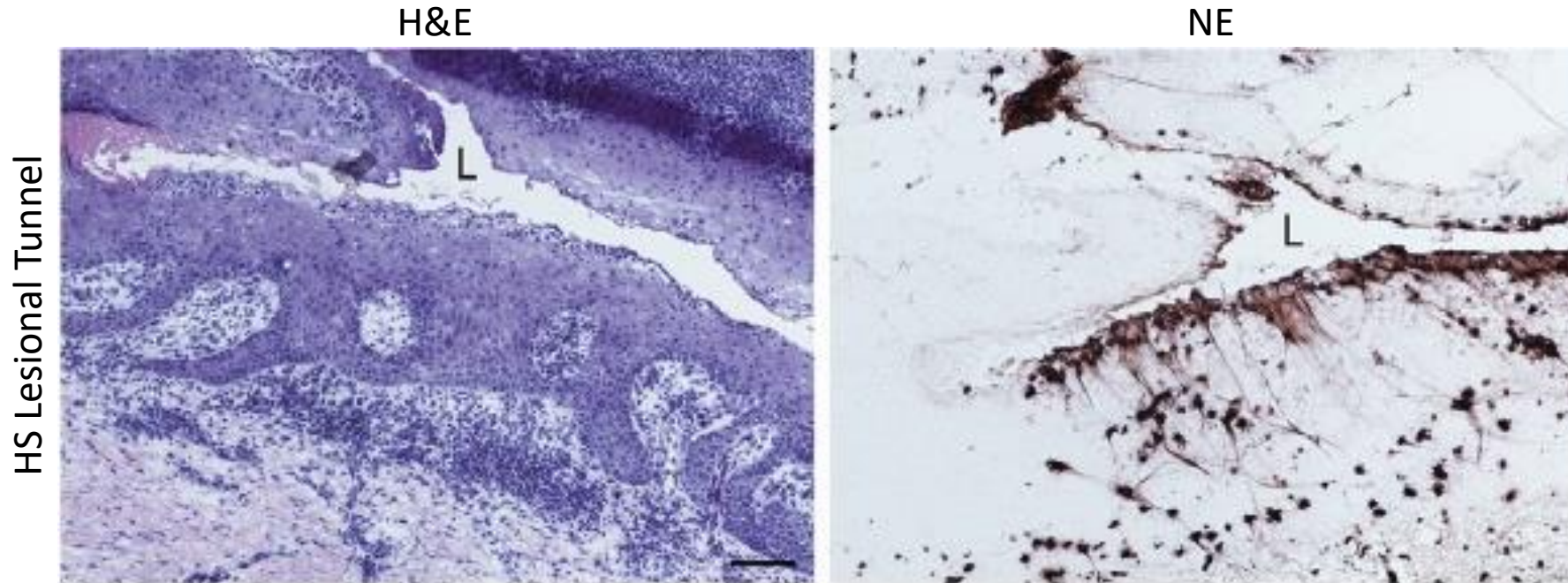


## C5A MODE OF ACTION ON NEUTROPHILS

- Chemotaxis of neutrophils (Shin et al 1968, Science 162,361-3)
- Enzyme release (Goldstein et al 1974, J. Immunol. 113, 1583-8)
- Production of O<sub>2</sub>-radicals in neutrophils (Sacks et al 1978, J Clin Invest 161, 1161-7)
- Netosis induction (Skendros et al. J Clin Invest. 2020;130(11):6151–6157. Ortiz-Espinosa et al. Can Letters, 2021 Dec)



# Neutrophils are Key in HS Pathogenesis and Draining Tunnels



- dTs are infiltrated by and surrounded by neutrophils, indicating they are immunologically active
- dTs often form epithelial linings and become chronic structures, although may become less inflamed with treatment

➤ **C5a is a key chemo-attractant and a strong activator of neutrophils and Neutrophil Extracellular Traps (NET)**

# C5a is at the Center of Inflammation

## **Proliferation:**

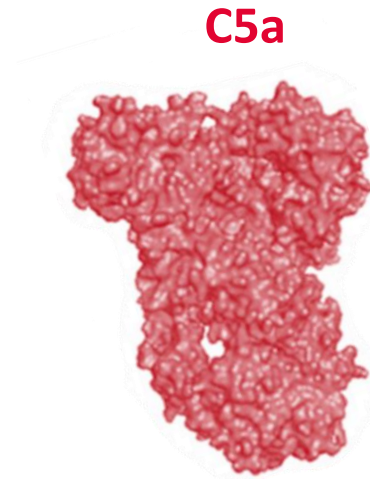
- NF $\kappa$ B
- Tumorigenesis
- Angiogenesis

## **Cutaneous sensitization:**

- Increase AMPs
- C5aR expression
- TLR4 expression

## **Inflammatory cytokines:**

TNF, IL-1, IL-17, IL-23, IL-6, IL-8



Th1/17 differentiation

## **Neutrophils:**

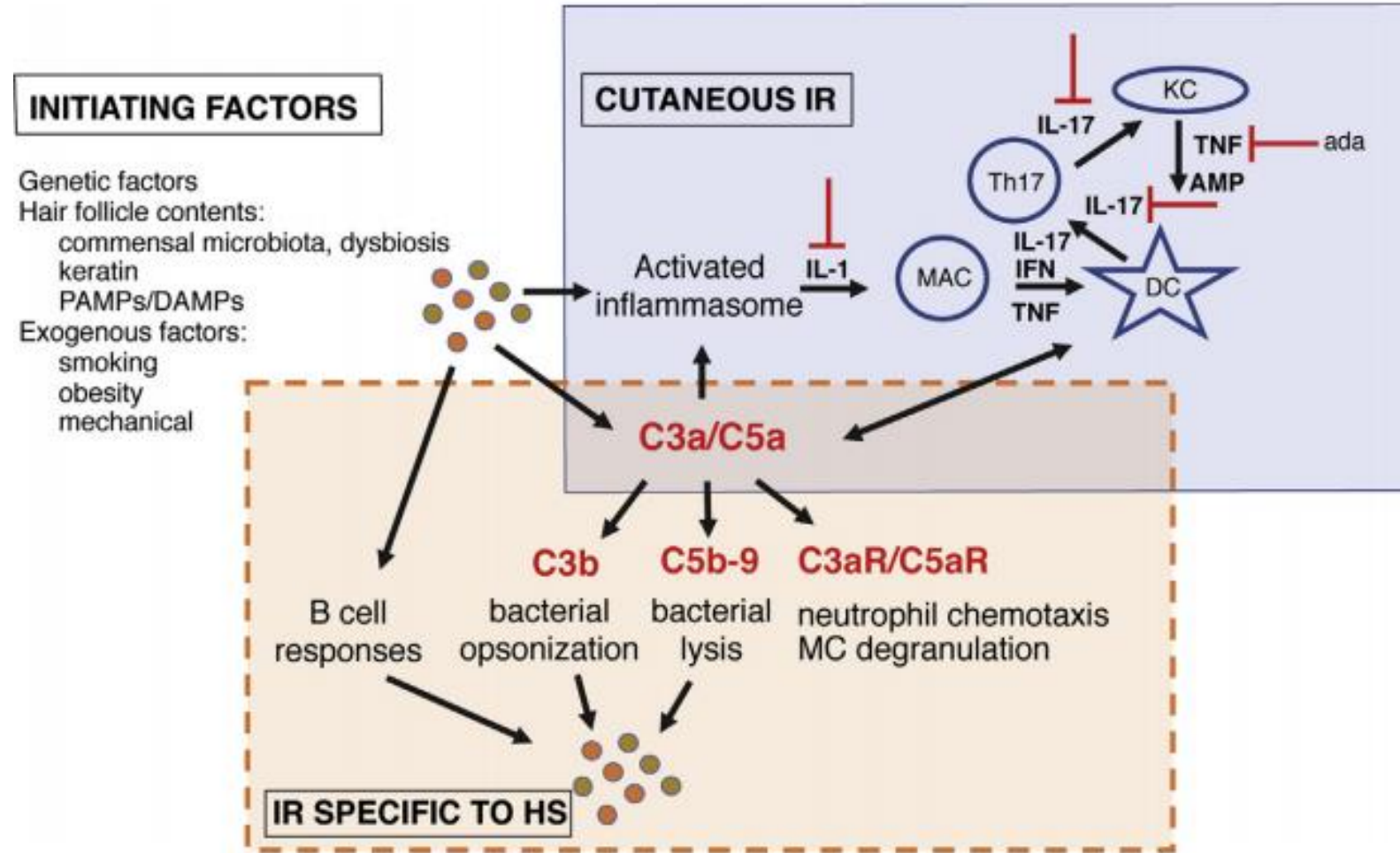
- Chemotaxis
- Activation
- NETosis

**Mast cell and Macrophage degranulation**  
Vasodilation  
Edema

## **Tissue remodeling:**

- MMPs, fibrosis
- Scar

# Complement in HS

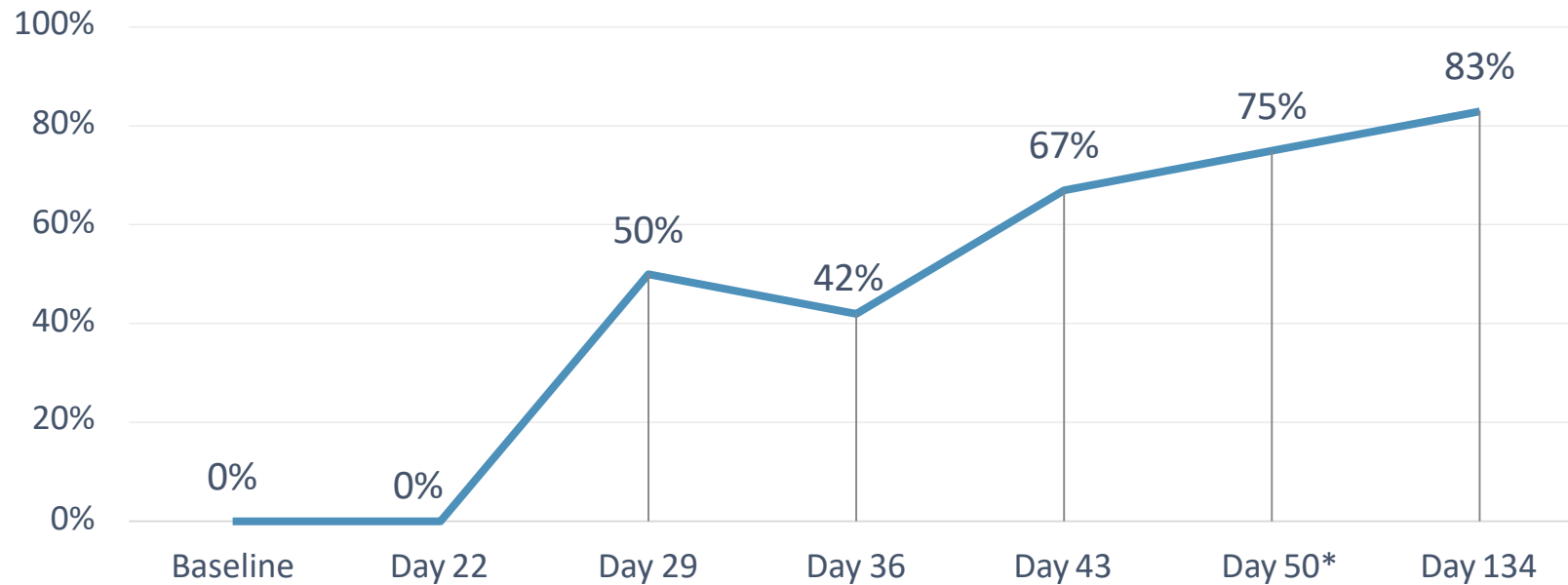


Ghias MH, Hyde MJ, Tomalin LE, Morgan BP, Alavi A, Lowes MA, Piguet V. Role of the Complement Pathway in Inflammatory Skin Diseases: A Focus on Hidradenitis Suppurativa. J Invest Dermatol. 2020 Mar;140(3):531-536.e1. doi: 10.1016/j.jid.2019.09.009. Epub 2019 Dec 20. PMID: 31870626.



# Vilobelimab: Intravenous C5a Inhibitor

## Open Label Phase IIa Study in Hidradentitis Suppurativa: HiSCR Response



HiSCR response in HS patients

### DESIGN

Open label / single center / 12 patients / 1 dose group with weekly i.v. 800 mg until week 8 (plus one additional loading dose on day 4)

### EFFICACY OUTCOME

**75% of patients HiSCR responders at week 8 and 83% at end of trial** (late-stage patients who previously failed to respond to SOC incl. TNF-alpha blockade)

### SAFETY / TOLERABILITY RESULTS

Repeated high dose i.v. administration of vilobelimab was well tolerated with a good safety profile

\* Last vilobelimab administration

# Key Conclusions

- HS is a devastating disease with limited treatment options
- Humira® (adalimumab) is the only FDA-approved treatment, although only 50% of patients responded in Phase III trials and the difference to placebo response was only about 25 – 30% and many of the responders lose response during the first year of treatment.

## ➤ More effective drugs needed

- Draining tunnels have the most negative impact of all lesions, but are not fully accounted for in HiSCR response measures
- C5a is strong neutrophil activator and is highly elevated in HS patient plasma

## ➤ Early studies of C5a inhibitor vilobelimab demonstrated reduced disease activity and reduction in draining tunnels



A photograph of a modern building at night, featuring large glass windows and balconies. The interior lights are on, and the building's structure is visible against the dark sky.

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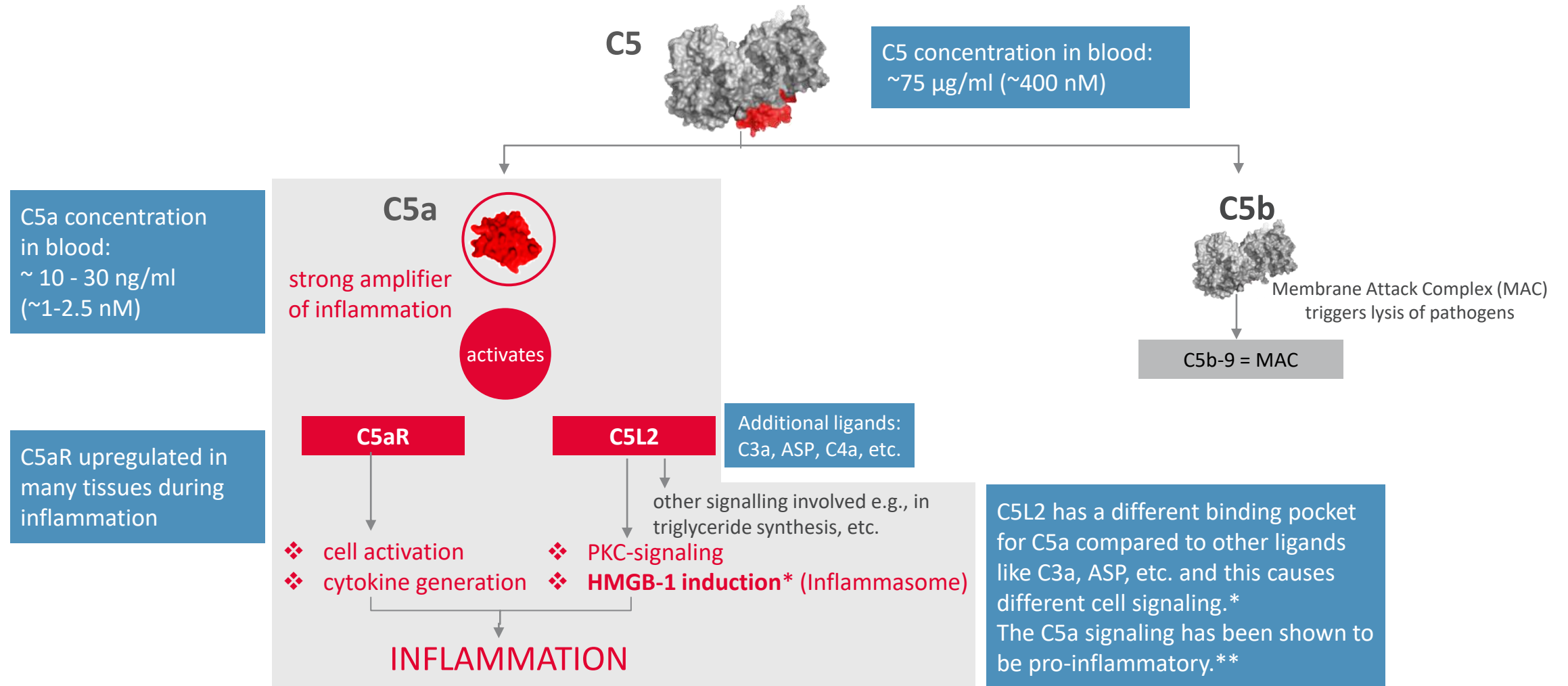
# Vilobelimab

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Overview & Mode of Action



# The Terminal Complement Pathway

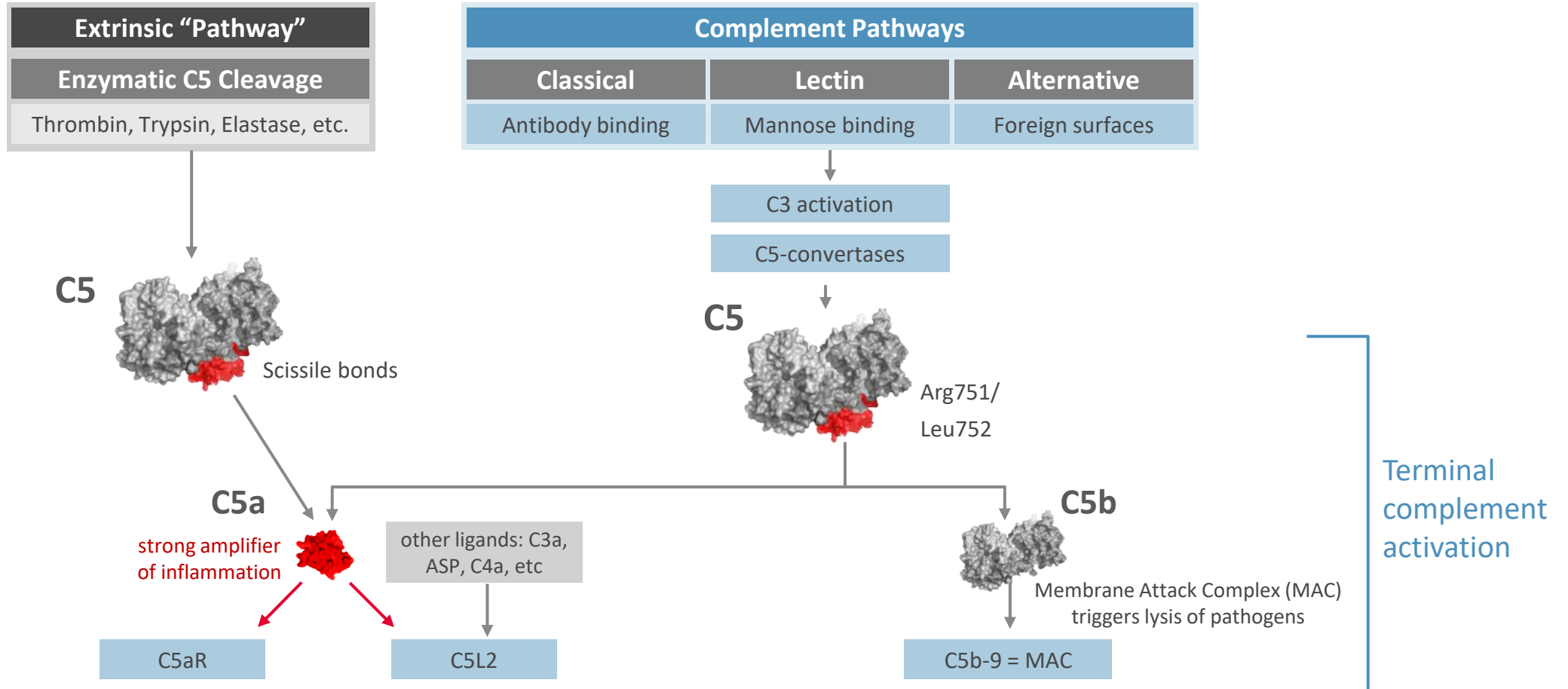


\* Kalant D. et. al. J. Biol. Chem. 2003. 278 (13) 11123–11129

\*\*Rittirsch et al. Nat Med. 2008 May ; 14(5): 551; Colley et al. MABS. 2018.10 (1). 104 Songlin et. al. J. Biol. Chem. 2019; 294(21) 8384–839 Muenstermann et al.. Virulence. 2020; 10(1) 677-694



# The Complement System and C5a Activation



The extrinsic pathway represents an additional route, outside of the known complement pathways, to cleave C5a from C5

# Vilobelimab Mode of Action



## Cleavage of C5 through:

- Complement pathway activation or
- Directly through other enzymes via "extrinsic" pathway

C5a is a key chemo-attractant and a strong activator of neutrophils leading to the formation of Neutrophil Extracellular Traps (NET) which are believed to be a disease driver in HS; Vilobelimab targets this key mechanism

## Key Features:

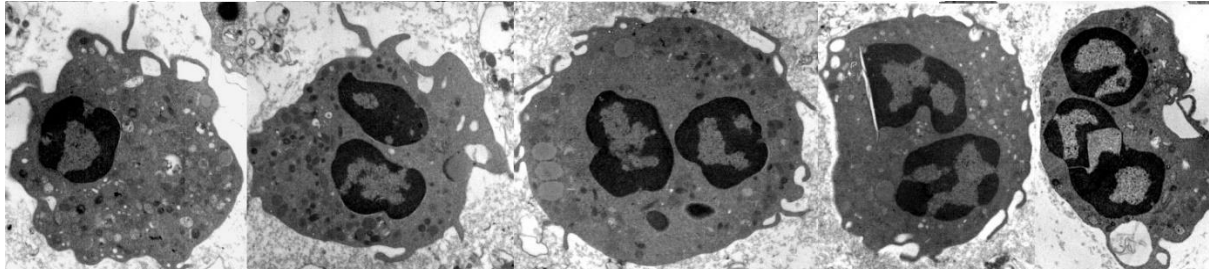
- Blocks C5a biological effects up to 100% in human blood
- Fully selective – Leaves MAC formation intact
- Binds with high affinity to the discovered epitope

# Neutrophil Activation by C5a

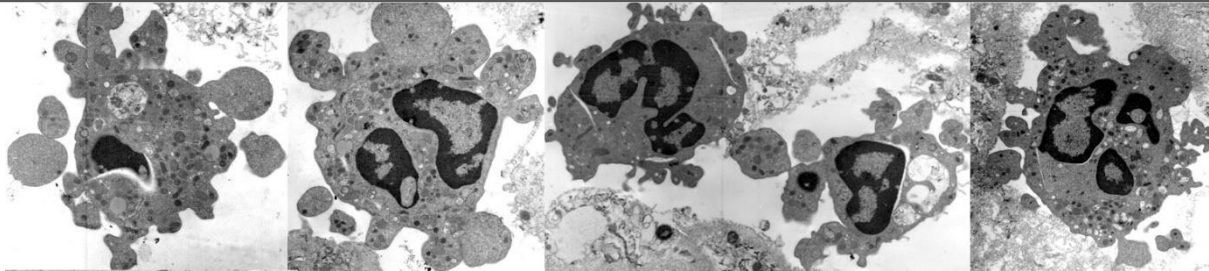


## NEUTROPHILS (4,600X ENLARGED)

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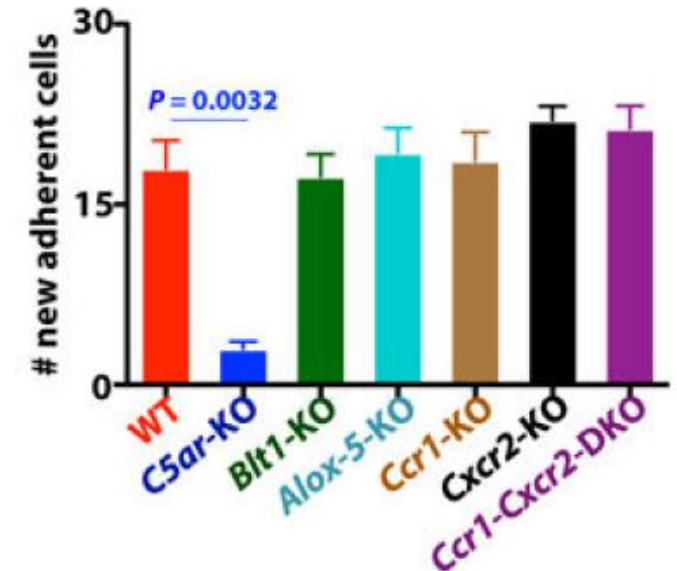
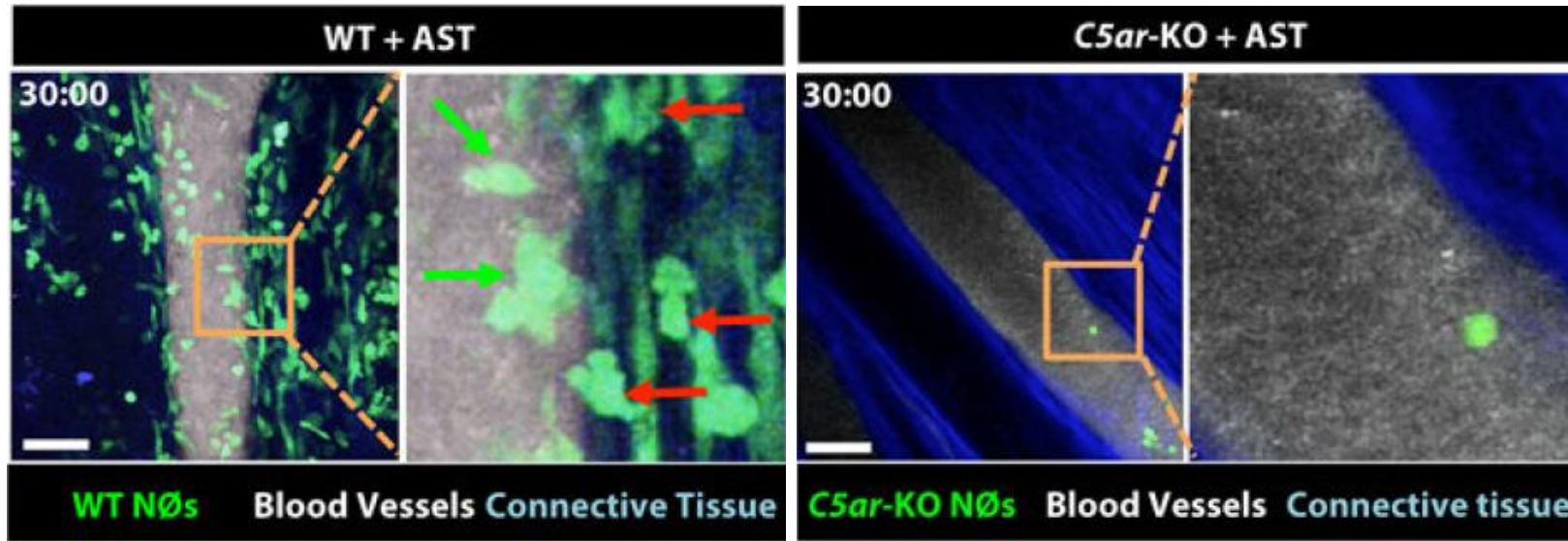
Data Source: Prof. Peter Ward, University of Michigan



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# Role of C5a/C5aR for Neutrophil Adhesion to Endothelial Cells and Migration into Tissue – Live Joint Vessel Imaging



## C5A/C5AR INTERACTION AS KEY DISEASE INITIATING EVENT IN RA\*

- C5a/C5aR interaction is the key driver of neutrophil adherence to the endothelial wall (activated Mac-1 and LFA-1)
- LTB<sub>4</sub> / BLT1 engagement is initiated by C5a and will lead to subsequent vessel wall transmigration of neutrophils
- Various other chemokines are involved in the following chemotaxis to the inflamed joint

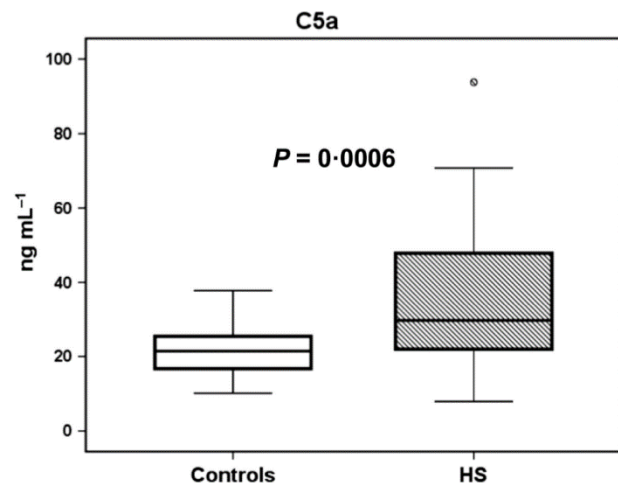
\* Miyabe et. Al., Sci Immunol. 2017 January ; 2(7)

# Vilobelimab in Hidradenitis Suppurativa



## RATIONALE FOR TARGETING C5A

**InflaRx established** that HS patients have **significant complement activation** with elevated C5a levels



Concentrations of C5a in the plasma of 14 healthy controls and of 54 patients with HS. P-values symbolize significant differences between patients and controls.

Kanni et al, 2018

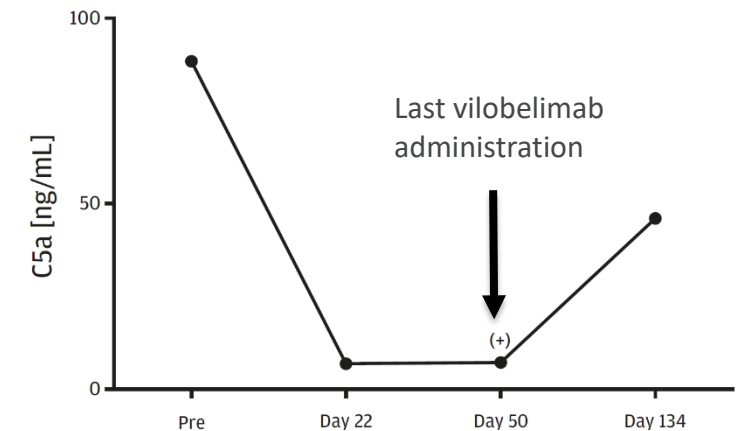
**C5a is key neutrophil activator in HS patient plasma**

HS patient plasma strongly provoked neutrophil activation in healthy donor blood; this effect could be completely blocked by the addition of vilobelimab

Guo et al. 2019 Aug. US Patent No. 10,376,595

**C5a levels in HS patients are significantly controlled by vilobelimab**

Phase IIa Study



*InflaRx in-house data*





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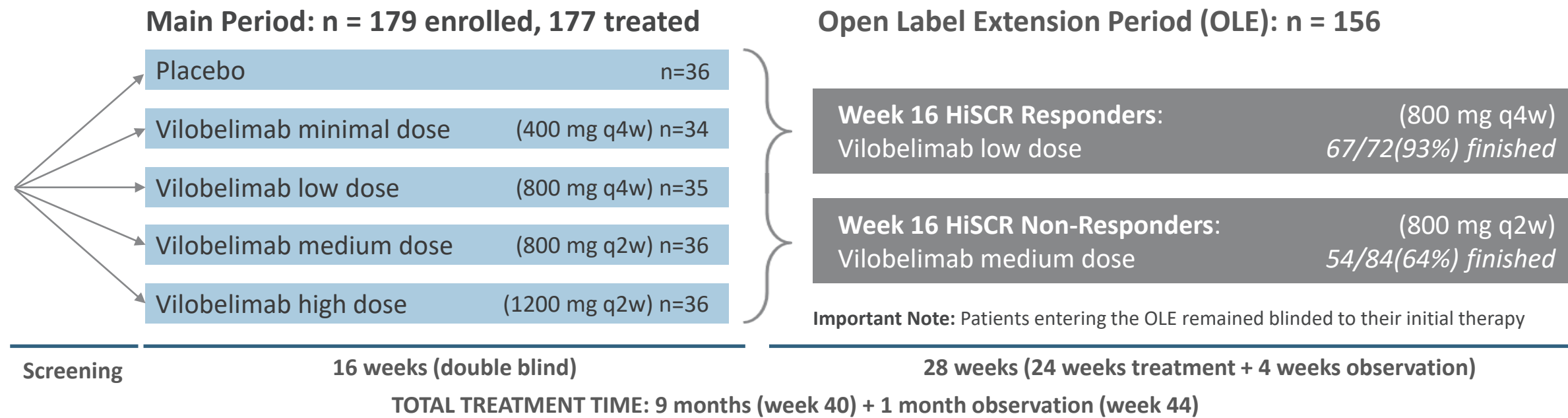
COMPLEMENT

# Vilobelimab

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- SHINE study results and learnings
- New primary endpoint: m-HiSCR
- Phase III trial

# Vilobelimab in HS: Phase IIb SHINE Study Details

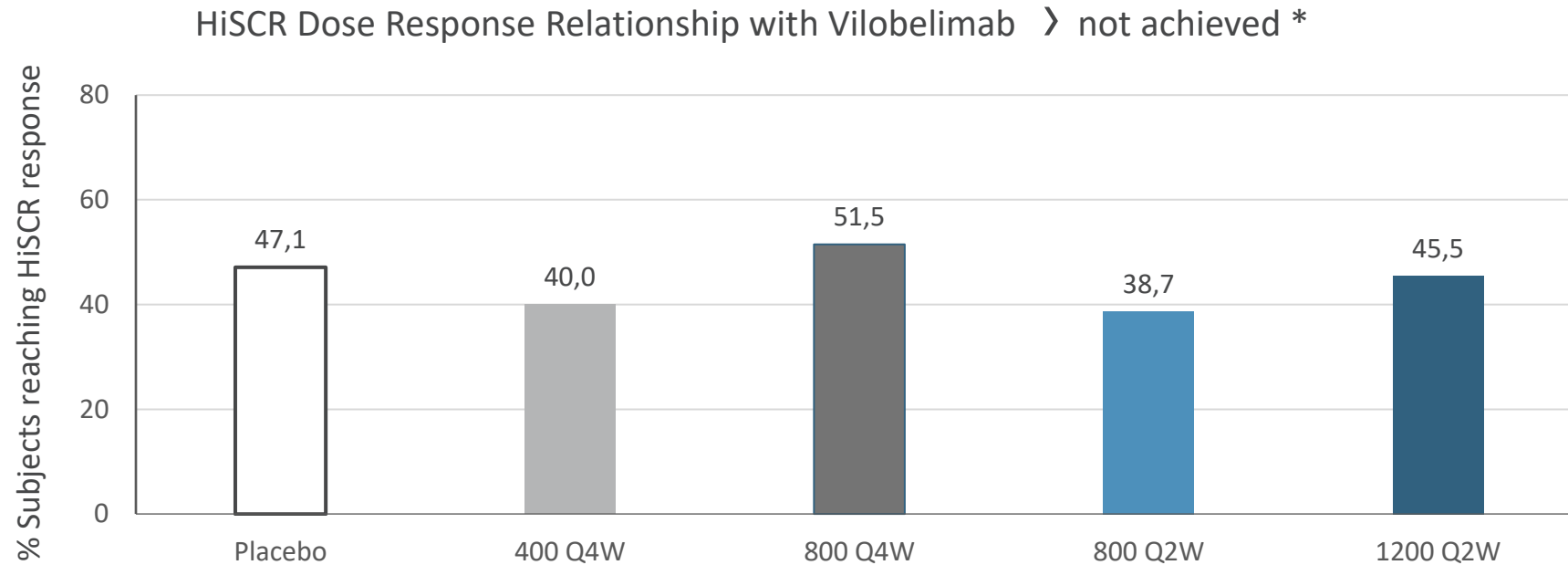


## MAIN GOALS

- Test a dose-dependent effect of vilobelimab on HiSCR\* response at week 16 (primary endpoint)
- Assess long-term safety of vilobelimab
- Test durability of response with lower maintenance therapy in OLE

\*HiSCR response defined as: At least 50% reduction in total AN count (abscesses & inflammatory nodules) with no increase in the number of abscesses from baseline and no increase in the number of draining fistulas from baseline

# SHINE Study: Primary Endpoint – HiSCR Week 16

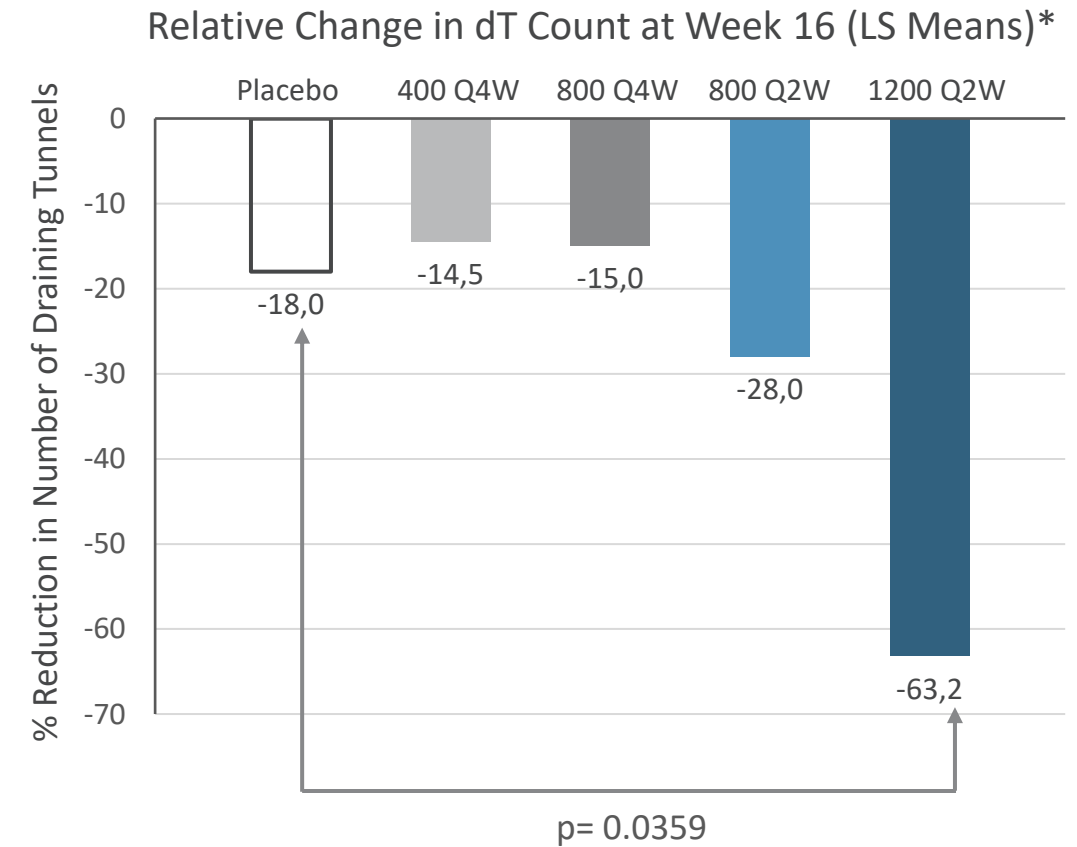
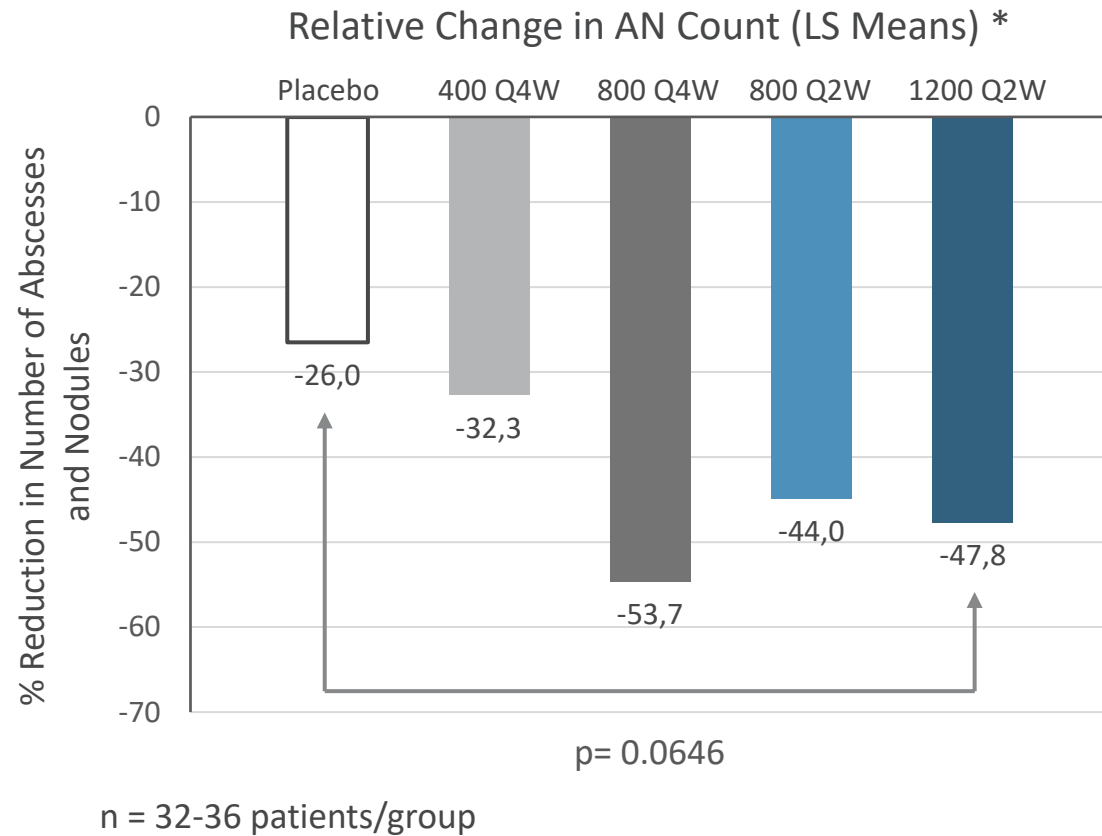


## HISCR RESPONSE DEFINITION:

- I. at least a 50% reduction in total count of abscesses and inflammatory nodules (AN count) from baseline
- II. no increase in abscess count from baseline and
- III. no increase in draining fistula (now named draining tunnel “dT”) count from baseline

\*IFRX internal data

# SHINE Study: Reduction of Lesions – Week 16

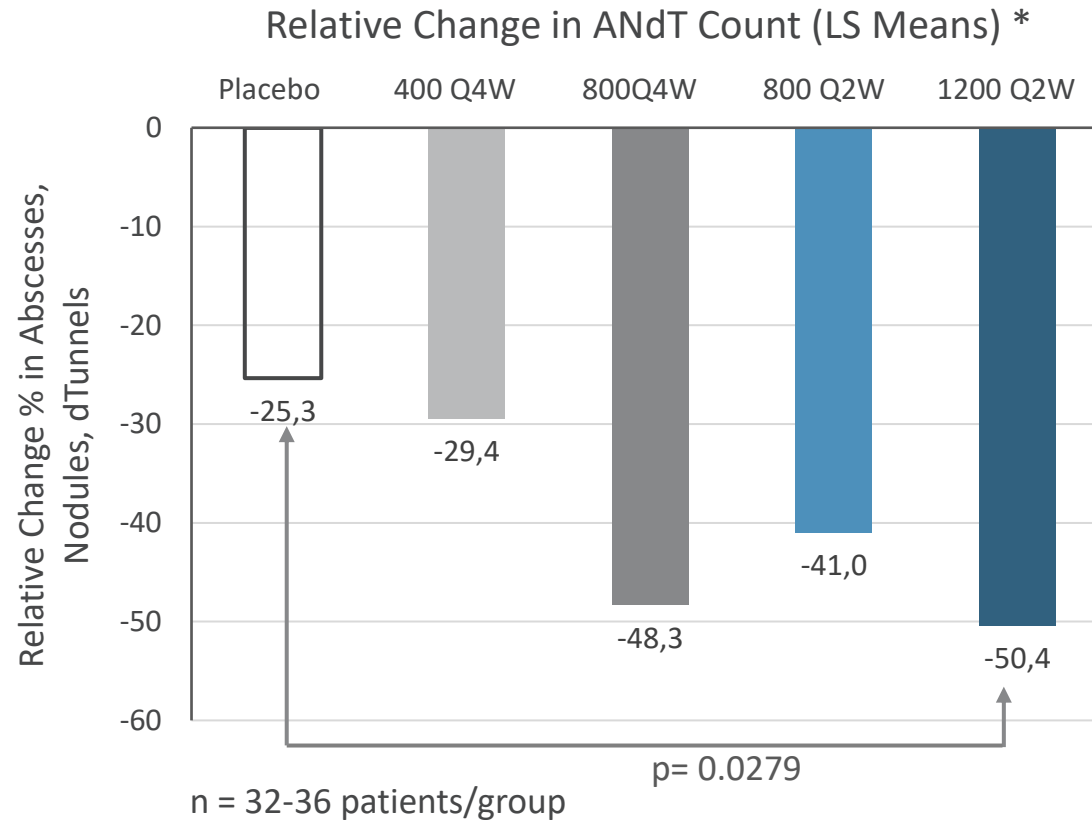


➤ Compared to placebo, a significant effect on dTs observed with highest vilobelimab dose

\* Full analysis set



# SHINE Study: Total Inflammatory Lesion Count Reduction (Abscesses, Nodules, Draining Tunnels (ANdT)) – Week 16



> Vilobelimab reduced all three inflammatory lesions in moderate to severe HS patients  
Vilobelimab 1200 mg showed statistically significant superiority versus placebo in reduction of ANdT

\* Full analysis set

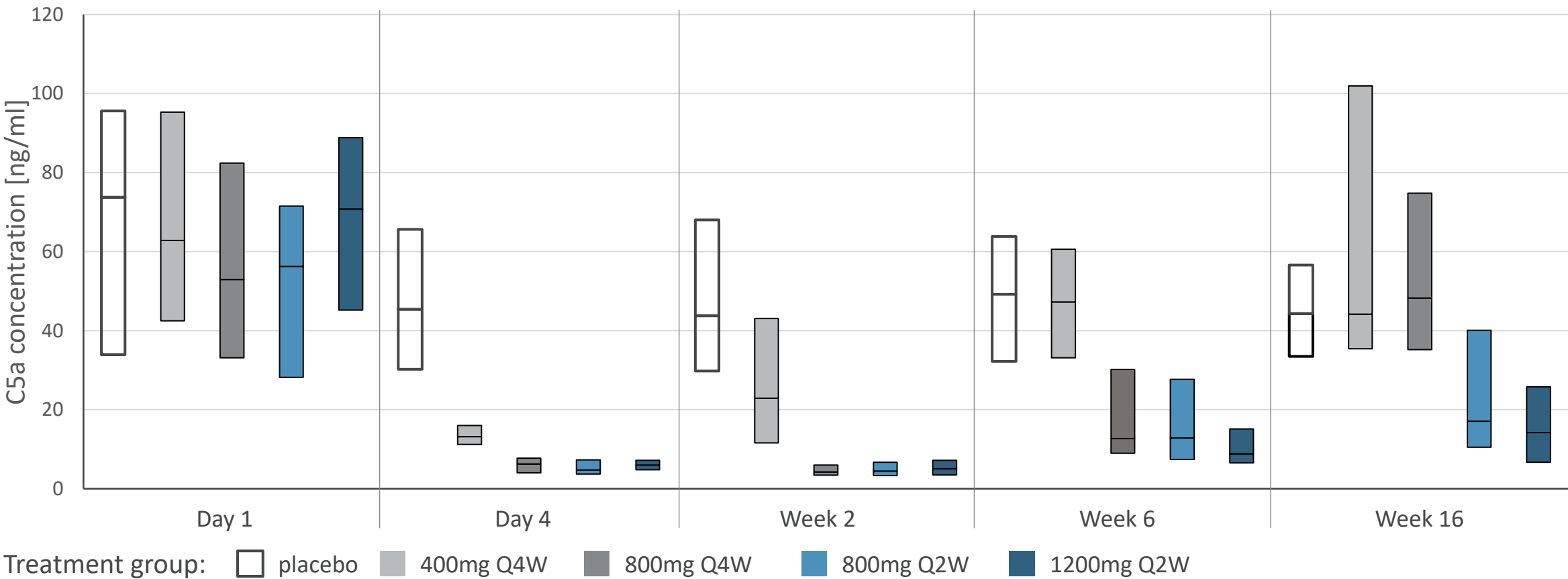
# SHINE Study: Correlation of Different Lesion Types with Patient Reported Outcomes\*

	Percentage Change of Lesion Count from Baseline of each Lesion Type		
Patient reported outcome	Abscesses	Inflammatory Nodules	Draining Tunnels
DLQI	0.17 (0.0683)	0.21 (0.0105)	0.33 (0.0004)
Worst skin pain	0.05 (0.6200)	0.21 (0.0268)	0.25 (0.0205)
Drainage	0.13 (0.2637)	0.04 (0.6909)	0.27 (0.0114)

➤ Lesion type with highest correlation to disease symptoms reported by the patients are draining tunnels

\*Data from SHINE study at Week 16 pooled for all treatment groups. Spearman correlation coefficients (including p-value) between percentage change in abscess, inflammatory nodule and draining tunnel counts and percentage change in patient reported outcomes

# SHINE Study: C5a Concentration by Time Point and Dose Cohort



**Vilobelimab dosing was not high enough for consistent and continuous C5a suppression**

horizontal lines in the box within graph = median values , box = IQR

# SHINE Study: Key Learnings

- ▶ **Reduction in dT is very important for patients suffering from dT, which is not reflected in HiSCR**
- ▶ **The HiSCR has several shortcomings:**
  - **High placebo rate** as in recently reported studies, (e.g., guselkumab trial: 39% Plc vs 45: active drug)
  - Does **not take into account reduction of dT count**, which has the greatest impact on patient physical functions, emotional parameters and quality of life
  - Response **primarily driven by AN count reduction requirement**, because A and N are the most frequent lesions with high fluctuation but lower impact on patient suffering
- ▶ **Vilobelimab was underdosed**



# Need for a New Primary Efficacy Endpoint in Actively Draining HS: Modified HiSCR (m-HiSCR)

**For a patient population suffering from dT, a score capturing dT reduction is needed**

## **Modified HiSCR:**

- a. Considers reduction of all 3 inflammatory lesions
- b. Emphasizes reduction of draining tunnels
- c. Anticipated to help to control placebo response rate
- d. Dichotomous and non-weighted score

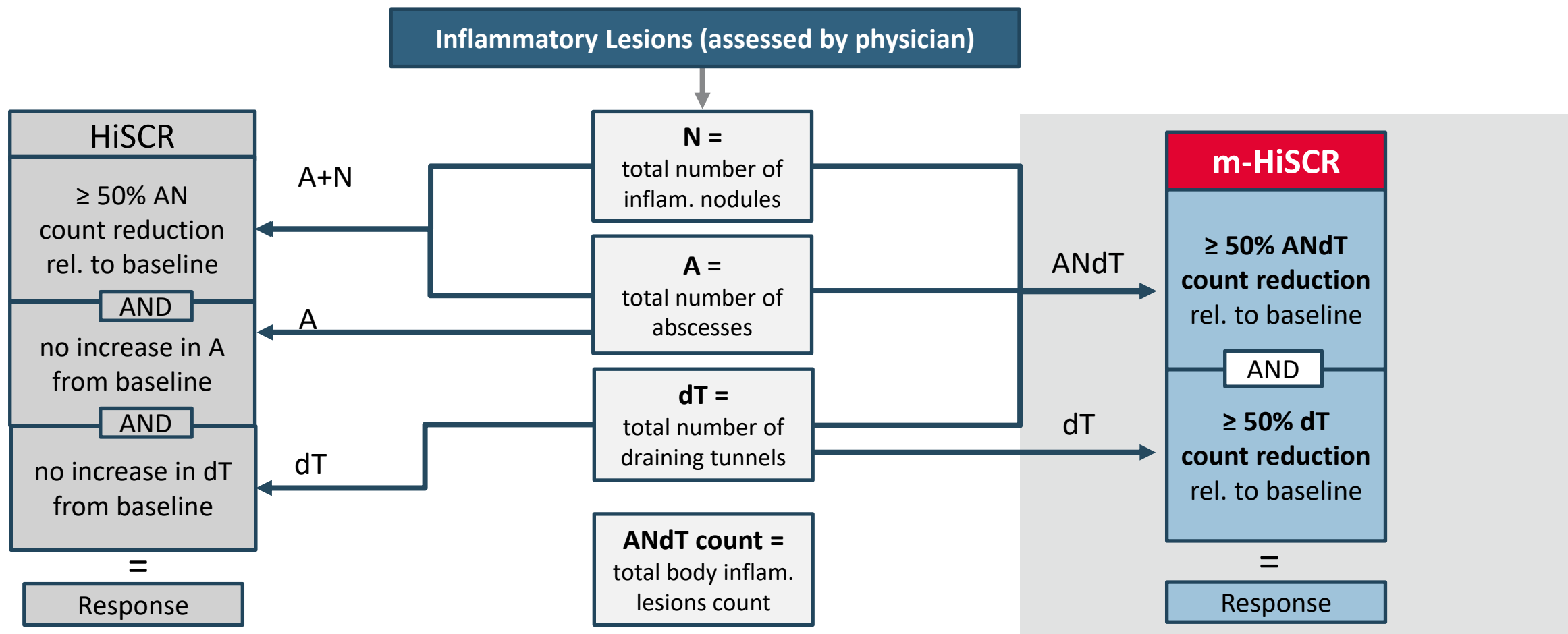
**Importance of dT was acknowledged by FDA**



**Suggested adaption of HiSCR to include improvement in dT was supported by the FDA during Type A meeting**

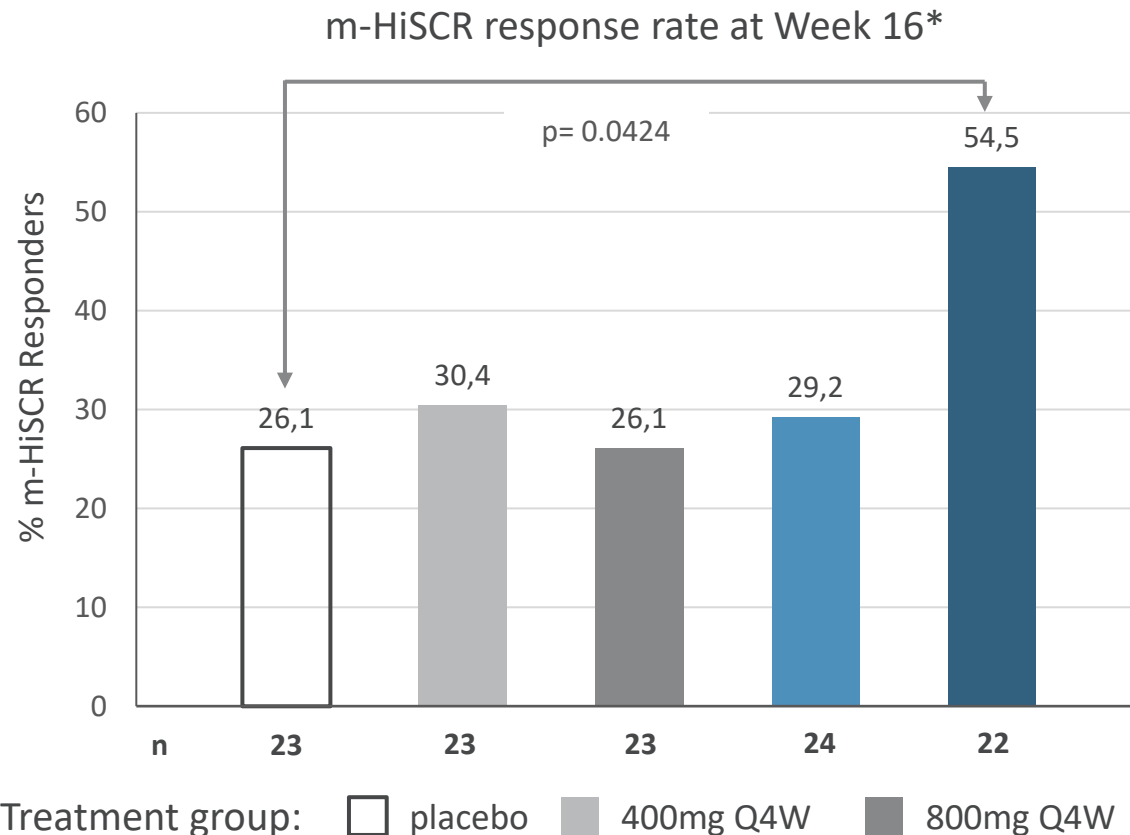
**New response definition: modified HiSCR**

# The New **Modified (m-)HiSCR** as Primary Endpoint is a Responder Score which is Based on All Three Inflammatory Lesions in HS



➤ New endpoint m-HiSCR for better evaluation of outcome in patients with actively draining disease

# SHINE Study: m-HiSCR Responders in Moderate to Severe HS with at least one dT *(Relative to Baseline, at least 50% Reduction of ANdT Count with 50% Reduction of dT Count)*



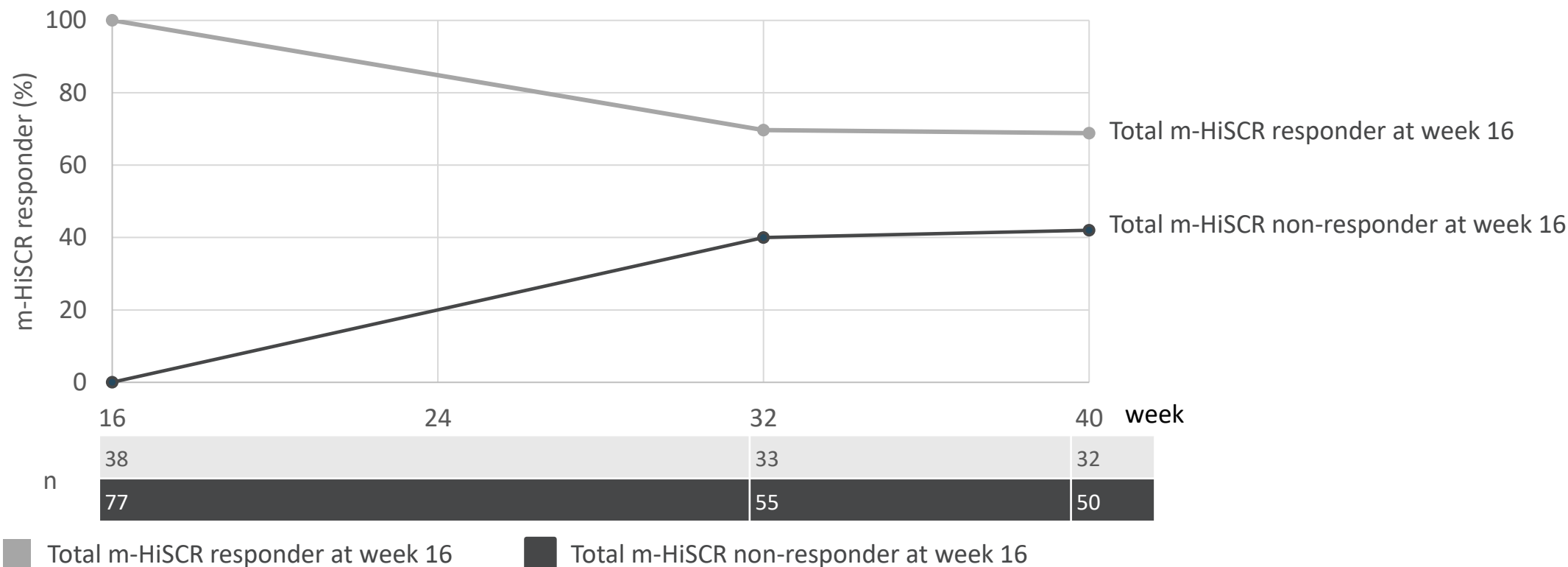
- In SHINE, significant reduction of dT count only achieved with high dose (as shown before)
- m-HiSCR response demands at least 50% reduction of dT count
- Significant improvement on m-HiSCR only observed for high dose group, the only group with significant reduction of dT count

> **Vilobelimab high dose offers a very good separation of m-HiSCR response compared to placebo treatment in patients with actively draining disease (at least 1 dT at baseline)**

\*subgroup of moderate to severe Hurley stage II-III patients with at least 1 dT at baseline; data from post-hoc analysis

# SHINE Study: Open Label Extension Period – m-HiSCR Response

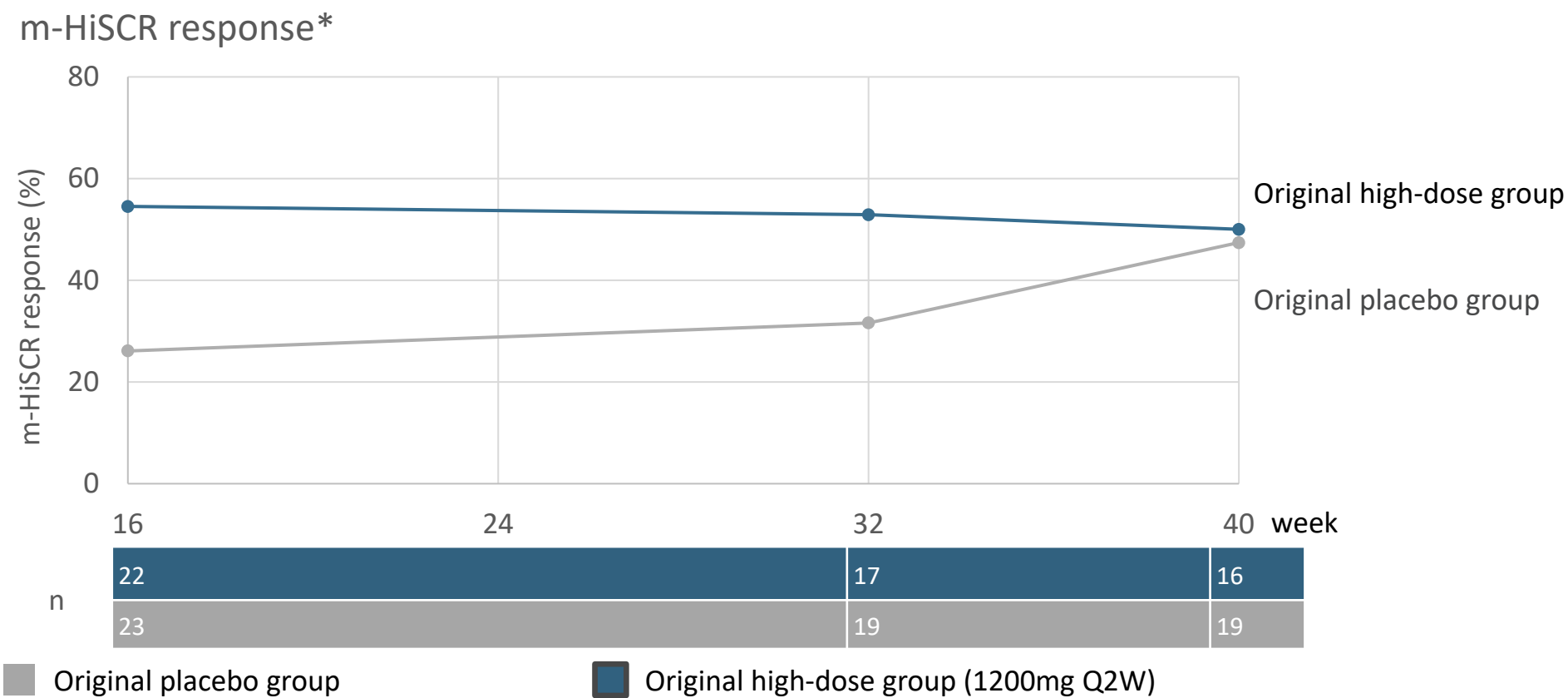
Patients group categorized according to m-HiSCR response at end of main phase\*



➤ **Although suboptimal dosing was used in OLE, m-HiSCR non-responders substantially benefitted from vilobelimab treatment**

\*subgroup of moderate to severe Hurley stage II-III patients with at least 1 dT at baseline; data from post-hoc analysis

# SHINE Open Label Extension Period – Placebo and High-dose Group m-HiSCR Responses



➤ Although suboptimal dosing was used in OLE, m-HiSCR placebo group patients (from main period) benefitted from vilobelimab treatment

\*subgroup of moderate to severe Hurley stage II-III patients with at least 1 dT at baseline; data from post-hoc analysis



# Correlations between m-HiSCR and Change of Selected Endpoints from Baseline to Week 16\*

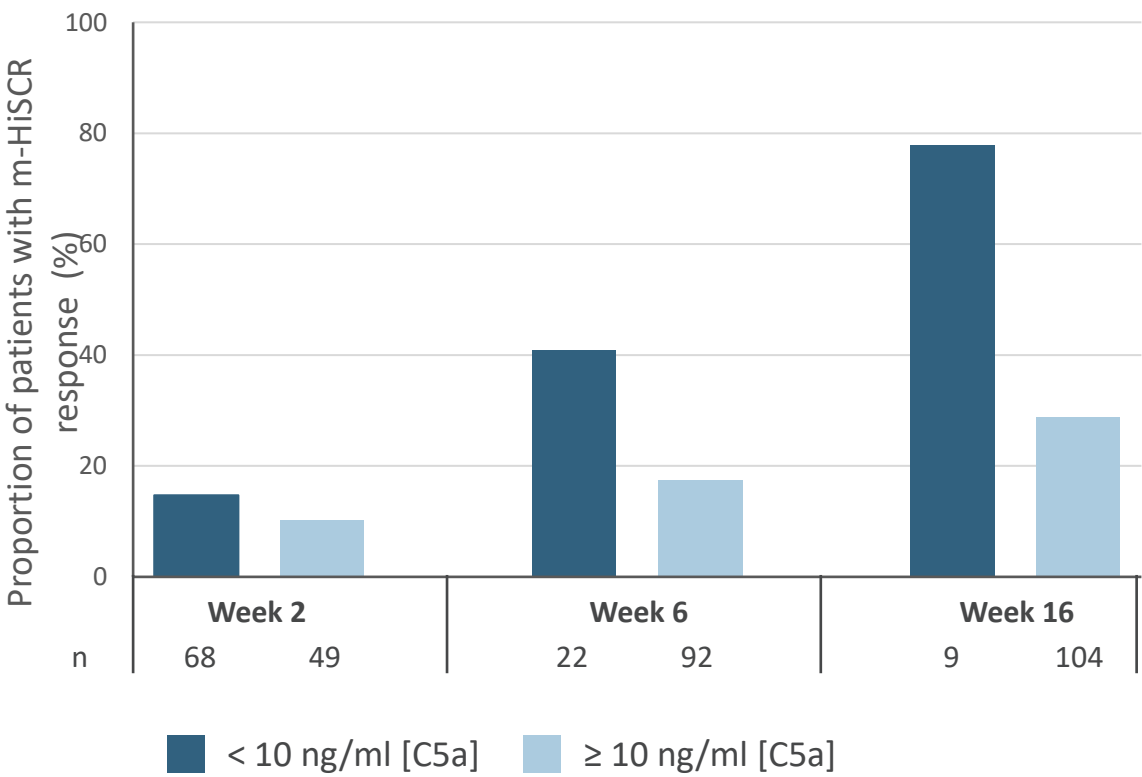
Item	Correlation
IHS4	-0.60472 (p=<0.0001)
IHS4 50% reduction	0.84191 (p=<0.0001)
HiSCR	0.62917 (p=<0.0001)
Worst skin pain relative change	-0.24853 (p=0.0203)
DLQI score relative change	-0.27233 (p=0.0038)
Drainage relative change	-0.14665 (p<0.0001)

**> m-HiSCR correlates with established endpoints (HiSCR, IHS4) and patient-reported symptoms and QoL even within a small data set**

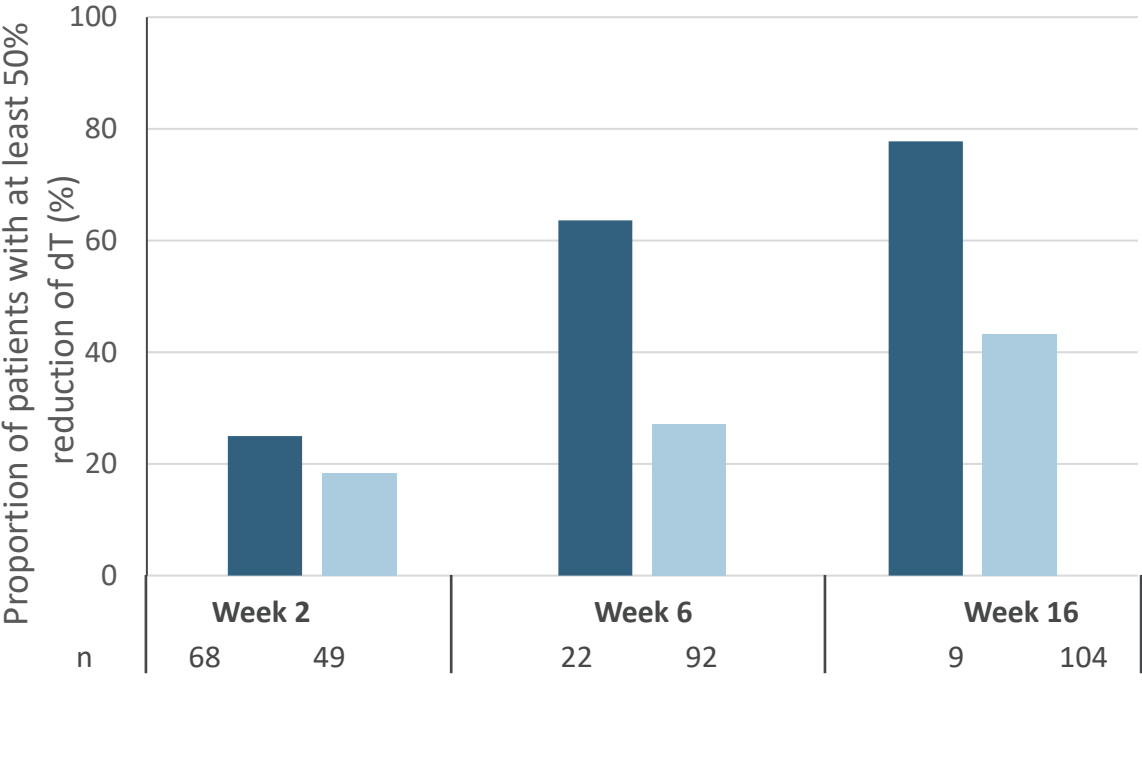
\* all treated patients; Spearman Correlation Coefficient + p-value

# Pharmacodynamics (C5a): Response Relationship to m-HiSCR and dT Reduction

m-HiSCR responder proportion by C5a level\*



50% reduction of dT proportion by C5a level\*



**> m-HiSCR and 50% reduction of dT show a relationship between pharmacodynamics (C5a) and clinical response**  
**This relationship could not be observed with the traditional HiSCR**

\*subgroup of moderate to severe Hurley stage II-III patients with at least 1 dT at baseline; data from post-hoc analysis

# m-HiSCR Covers Important Aspects for New Primary Endpoint

## **m-HiSCR, a new primary endpoint for patients suffering from active draining disease**

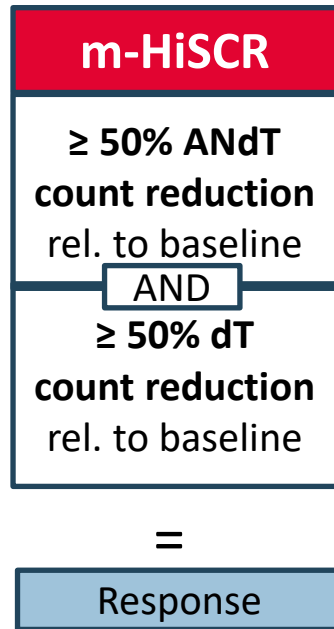
- a. Considers reduction of all 3 inflammatory lesions
- b. Emphasizes reduction of draining tunnels
- c. Anticipated to help to control placebo response rate
- d. Dichotomous and non-weighted score



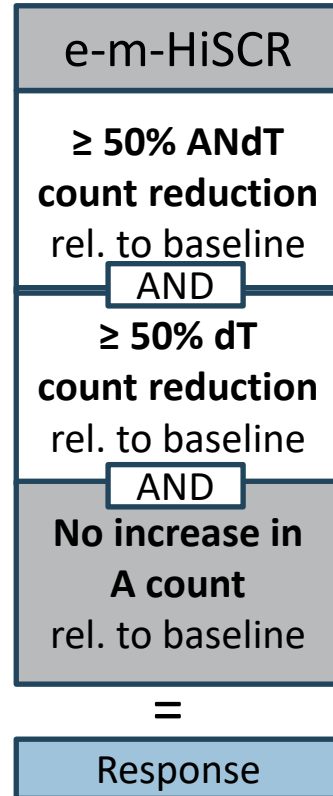
**modified HiSCR: chosen as primary endpoint for pivotal development program and shows significant correlation to other scores**

# The Extended (e)-m-HiSCR is a Secondary Endpoint: Adding 1 Additional Criterion to m-HiSCR

## Primary Endpoint



## Secondary Endpoint



- e-m-HiSCR introduced as secondary endpoint based on recommendation of FDA to include the aspect of no increase in abscesses from baseline in an efficacy endpoint
- e-m-HiSCR response when applied to SHINE data set followed similar patterns with respect to response numbers, correlation to other endpoints and patient reported outcomes when compared to m-HiSCR with only a few patients differing in the data set in responses between m-HiSCR and e-m-HiSCR.



New secondary endpoint e-m-HiSCR to address no increase in abscesses from baseline in an efficacy endpoint

# Current Status: Phase III Program Initiated in January

## PHASE III STUDY INITIATED

- Upon submission of study protocol for approval, InflaRx received no comments from FDA within 30-day and 60-day review periods. Thus, InflaRx expects no critical protocol review issues pending with FDA
- Company initiated trial activities for pivotal Phase III study with newly designed primary endpoint m-HiSCR
- Company expects to continue its interactions with the FDA with respect to trial protocol

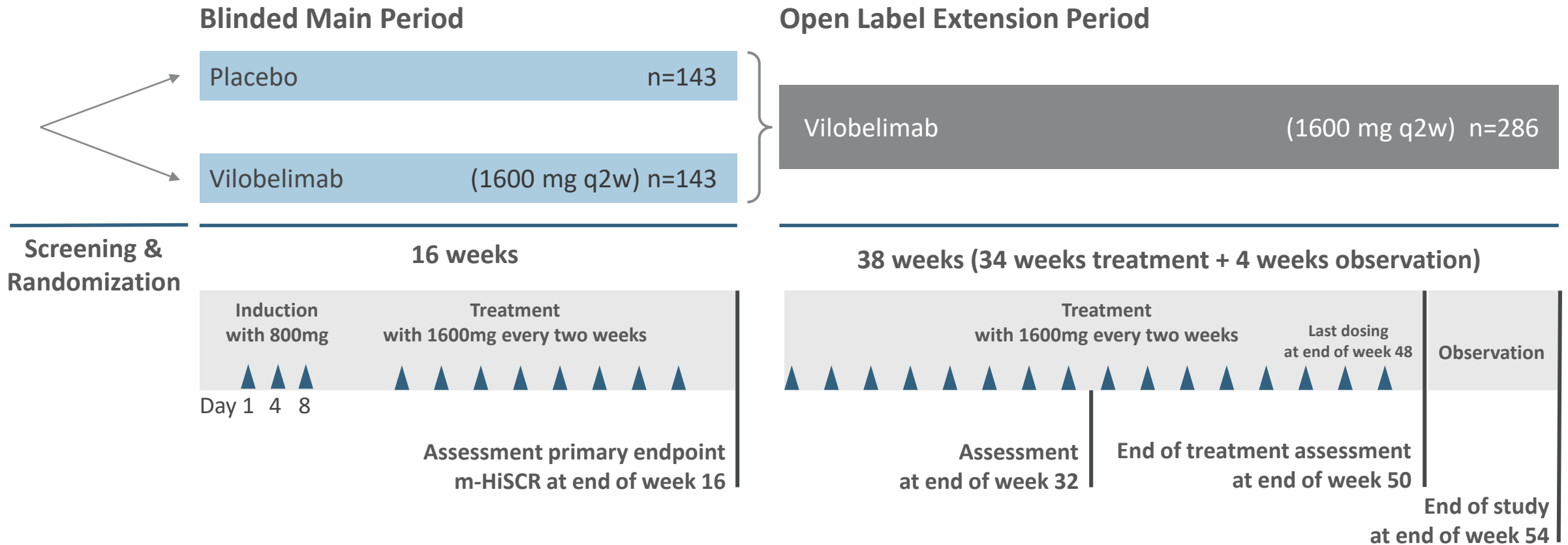
## PHASE III STUDY DETAILS

- Study population: moderate to severe Hurley stage II-III HS patients with at least one active draining tunnel (estimated to be approx. 70 - 75% of Hurley stage II-III moderate to severe study patients)
- Patient enrollment projected to start in Q2 2022
- Approx. 60 study centers planned in USA, Canada, EU





# Vilobelimab Phase III Trial in HS: Study Design



> A randomized, double-blind, placebo-controlled, multicenter pivotal study to determine efficacy and safety of vilobelimab in patients with moderate to severe HS and at least one actively draining tunnel

# Vilobelimab Phase III Study in HS: Endpoints

## PRIMARY ENDPOINT (WEEK 16)

### **modified Hidradenitis Suppurativa Clinical Response (m-HiSCR)**

Response defined as proportion of patients achieving both

- i. total body inflammatory lesion count (**ANdT**) **reduction from baseline of at least 50% and**
- ii. draining tunnel (**dT**) **count reduction from baseline of at least 50%**

## SECONDARY ENDPOINTS (WEEK 16 AND LONG TERM)

- extended m-HiSCR
- HiSCR
- IHS4
- m-HiSCR (long term)
- Patient reported outcomes
- Safety

# Vilobelimab Phase III Study in HS: Key Inclusion Criteria

## PATIENT POPULATION

- Moderate to severe HS (Hurley stage II or III) and an AN count  $\geq 3$
- Patients must have at least one dT at screening and at baseline
- Diagnosis of HS for at least 1 year
- Stable HS for at least 2 months before screening
- Patients must have had an inadequate response to at least a 3-month (90 days) treatment of oral antibiotics for treatment of HS or demonstrated intolerance to or have a contraindication to oral antibiotics for treatment of their HS

# Vilobelimab Phase III Study in HS: Key Exclusion Criteria

## PATIENT MAY NOT HAVE

- Any other skin disease or condition that may interfere with assessment of HS or uncontrolled active infection
- Treatment with intravenously administered anti-infectives or oral anti-infectives other than tetracyclines within 4 weeks prior to baseline
- Any systemic medical treatment for HS within 4 weeks prior to baseline
- Other therapies which interfere with response measurement in this study
- Chronic systemic corticosteroid therapy within 3 weeks prior to baseline
- Deroofing surgery for HS within 6 weeks prior to baseline
- History of certain preconditions related to other inflammatory diseases

# Summary

InflaRx had 3 key learnings from SHINE related to

- Pitfalls and limitations of HiSCR
- Importance of dT
- Dosing of vilobelimab in HS



IFRX developed a new primary endpoint, m-HiSCR, to address the need of patients with active draining disease

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IFRX is currently conducting a Phase III program with this endpoint

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IFRX is the pioneer in working out the role of complement C5a in immunodermatology and continues to build out its expertise and stronghold in this field



A photograph of a modern building at night, featuring large glass windows and balconies. The interior lights are on, and the building's structure is visible through the glass. The sky is dark blue.

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INNOVATION

TEAMWORK

DISCOVERY

COMPLEMENT

# Q&A

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