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CONTROLLING INFLAMMATION

Phase IIa Pyoderma Gangraenosum
Top-Line Results Conference Call

October 27, 2021

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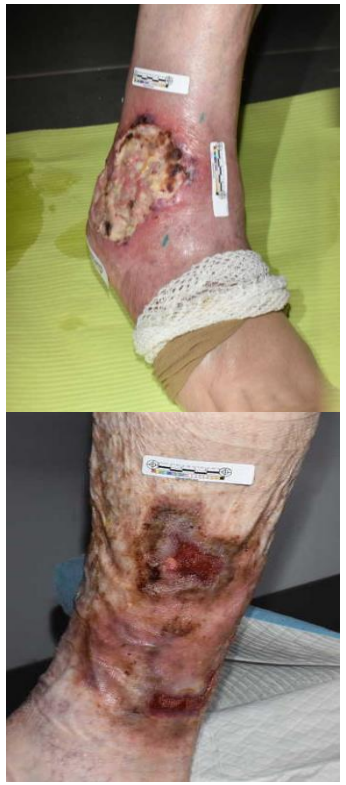
AGENDA

- OVERVIEW OF PYODERMA GANGRAENOSUM & PGA SCORE
- STUDY DESIGN AND RESULTS
- CASE STUDIES

Pyoderma Gangraenosum (PG)

AN AUTOIMMUNE CONDITION WITH HIGH UNMET NEED



CLINICAL FEATURES

- PG is a rare but potentially life-threatening skin disorder that can lead to chronic, highly painful and difficult-to-treat wounds
- Many PG patients also suffer from other autoimmune disorders, such as ulcerative colitis, rheumatoid arthritis, and hematological diseases
- Patients suffer from severe pain, long healing times, and frequent relapses

INCIDENCE

- Rare - Estimated that up to 50,000 patients in the US and Europe are affected

CURRENT TREATMENT – MEDICAL NEED

- No drugs currently approved in the US or EU
- For less severe cases, topical or intralesional treatments can be used, including topical steroids
- Use of systemic immunosuppression in rapidly progressing cases
- Mixed reports about efficacy, long treatment durations, relapses are frequently seen

› Strong rationale for treatment with vilobelimab: PG associated with neutrophilic skin infiltration in affected areas and lesions, potentially triggered by C5a.

Photo Source: InflaRx study

PGA Score – Physician‘s Global Assessment Score

PGA SCORE IN THIS TRIAL

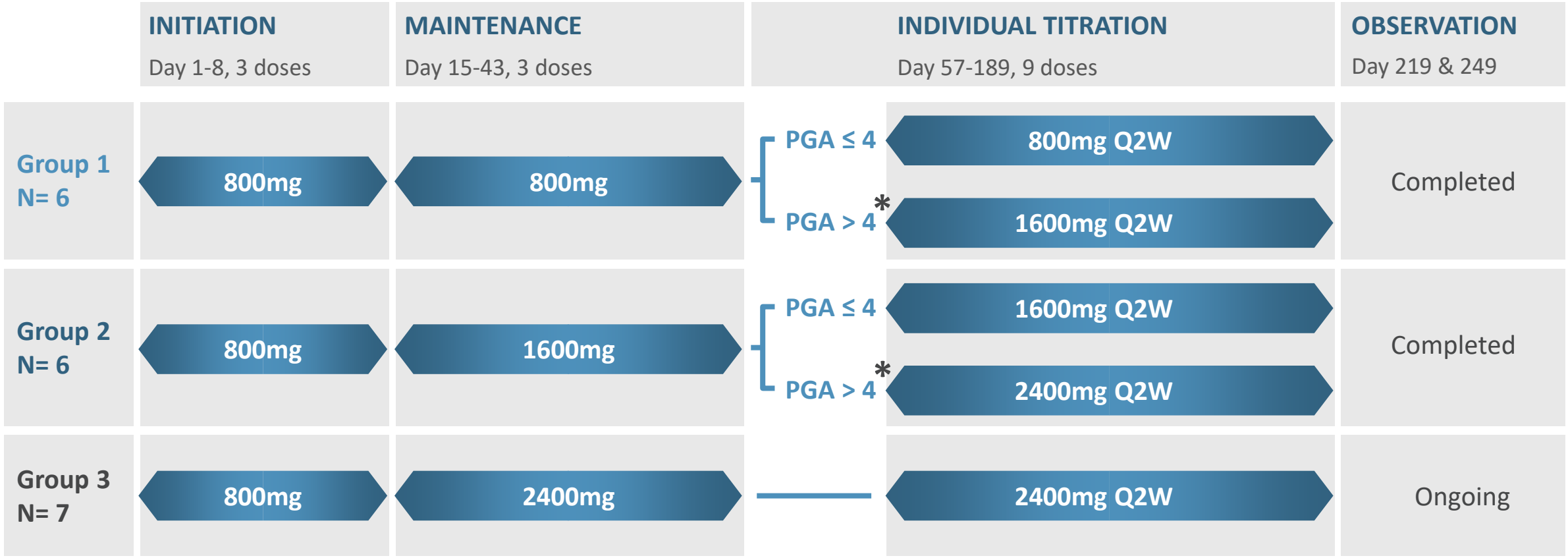
- PGA classifies physician-assessed target ulcer improvement compared to photography at Day 1
- No PGA score at baseline (Day 1)
- PGA score is collected from Day 4 until end of study
- **PGA score of ≤ 3 is considered clinical response**
- **PGA score of ≤ 1 is considered clinical remission and closure of target ulcer**

PGA SCORE

0	Completely clear	except for possible residual hyperpigmentation
1	Almost clear	very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration
2	Marked improvement	significant improvement (about 75%); however, a small amount of disease remaining (i.e., remaining ulcers, although have decreased in size, minimal erythema and/or barely perceptible border elevation)
3	Moderate improvement	intermediate between slight and marked; representing about 50% improvement
4	Slight improvement	some improvement (about 25% up to 50%); however, significant disease remaining (i.e., remaining ulcers with only minor decrease in size, erythema or border elevation)
5	No change from baseline	
6	Worse	

Phase IIa Study Design

- Sequential enrollment of 19 patients reached in April 2021
- **Primary endpoint:** Safety
- **Key secondary endpoints:** Responder rate defined as PGA ≤3; Time to complete closure of target ulcer



*Uptitration to the next dose on day 57 **if** PGA > 4 and at least 5 patients treated with the current dose showed no safety issues

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Key Eligibility Criteria

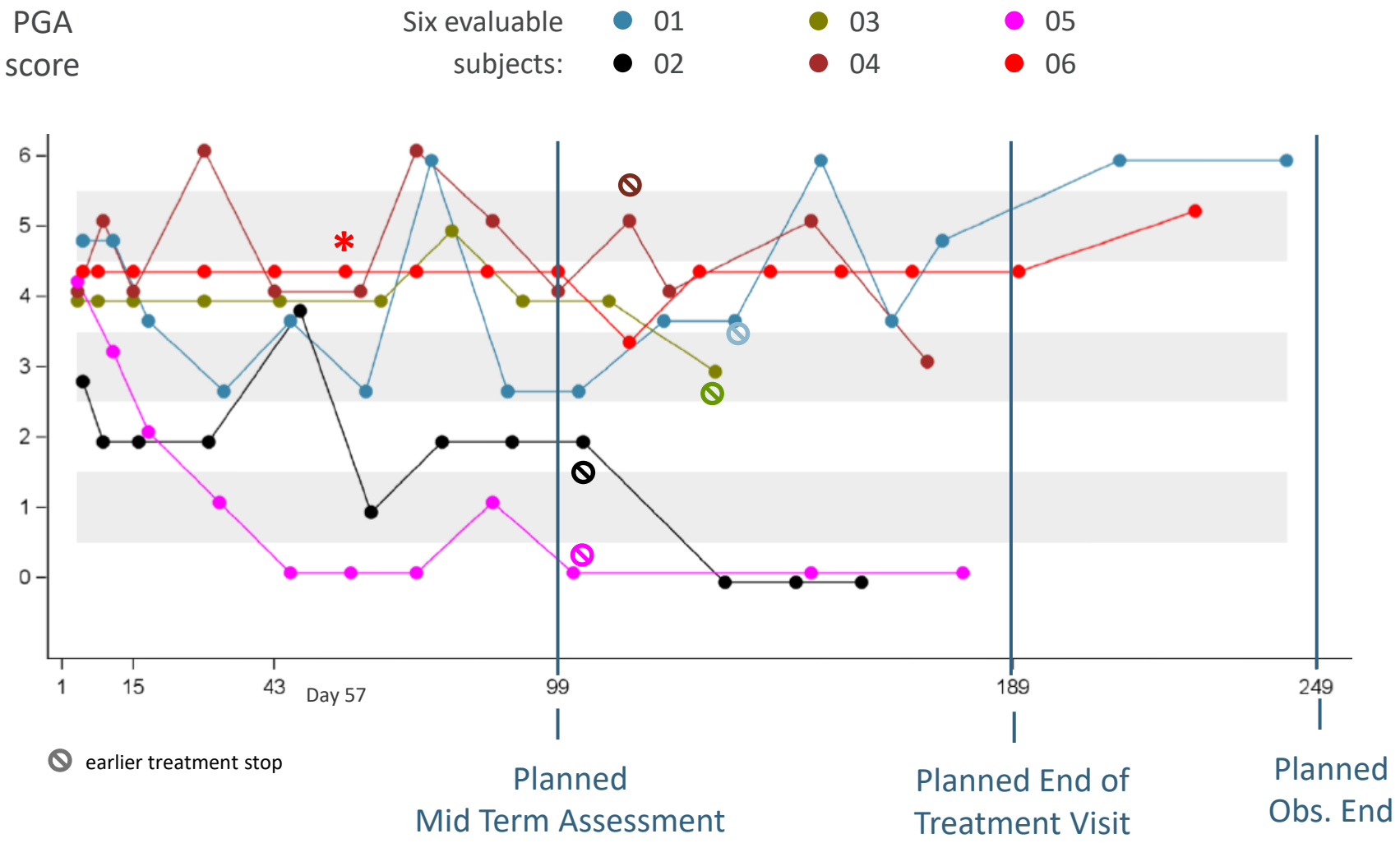
KEY INCLUSION CRITERIA

- Diagnosis of an ulcerative form of pyoderma gangraenosum confirmed by the investigator
- Must fulfill at least 3 of 6 PG-defining criteria at screening, including but not limited to pathergy, history of papule, pustule or vesicle that rapidly ulcerated, and clinical examination (or photographic evidence) of peripheral erythema, undermining border, and tenderness at site of ulceration
- Subject has a minimum of 1 evaluable ulcer (≥2 cm^2)

KEY EXCLUSION CRITERIA

- Pyoderma gangraenosum target ulcer for more than 3 years before screening
- Surgical wound debridement within the previous 2 weeks before screening
- Evidence of active tuberculosis
- Infection requiring suppressive anti-infective therapy (such as latent tuberculosis, pneumocystis, aspergillosis, cytomegalovirus, herpes simplex virus, herpes zoster and atypical mycobacteria)
- Use of intravenous antibacterial, antiviral, anti-fungal, or anti-parasitic agents within 30 days before screening
- Any drug treatment for pyoderma gangraenosum, including corticosteroids (>10 mg prednisone or prednisone equivalent), intralesional steroids, cyclosporine A, biologicals and immunosuppressives (with the exception of antibiotics for wound superinfection) used within a time of 5 half-lives of the drug before screening

Study Results – Group 1 (Low Dose)
PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)



Group 1 Results

- Two patients (02 and 05) achieved **complete remission of target ulcer**
- One patient (01) with initial response and fluctuating PGA
- Patients 02 and 05 stopped treatment before Day 189 based on investigator decision because of complete disease remission
- Patient 03 dosed until Day 130 but stopped treatment due to Covid situation. No follow up.

* Uptitration to 1600mg on day 57 **if** PGA > 4 and at least 5 patients treated with 800mg show no safety issues. Applied to patient 06

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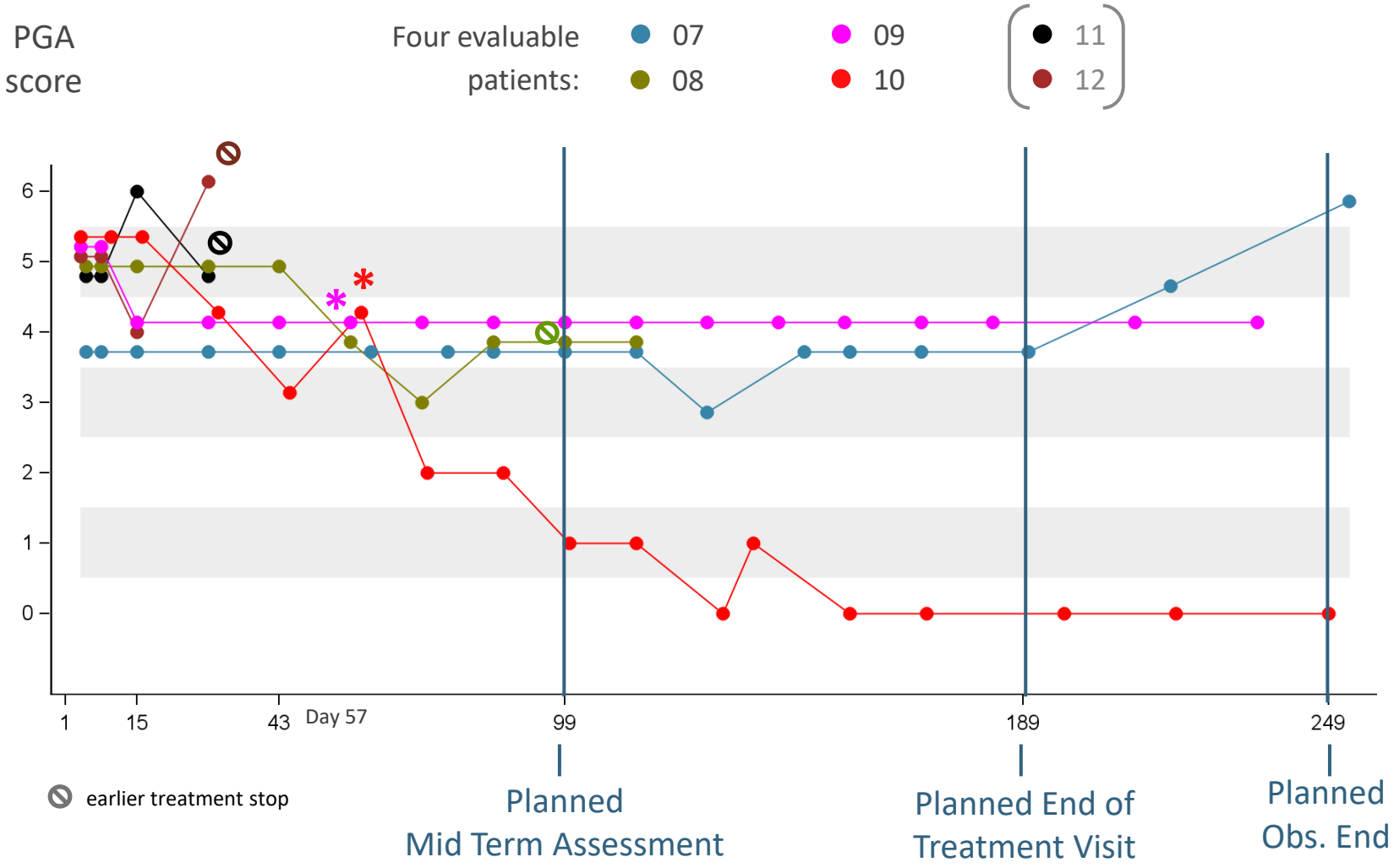
Study Results – Group 2 (Medium Dose)
PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)



Group 2 Results

- One patient (10) out of four **healed upon up-titration to 2400mg group on day 57** with PGA = 0 since visit 12 (closure of large target ulcer area)
- Two patients showed temporary response, not considered responder (Patients 08, 09)
- Two patients discontinued early in study and where non-evaluable (11, 12)

*Uptitration to 2400mg on day 57 **if** PGA > 4 and at least 5 patients treated with 1600mg show no safety issues. Applied to patients 09 and 10.

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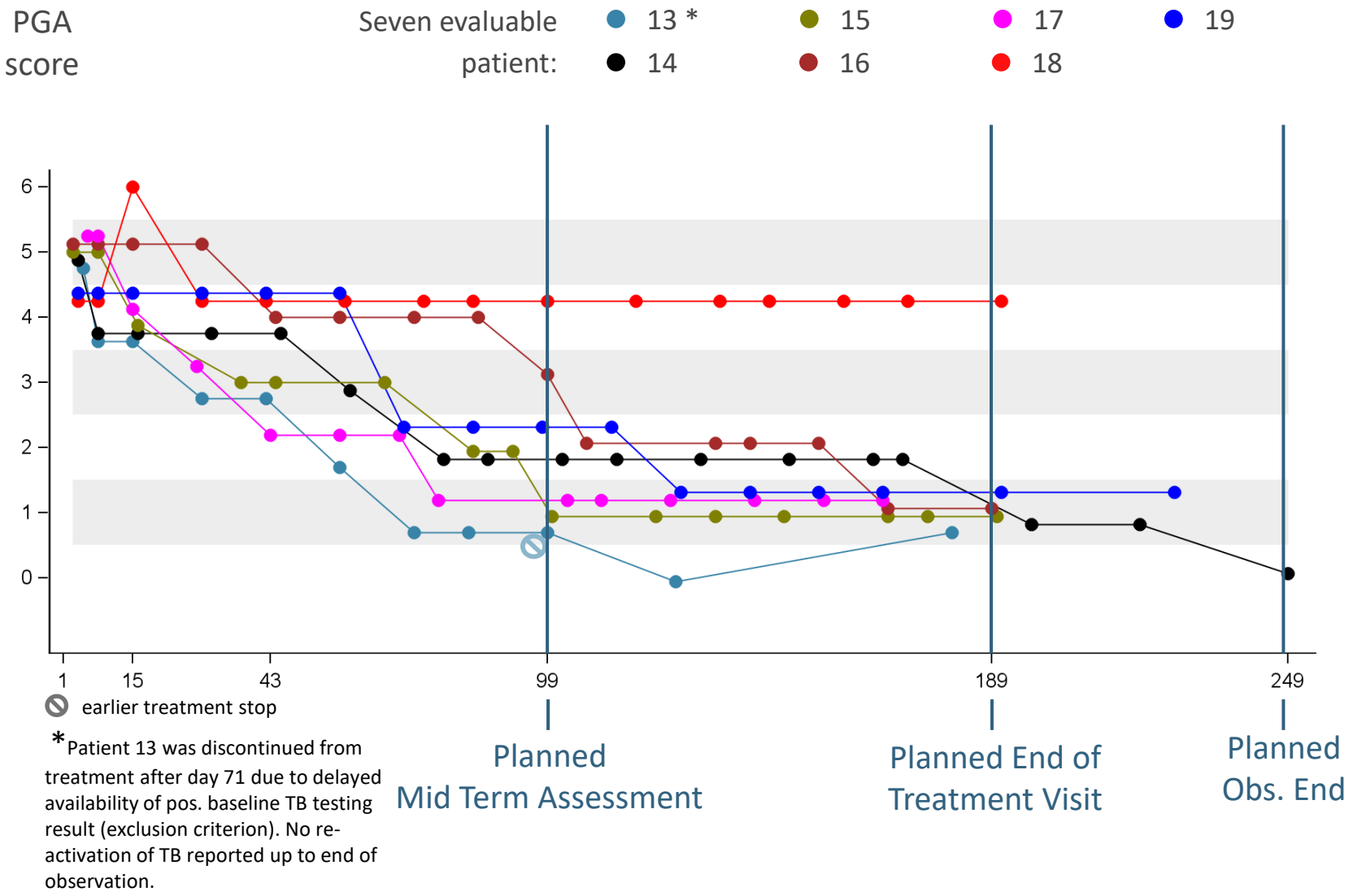
Study Results – Group 3 (High Dose)
PGA-line plot of absolute values over time by patient (Actual days displayed acc. to visit windows)

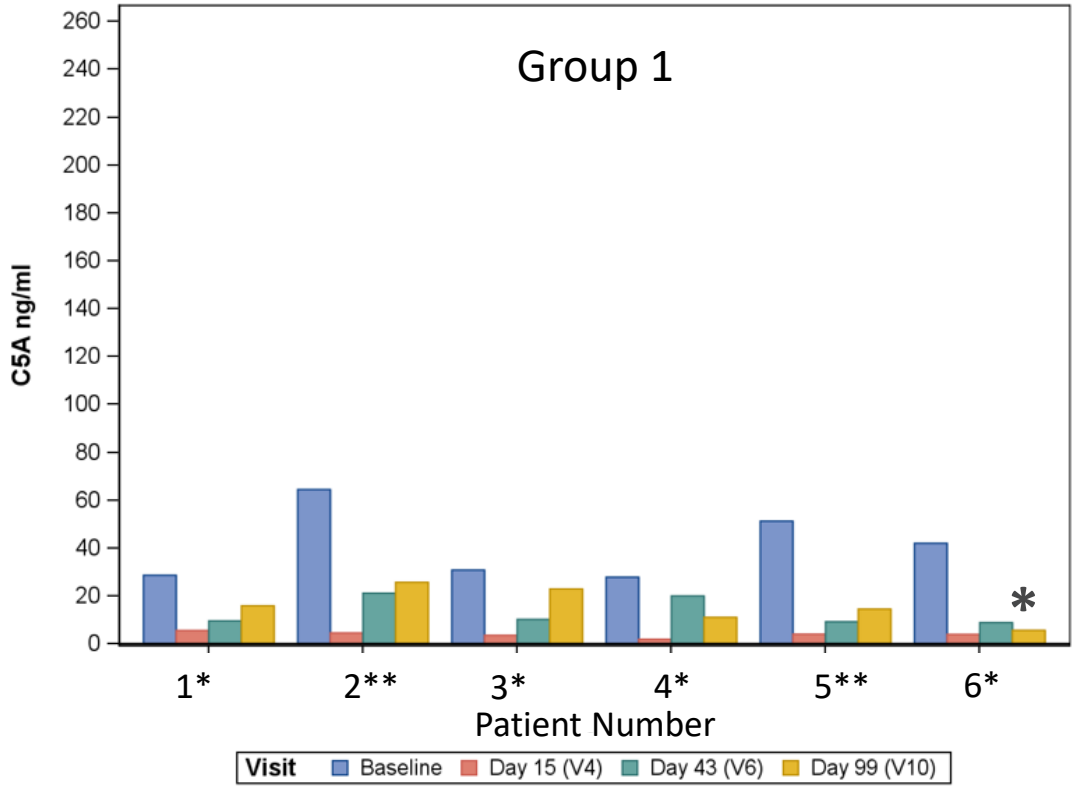


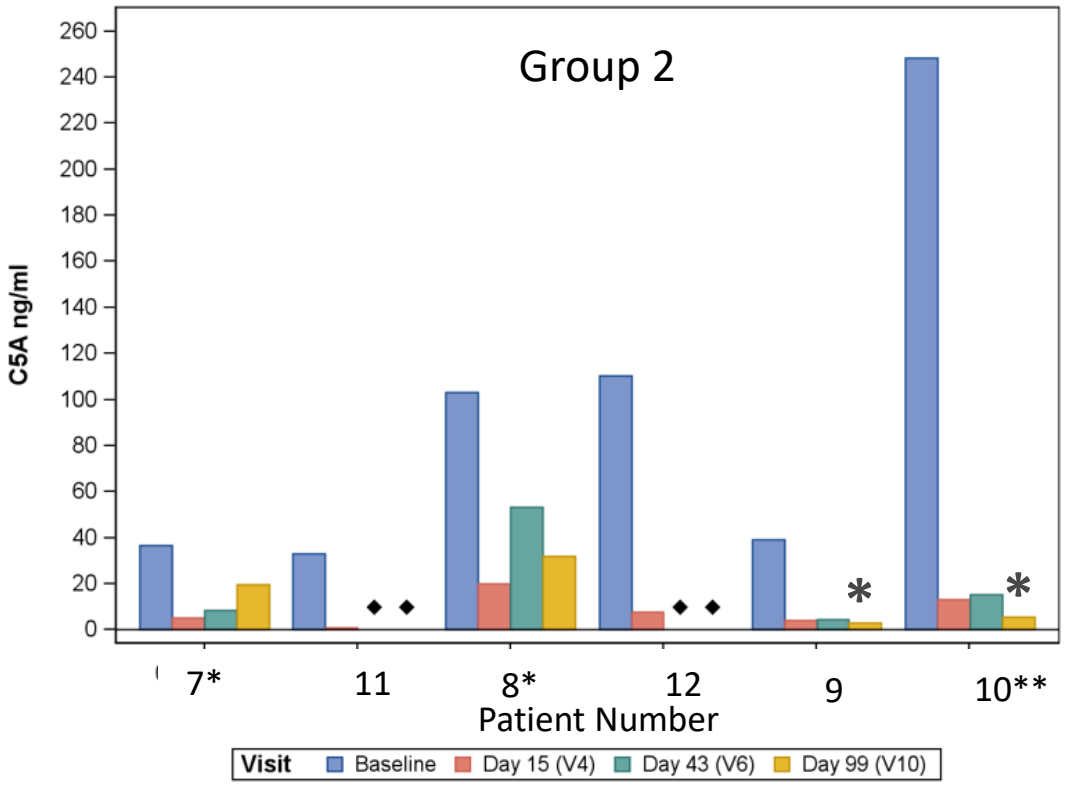
*Patient 13 was discontinued from treatment after day 71 due to delayed availability of pos. baseline TB testing result (exclusion criterion). No re-activation of TB reported up to end of observation.

Group 3 Results

- Six patients out of 7 achieved PGA score of ≤ 1 (remission)
- One patient (18) experienced target ulcer area decrease >50%; however, new PG lesions developed
- Patient 19 with complicated disease course
  - Pre-existing diabetes and wound infection in target ulcer area on day 1 with start of antibiotics
  - Wound infection and local progression in target ulcer area on day 50
  - Broad spectrum antibiotics and cyclosporin A starting day 50
  - Closure of target ulcer on day 127
- Patient 16 started 10 mg/d prednisone on day 72 (allowed per protocol)

Study Results – Group 1 and Group 2
C5a levels





Clinical observations

- Patient 10 in Group 2 reached clinical remission at Day 99 after uptitration to 2400mg at Day 57

* Responder (PGA Score ≤ 3)

** Responder in remission (PGA ≤1)

◆ Values not available

✻ Patients 6, 9, and 10 were uptitrated on day 57

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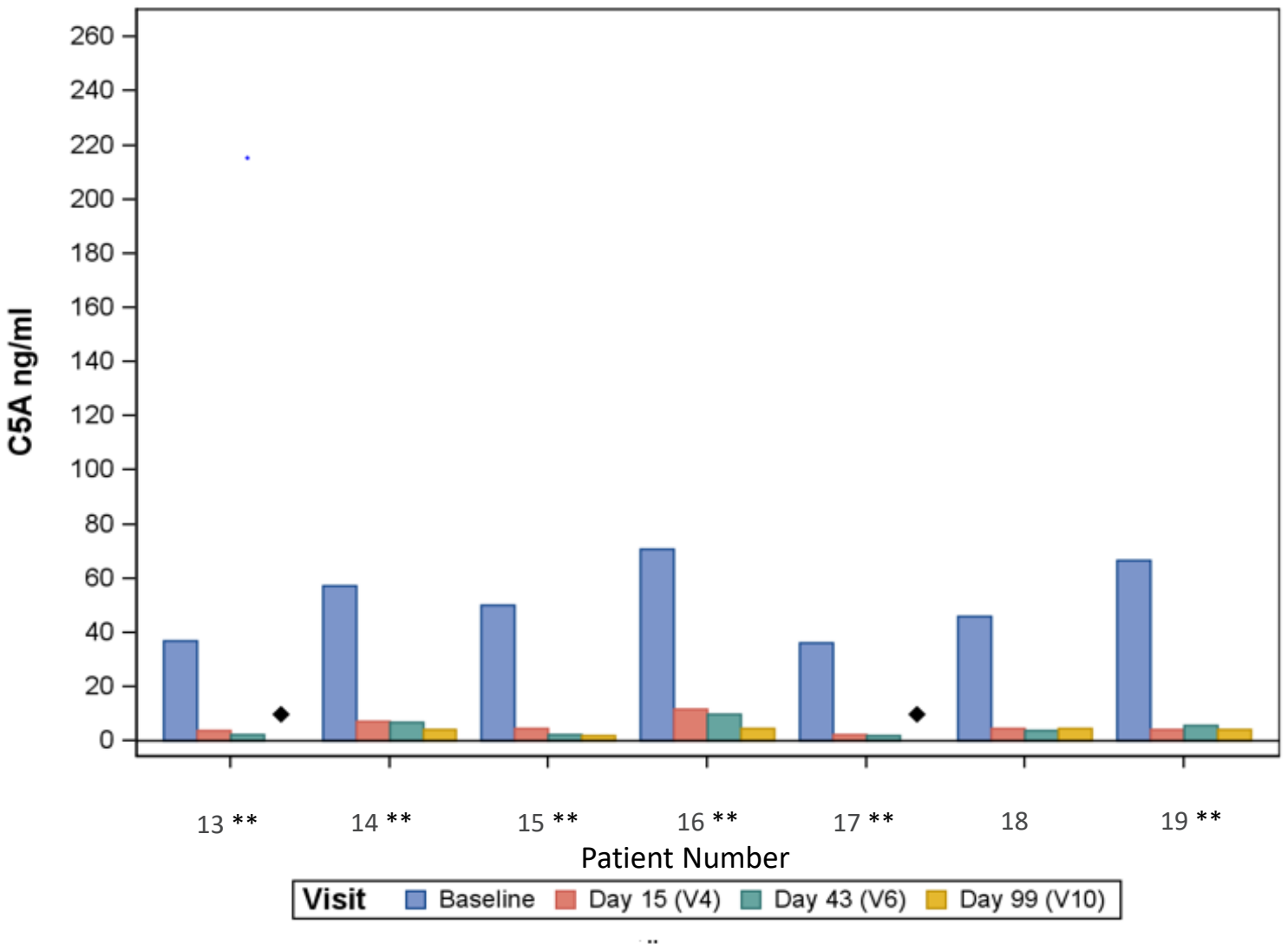
Study Results – Group 3
C5a levels



Clinical observations

- Six patients reached PGA≤1
- Patient 18 only showed minor improvement of target ulcer but no remission

** Responder in remission (PGA ≤1)

◆ Values not available

Summary and Conclusion

SAFETY CONCLUSION

- No infusion-related reactions observed
- For 2 patients, related SAEs were reported:
  - Erysipelas leading to hospitalization (judged as non-related by sponsor)
  - Rash due to delayed hypersensitivity reaction
- Observed AE profile in line with patients' underlying diseases
- No dose-related AE detected

CLINICAL RESPONSE CONCLUSION

- Out of 17 evaluable patients at end of treatment visit or day of last drug administration
  - Clinical Remission (PGA ≤ 1): 9 patients (53%)
  - Clinical Response (PGA ≤ 3): 1 additional patient (6%)
  - Slight Improvement (PGA = 4): 7 patients (41%)
- **High Dose Group shows highest rate of target ulcer closure and clinical remission (85.7%)**

WE WILL MEET WITH FDA TO DISCUSS NEXT STEPS

Vilobelimab Q2W shows good safety and tolerability
Evidence for dose-dependent drug activity in PG

Patient Case Studies

Patient 10 Case Study

TARGET ULCER REAPPEARED IN AUGUST 2020

MH: PG since Jun 2019, Hypertension since 1998; **Study Day 1:** Feb 2021

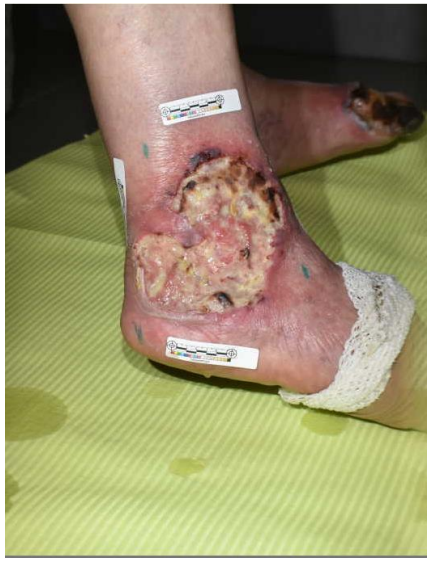
Cohort 2: 1600 mg Q2W, individual uptitration to 2400 mg at D57, treatment completed

Previous PG medication: Methylprednisolone only in Jun 2019, Dapsone Jun 2019- Aug 2020, Cyclosporine Oct 2019- Aug 2020 -> ulcer healed and reappeared soon after discontinuation of immunosuppressants

Concomitant Medication: Prednisone 10 mg for PG since October 2020

Baseline

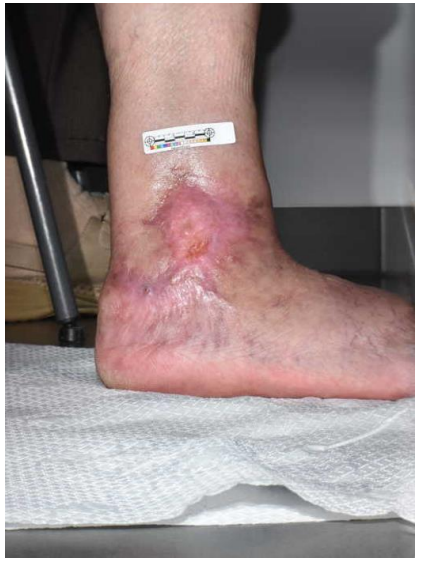
Area: 3695 mm^2



Day 99

PGA = 1

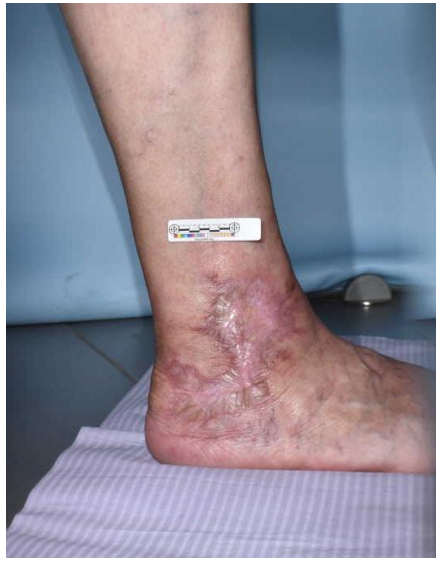
Area: 0.00 mm^2



Day 189, V16 (20 days after last vilo. admin.)

PGA = 1

Area: 0.00 mm^2



Patient 14 Case Study

PG TREATMENT HISTORY: CICLOSPORIN, DAPSONE

MH: PG since October 2018, Obesity since longer time (no exact day available)

Treatment Start: February 2021

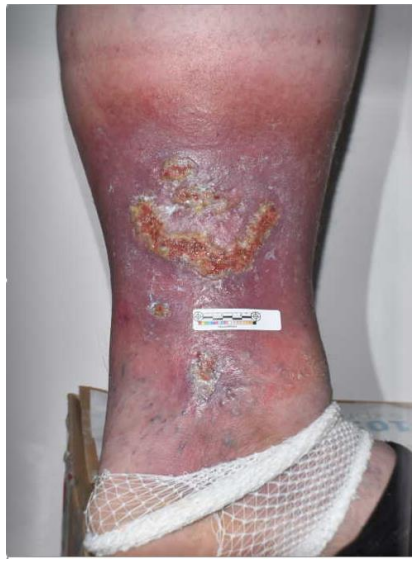
Cohort 3: 2400 mg Q2W treatment completed

Previous PG medication: Ciclosporin and methylprednisolone October 2018 – September 2019, failed. Dapsone September 2020 – November 2020.

Concomitant Medication: Prednisone 10 mg since October 2018

Baseline

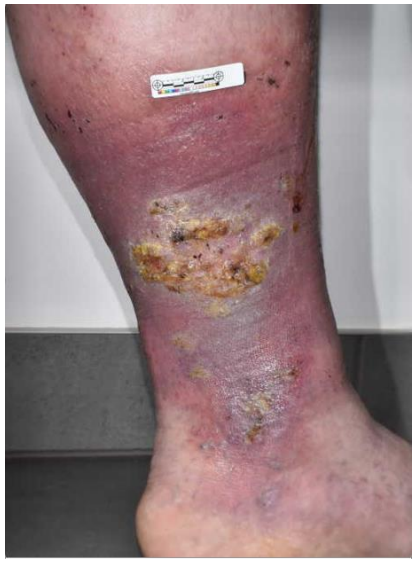
Area: 1285 mm^2



Day 99

PGA = 2

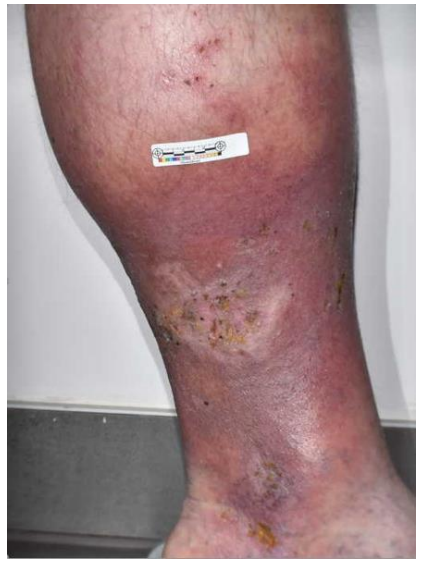
Area: 0.0 mm^2



Day 189, V16 (20 days after last vilo. admin.)

PGA = 1

Area: calculation not yet available



Patient 13 Case Study

TARGET ULCER OPENED IN NOVEMBER 2020 WHILE ON STABLE ADALIMUMAB

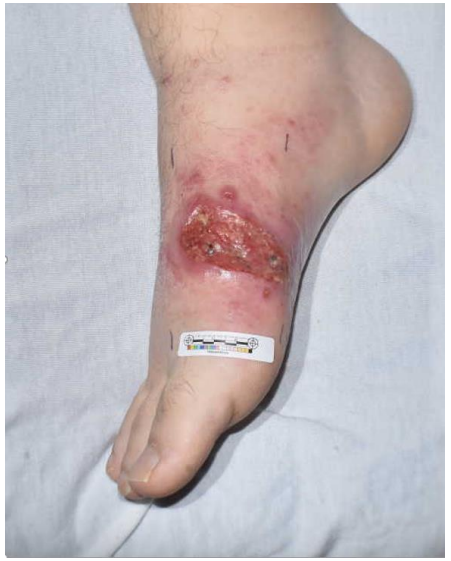
MH: PG since August 2020, Psoriasis since 2017
Treatment Start: March 2021
Previous PG medication: None

Cohort 3: 2400 mg Q2W up to Day 85 → exclusion after 9 doses due to delayed availability of pos. baseline TB testing result (no TB activation!)

Concomitant Medication: Adalimumab for psoriasis 40 mg QD since 2017

Baseline

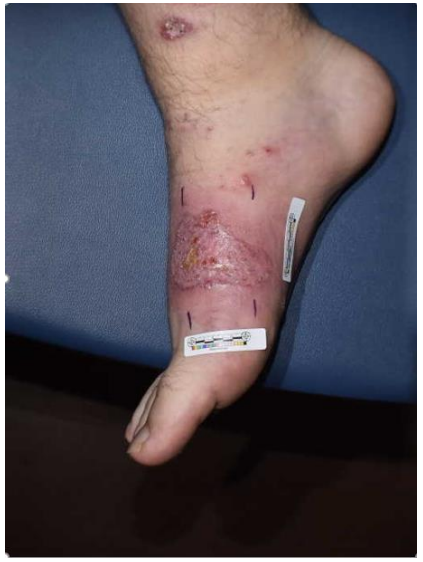
Area: 1136 mm^2



Day 85

PGA = 1

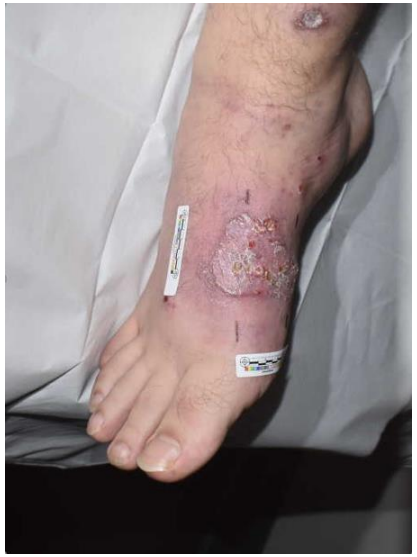
Area: 0.00 mm^2



Day 98, end of treatment visit

PGA = 1

Area: calculation not yet available



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