Immunic Therapeutics

IMU-935: Phase 1 SAD/MAD Data in Healthy Human Subjects and Preclinical Update

NASDAQ: IMUX | December 14, 2021

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Forward-looking statements included in this presentation are based on information available to Immunic as of the date of this presentation. Immunic does not undertake any obligation to update such forward-looking statements except as required by applicable law.

Development Pipeline

Program	Target	Preclinical	Phase 1	Phase 2	Phase 3	Key 2021/22 Milestones
vidofludimus calcium (IMU-838)	DHODH	Relapsing Multiple Sclerosis (RMS)				▪ Phase 2 UC: top-line data expected in Q2/2022
		Progressive Multiple Sclerosis (PMS)				
		Ulcerative Colitis (UC)				
		Crohn's Disease (CD)				
		Primary Sclerosing Cholangitis (PSC)				
IMU-935	RORγt	Psoriasis				▪ Phase 1b psoriasis: initial data expected in Q2/2022
		Castration-Resistant Prostate Cancer (CRPC)				▪ Phase 1 CRPC: initial data expected in Q3/2022
		Guillain-Barré Syndrome (GBS)				
IMU-856	Intestinal Barrier Function	Gastrointestinal Diseases				▪ Phase 1 healthy volunteers: unblinded SAD/MAD safety data expected in Q3/2022

▪ Completed or ongoing ▪ In preparation or planned

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IMU-935: Phase 1 SAD/MAD Data in Healthy Human Subjects and Preclinical Update

01 **Phase 1 Clinical Trial of IMU-935**
- Trial Design and Status
- Results Part A: Single Ascending Doses
- Results Part B: Multiple Ascending Doses
- Ongoing Part C in Psoriasis Patients

02 Newly Obtained *In Vivo* Data

03 Summary

Autoimmune Diseases and IMU-935

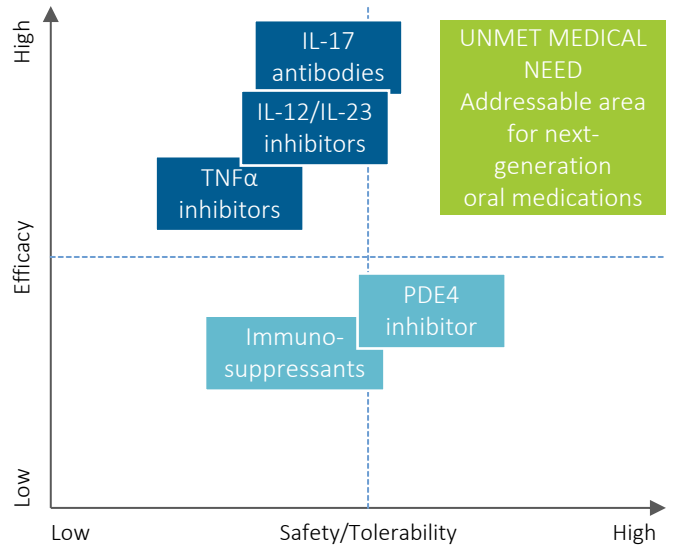
IL-17 in Autoimmune Diseases

- Autoimmune diseases affect millions of patients worldwide[1]
- Th17/IL-17/RORγt axis plays an important role in auto immunity-related diseases[2]
- Antibodies targeting this axis corroborate IL-17's role in autoimmune diseases, but are more complex, costly and less patient friendly than oral drugs[2]

Goal

- Develop an orally available and potent IL-17 inhibitor for the safe and efficacious treatment of autoimmune diseases
- Small molecule inhibitor of the pathologic functions of RORγt in autoimmune diseases without affecting physiological functions of RORγt

Unmet Need in Psoriasis Care



Strong Medical Need for Oral IL-17 Pathway Inhibitors such as IMU-935

[1] Rose, Noel R. American journal of epidemiology 2016; 183.5: 403-406 [2] Fasching, Patrizia, et al. Molecules 2017 22.1: 134
Th: T helper; IL: interleukin; TNF: tumor necrosis factor; PDE4: phosphodiesterase type 4; RORγ: retinoic acid receptor-related orphan nuclear receptor gamma

01

Phase 1 Clinical Trial of IMU-935

Trial Design and Status

Results Part A: Single Ascending Doses

Results Part B: Multiple Ascending Doses

Ongoing Part C in Psoriasis Patients

01

Phase 1 Clinical Trial of IMU-935

Trial Design and Status

Results Part A: Single Ascending Doses

Results Part B: Multiple Ascending Doses

Ongoing Part C in Psoriasis Patients

Clinical Trial Design Phase 1 IMU-935 and Current Status

PART A

Evaluation of single ascending doses (SAD)

—

Healthy volunteers randomized to receive single dose of either IMU-935 or placebo

- Dose escalation completed: 100, 200, 300 and 400 mg of IMU-935
- Final PK analysis ongoing
- 79 subjects enrolled
- IMU-935 was well-tolerated and showed dose-linear PK

PART B

Evaluation of multiple ascending doses (MAD)

—

Healthy volunteers randomized to receive 14-day treatment of either IMU-935 or placebo

- Dose escalation completed: 150 mg QD and 150 mg BID of IMU-935
- Final PK analysis ongoing
- 15 subjects enrolled
- IMU-935 was well-tolerated and steady-state was achieved after 3-6 days of dosing

PART C

Evaluation of moderate-to-severe psoriasis patients receiving 28-day treatment of either IMU-935 or placebo

- 150 mg QD and 150 mg BID of IMU-935
- Approximately 52 patients planned to be enrolled
- Initial data expected to be available in Q2/2022

PK: pharmacokinetic; QD: quaque die = once-daily; BID: bis in die = two times daily

01

Phase 1 Clinical Trial of IMU-935

Trial Design and Status

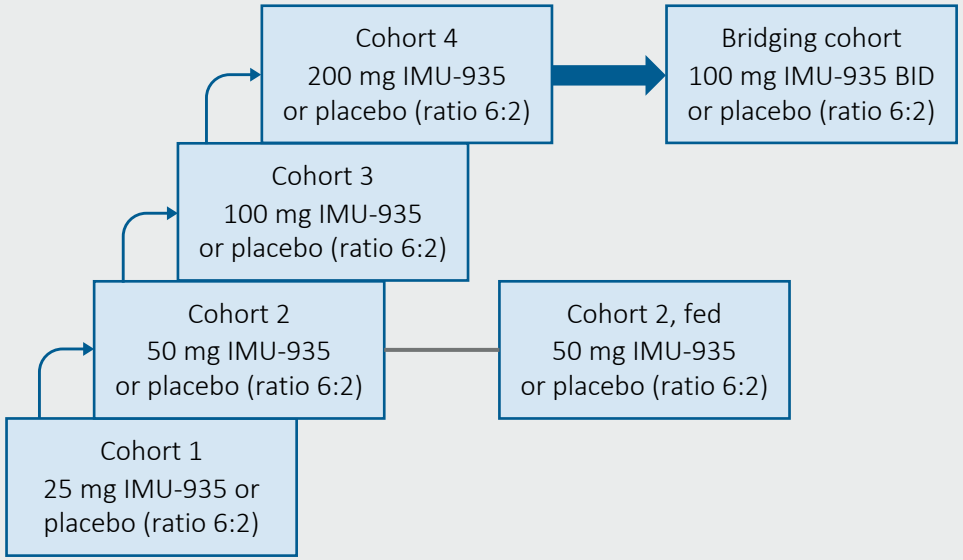
Results Part A: Single Ascending Doses

Results Part B: Multiple Ascending Doses

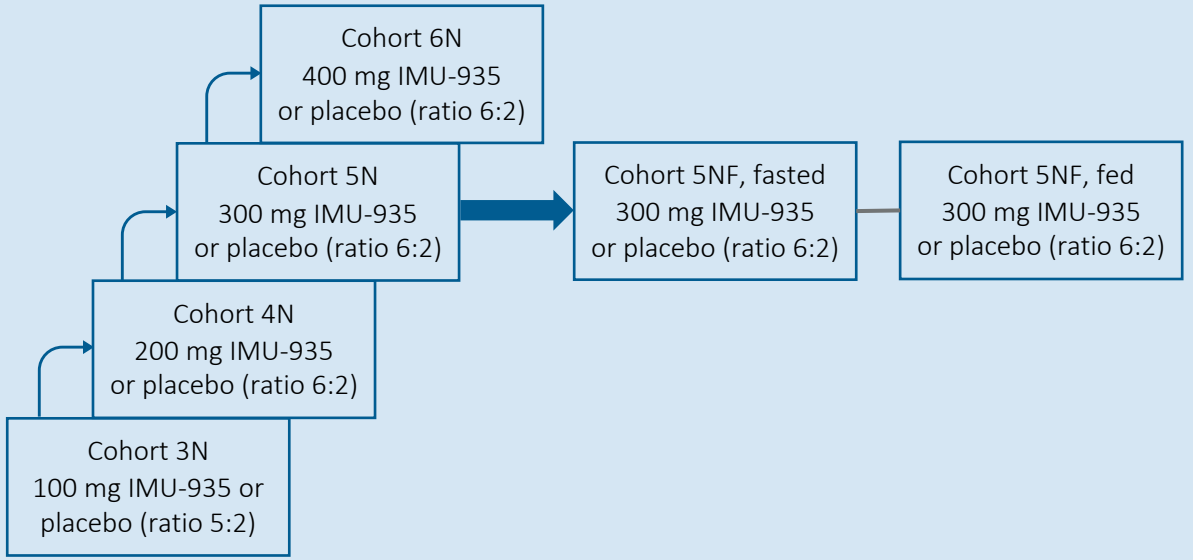
Ongoing Part C in Psoriasis Patients

Dose Escalation Scheme
Part A: Single Ascending Doses

Part A: Initial Lipid-Based Pilot Formulation



Part A-N: Powder-in-Capsule Formulation



BID: bis in die = two times daily
If no dosing regimen is specifically mentioned, then once daily administration in fasted condition was performed.
For full disclosure, data for the Part A pilot formulation can be found in the Extended Information section of this presentation, but will not be presented. The presentation will focus on the powder-in-capsule formulation (Part A-N).

Summary of Safety and Tolerability Findings
Part A-N

Single Doses of IMU-935 in Healthy Human Subjects Were Found to Have a Favorable Safety and Tolerability Profile

- No serious adverse events
- No dose-dependency in adverse events
- No maximum tolerated dose reached
- No trends for post-dose changes in any laboratory parameter
- No related adverse events in the active treatment group regarding any laboratory parameter
- No medically relevant changes in vital signs or 12-lead electrocardiograms as compared to placebo

Most Common Treatment-Emergent Adverse Events
Part A-N

MedDRA Preferred Term	Number (%) of subjects with TEAEs occurring in more than 2 subjects [Number of TEAEs reported]							
	100 mg (N=5)	200 mg (N=6)	300 mg (N=6)	300 mg fasted (N=6)	300 mg fed (N=6)	400 mg (N=6)	Active (N=29)	Placebo (N=10)
Headache	-	1 (17%) [1]	-	3 (50%) [5]	1 (17%) [1]	1 (17%) [1]	5 (17%) [8]	3 (30%) [4]
Dizziness	-	-	2 (33%) [2]	1 (17%) [1]	-	1 (17%) [1]	4 (14%) [4]	-
Catheter site pain	1 (20%) [1]	2 (33%) [2]	-	-	-	-	3 (10%) [3]	1 (10%) [1]
Constipation	-	1 (17%) [1]	-	-	-	2 (33%) [2]	3 (10%) [3]	-
Fatigue	-	-	-	2 (33%) [2]	-	-	2 (7%) [2]	1 (10%) [1]

Single doses of IMU-935 using the powder-in-capsule formulation were safe and well-tolerated with headache, dizziness, catheter site pain, constipation and fatigue being the most common TEAEs.

TEAE: Treatment-Emergent Adverse Event
Displayed are TEAEs that occurred in more than 2 subjects. The treatments 300 mg fasted and fed were given (in two periods) to the same subjects of cohort 5NF.

Summary of Safety and Tolerability Profile
Part A-N

- Serious AEs (SAE)
  - None (N=0)
- Treatment discontinuations due to AEs
  - None (N=0)
- Moderate TEAEs
  - Placebo (N=1/10; 10%)
    - Headache (2 events, unrelated)
  - IMU-935 (N=4/29, 14%)
    - Nausea, toothache, skin abrasion, AST increased (all unrelated)
    - Headache (related)

      Occurred after a single dose of 200 mg IMU-935 on day 2, resolved with treatment after 1 day
- Severe TEAEs
  - IMU-935 (N=1/29; 3%)
    - Blood creatine kinase increased (unrelated)

      Occurred after a single dose of 300 mg IMU-935 in the fed state, only elevated at end-of-study visit (day 14) and related to a rock climbing event

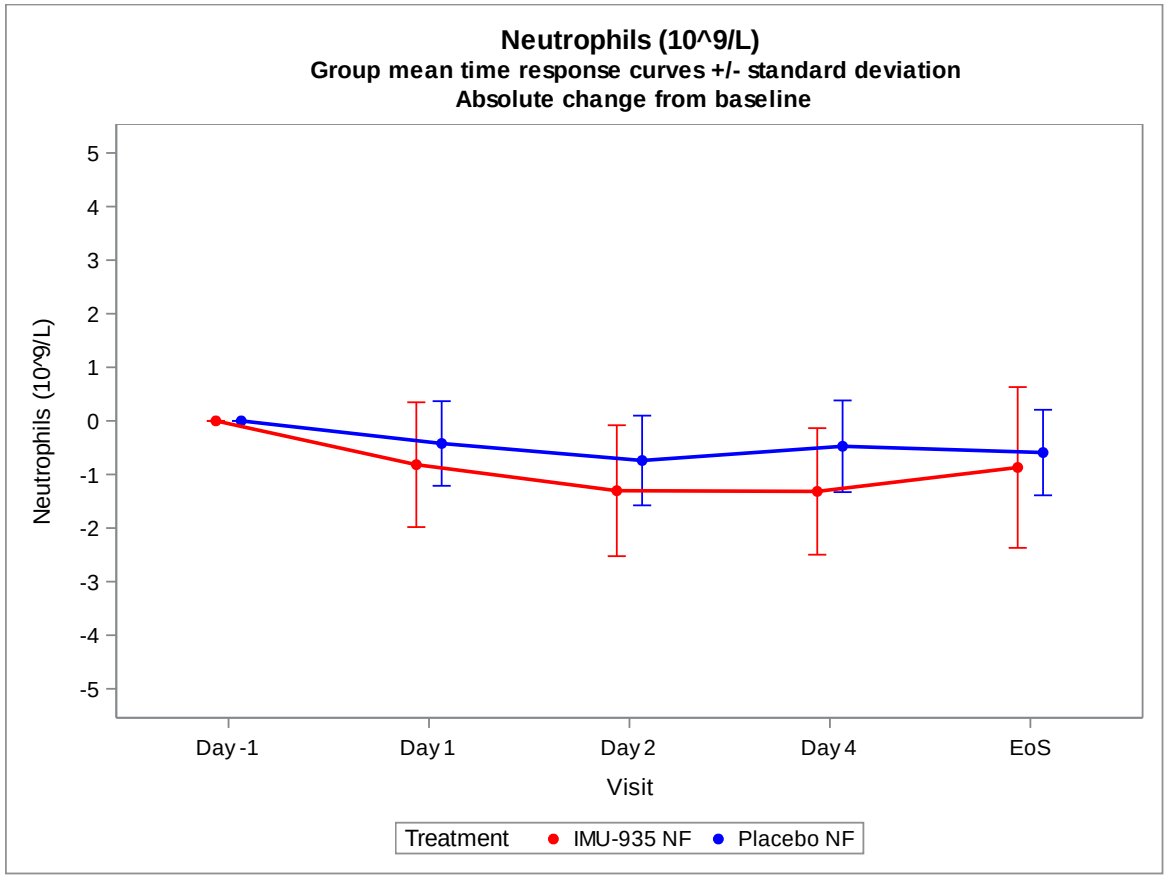
- Summary of laboratory variables
  - No trend for changes over time for any parameter
  - Shift tables showed no trend of individual changes beyond the normal range for any parameter
- TEAEs associated with laboratory abnormalities
  - Placebo (N=1/10; 10%)
    - Lipase increase (related)
  - IMU-935 (N=3/29; 10%)
    - All changes of laboratory parameters in these subjects have plausible explanations or can be clearly related to life events

      (for full disclosure, more detailed information about these events are contained in the Extended Information section of this slide deck)
- TEAEs associated with vital signs
  - None (N=0)
- TEAEs associated with 12-lead ECGs
  - None (N=0)

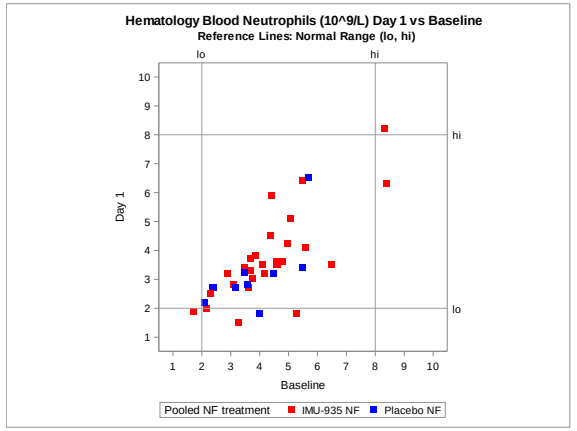
AE: Adverse Event; SAE: Serious Adverse Event; TEAE: Treatment-Emergent Adverse Event; ECG: electrocardiogram; AST: Aspartate Aminotransferase

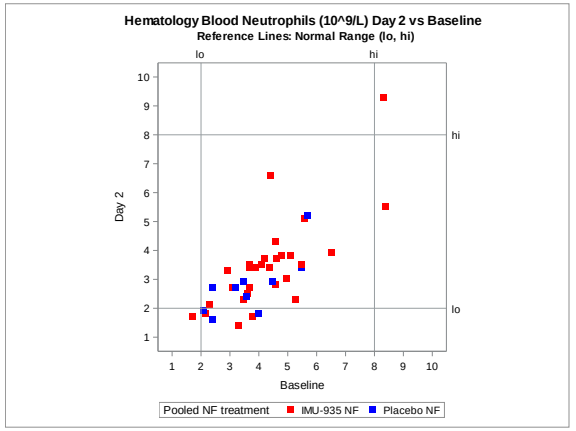
Laboratory Parameters: No Change in Neutrophils Compared to Placebo
Part A-N

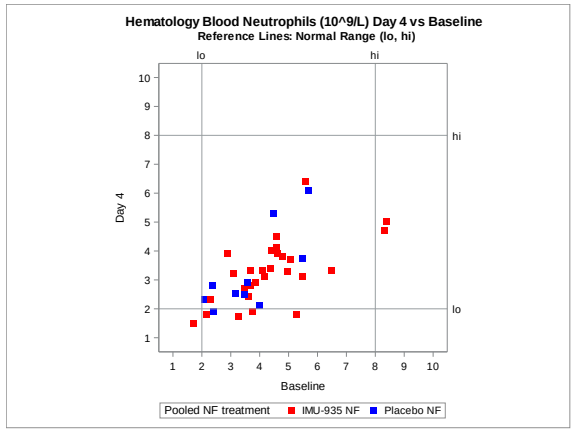
Laboratory Values Over Time
Hematology - Neutrophils

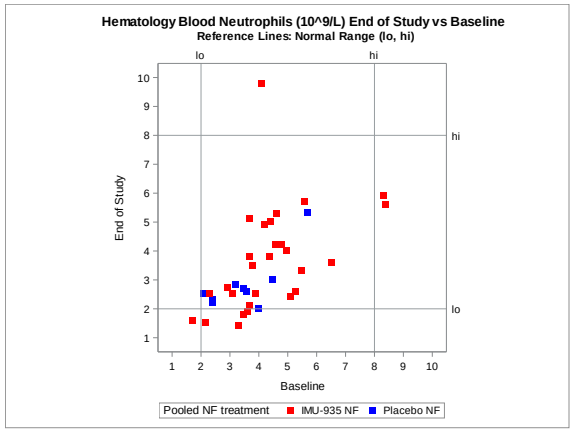


Individual Laboratory Values
Hematology - Neutrophils



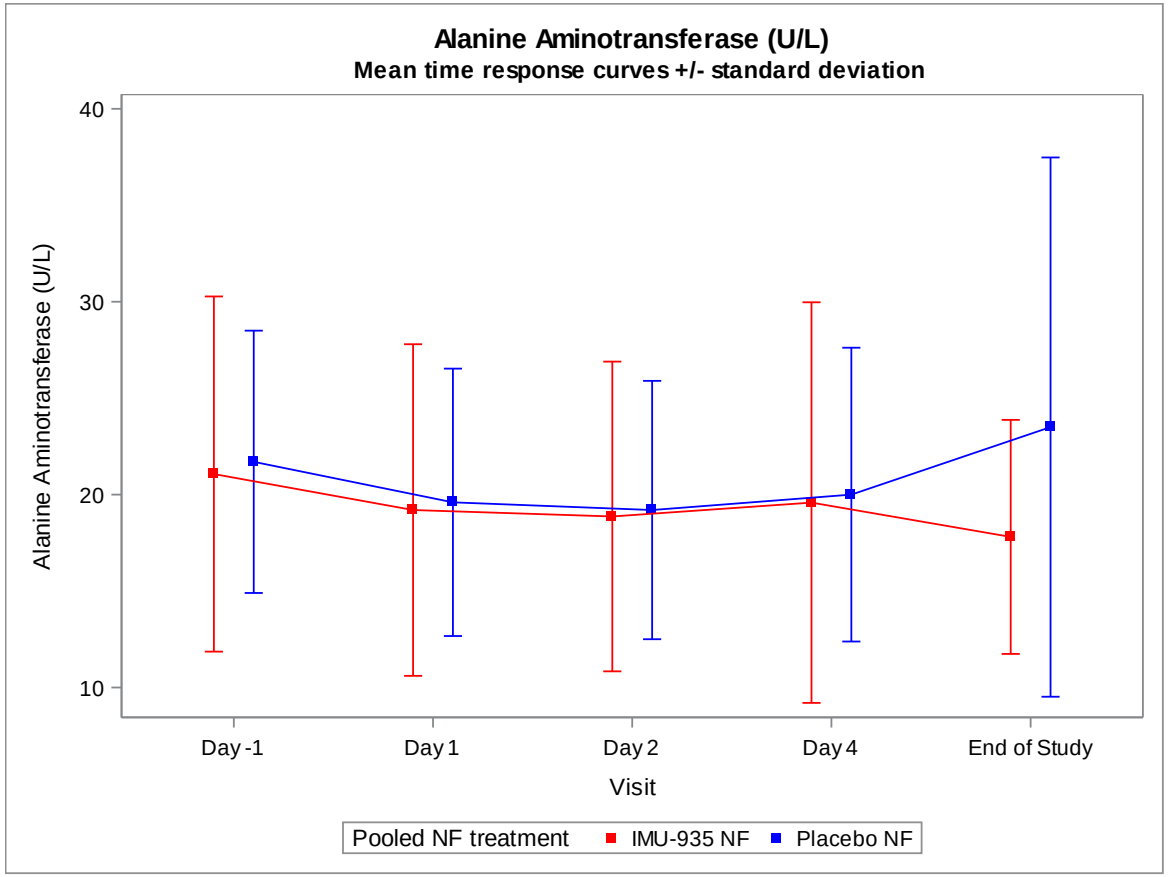




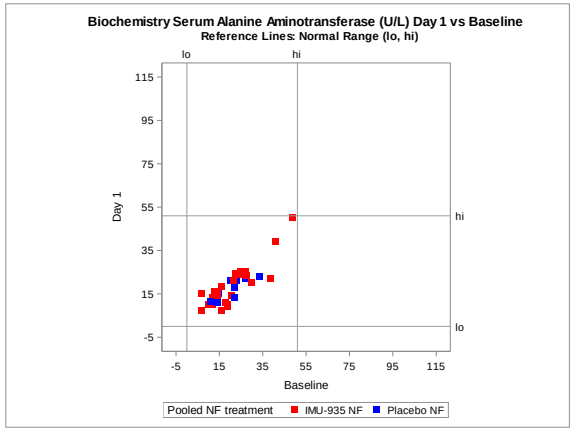


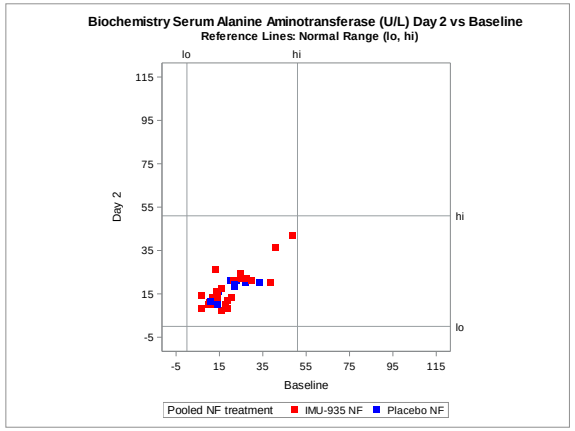
Laboratory Parameters: No Increase of ALT Compared to Placebo
Part A-N

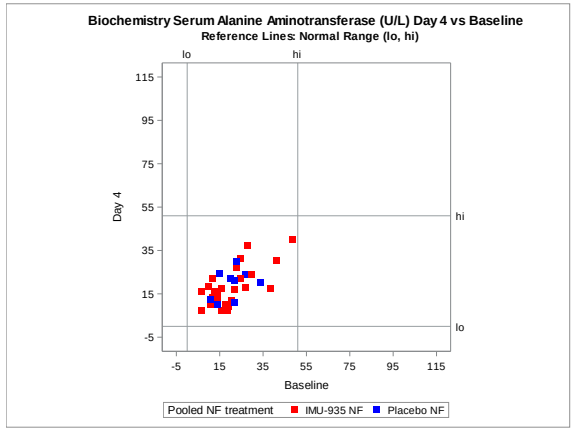
Laboratory Values Over Time
Biochemistry - ALT

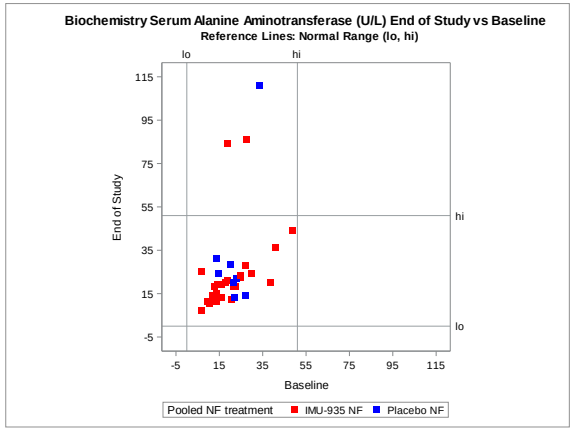


Individual Laboratory Values
Biochemistry - ALT







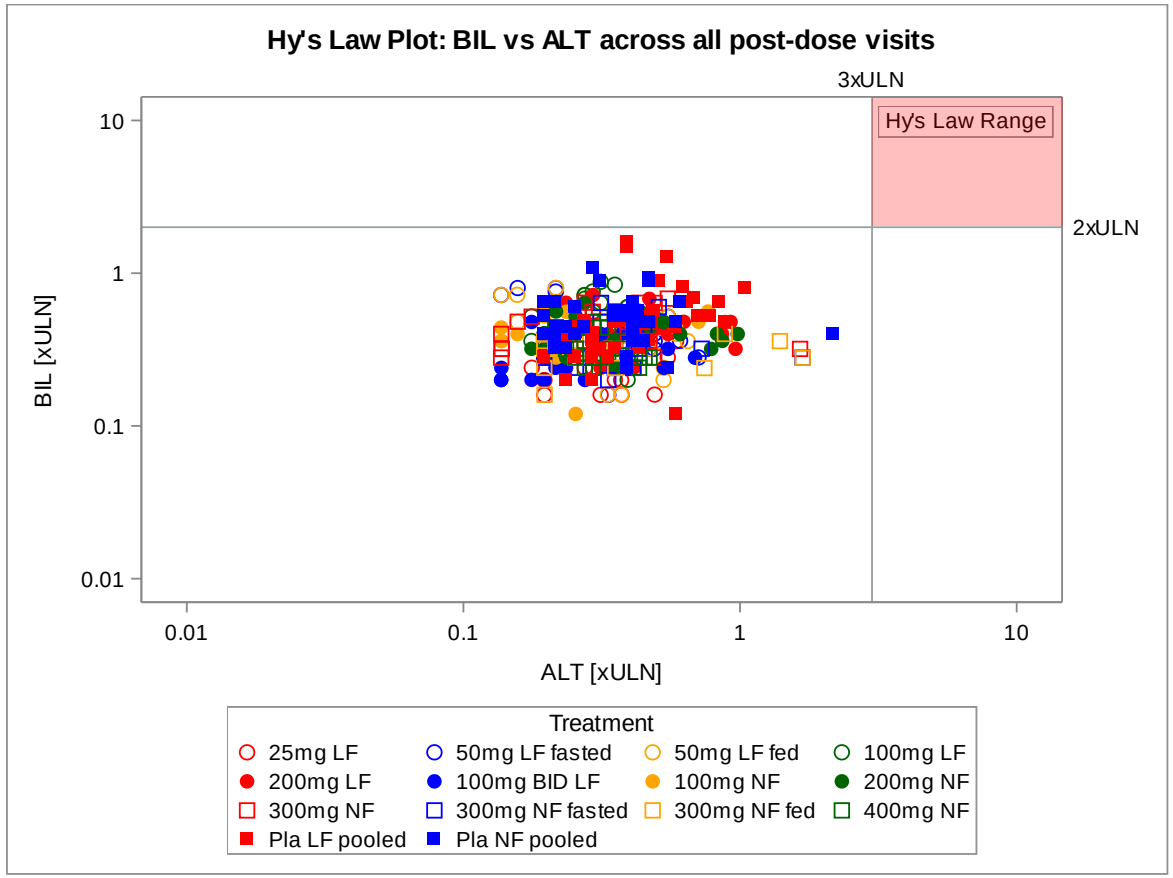


ALT: Alanine Aminotransferase

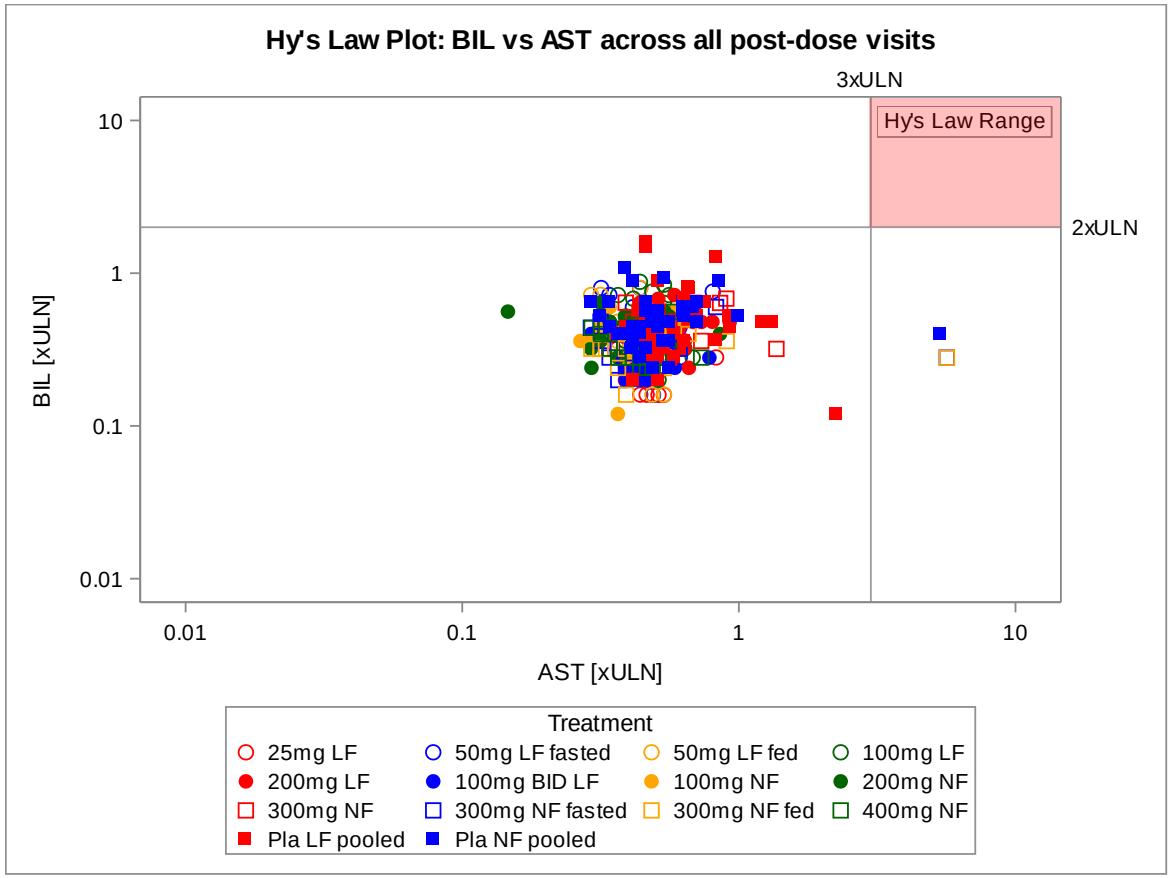
Laboratory Parameters: No Hy's Law Range Cases Observed

Part A and Part A-N Combined

Bilirubin vs. ALT Showed No Evidence of DILI Potential



Bilirubin vs. AST Showed No Evidence of DILI Potential



ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase; DILI: drug-induced liver injury; BIL: Bilirubin; ULN: Upper Limit of Normal; Pla: Placebo

Conclusions

Part A-N: Single Ascending Doses

- The powder-in-capsule formulation provided favorable pharmaceutical properties in Part A-N of this clinical trial.
- Its favorable safety and tolerability allowed smooth transition from Part A (SAD) to Part B (MAD) in healthy human subjects.

01

Phase 1 Clinical Trial of IMU-935

Trial Design and Status

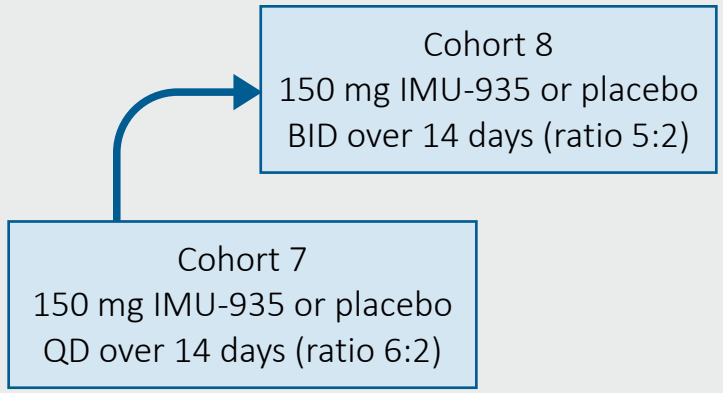
Results Part A: Single Ascending Doses

Results Part B: Multiple Ascending Doses

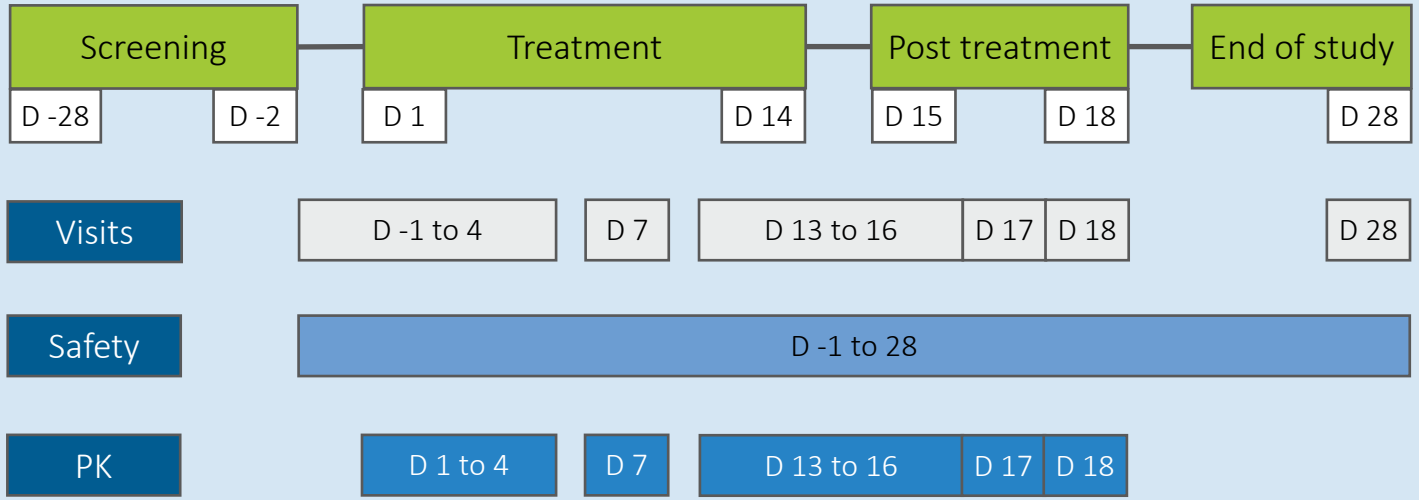
Ongoing Part C in Psoriasis Patients

Design of Part B: Multiple Ascending Doses of IMU-935

Dose Escalation Scheme



Study Period



QD: quaque die = once-daily; BID: bis in die = two times daily; D: day
Part B was performed with the powder-in-capsule formulation only.

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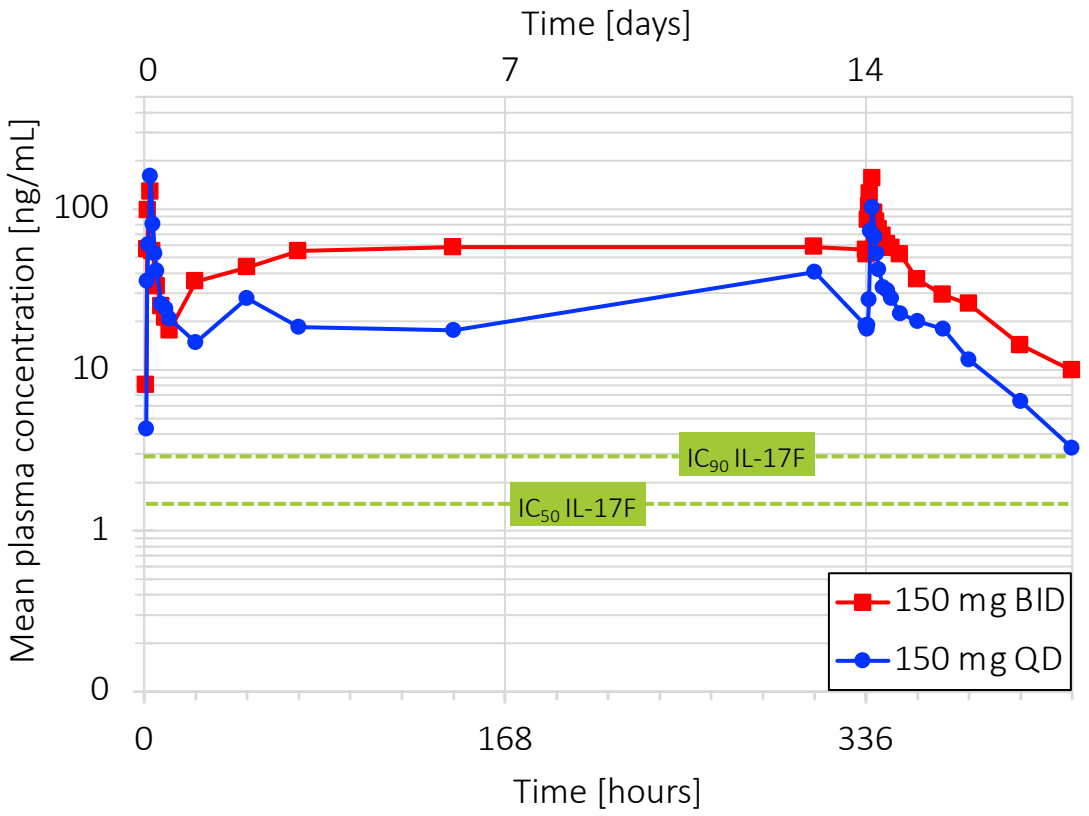
Pharmacokinetic Results

Part B: Summary of QD and BID Dosing Regimen for IMU-935

IMU-935 concentration time profiles (log-linear scale)



Favorable PK Properties for IMU-935 at Steady-State Observed

Pharmacokinetic parameters in steady-state (mean)	150 mg QD	150 mg BID
$C_{max, ss}$ (ng/mL)	124	206
$C_{min, ss}$ (ng/mL)	15.7	48.5
$T_{max, ss}$ (hr)	2.8	2.4
$t_{1/2, ss}$ (hr)	29.0	38.0
AUC_{last} (hr*ng/mL)	1540	3040

Non-compartmental analysis

- Fast achievement of steady-state within first week and stable steady-state trough levels over 14-day treatment period.
- Accumulation factors of 1.29 (150 mg QD) and 2.21 (150 mg BID) allowing predictable trough levels.

Interim data, PK analysis ongoing

QD: quaque die = once-daily; BID: bis in die = two times daily; PK: pharmacokinetic; C_{max}: maximum plasma drug concentration; T_{max}: time to reach maximum plasma concentration; hr: hours; $t_{1/2}$: half-life; AUC_{last}: area under the concentration-time curve from dosing to last measurement

Accumulation factors were calculated as the relationship of $AUC_{0\text{-}tau}$ of Day 14/Day 1 (after first dosing).

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Summary of Safety and Tolerability Findings
Part B

Daily Dosing of IMU-935 in Healthy Human Subjects Over 14 Days Was Found to Have a Favorable Safety and Tolerability Profile

- No serious adverse events
- No dose-dependency in adverse events
- No maximum tolerated dose reached
- No trends for post-dose changes in any laboratory parameter
- No adverse events regarding any laboratory parameter
- No medically relevant changes in vital signs or 12-lead electrocardiograms as compared to placebo

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Overall Summary of TEAE, SAE and AE Severity
Part B

Category	Treatment			
	150 mg QD (N=6)	150 mg BID (N=5)	Active (N=11)	Placebo (N=4)
Subjects with TEAEs, n (%)	6 (100%)	4 (80%)	10 (91%)	4 (100%)
Subjects with mild TEAEs, n (%)	6 (100%)	4 (80%)	10 (91%)	4 (100%)
Subjects with moderate TEAEs, n (%)	-	1 (20%)	1 (9%)	1 (25%)
Subjects with severe TEAEs, n (%)	-	-	-	-
Subjects with SAEs, n (%)	-	-	-	-
Subjects with TEAEs leading to withdrawal, n (%)	-	-	-	-
Number of TEAEs	15	7	22	15
Number of mild TEAEs	15	6	21	11
Number of moderate TEAEs	-	1	1	4
Number of severe TEAEs	-	-	-	-
Number of SAEs	-	-	-	-
Number of TEAEs leading to withdrawal	-	-	-	-

Daily 14-day dosing of IMU-935 using the powder-in-capsule formulation was found to be safe and well-tolerated:

- No dose-dependency in adverse events
- No SAEs
- No discontinuation due to AEs
- All mild TEAEs (except for 1 subject with moderate TEAEs in IMU-935 and placebo each)

QD: quaque die = once-daily; BID: bis in die = two times daily; TEAE: Treatment-Emergent Adverse Event; SAE: Serious Adverse Event; AE: Adverse Event

Most Common Treatment-Emergent Adverse Events
Part B

MedDRA Preferred Term	Number (%) of subjects with TEAEs occurring in more than 1 subject [Number of TEAEs reported]			
	150 mg QD (N=6)	150 mg BID (N=5)	Active (N=11)	Placebo (N=4)
Headache	2 (33%) [2]	3 (60%) [3]	5 (45%) [5]	2 (50%) [5]
Back pain	1 (17%) [1]	1 (20%) [1]	2 (18%) [2]	1 (25%) [1]
Epistaxis	2 (33%) [3]	-	2 (18%) [3]	-
Constipation	-	-	-	2 (50%) [2]
Catheter site irritation	1 (17%) [1]	-	1 (9%) [1]	1 (25%) [1]

Daily 14-day dosing of IMU-935 using the powder-in-capsule formulation was found to be safe and well-tolerated:

- Most common TEAEs were non-specific events, including headache, back pain, epistaxis, constipation and catheter site irritation

QD: quaque die = once-daily; BID: bis in die = two times daily; TEAE: Treatment-Emergent Adverse Event
Displayed are TEAEs that occurred in more than 1 subject

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Summary of Safety and Tolerability Profile
Part B

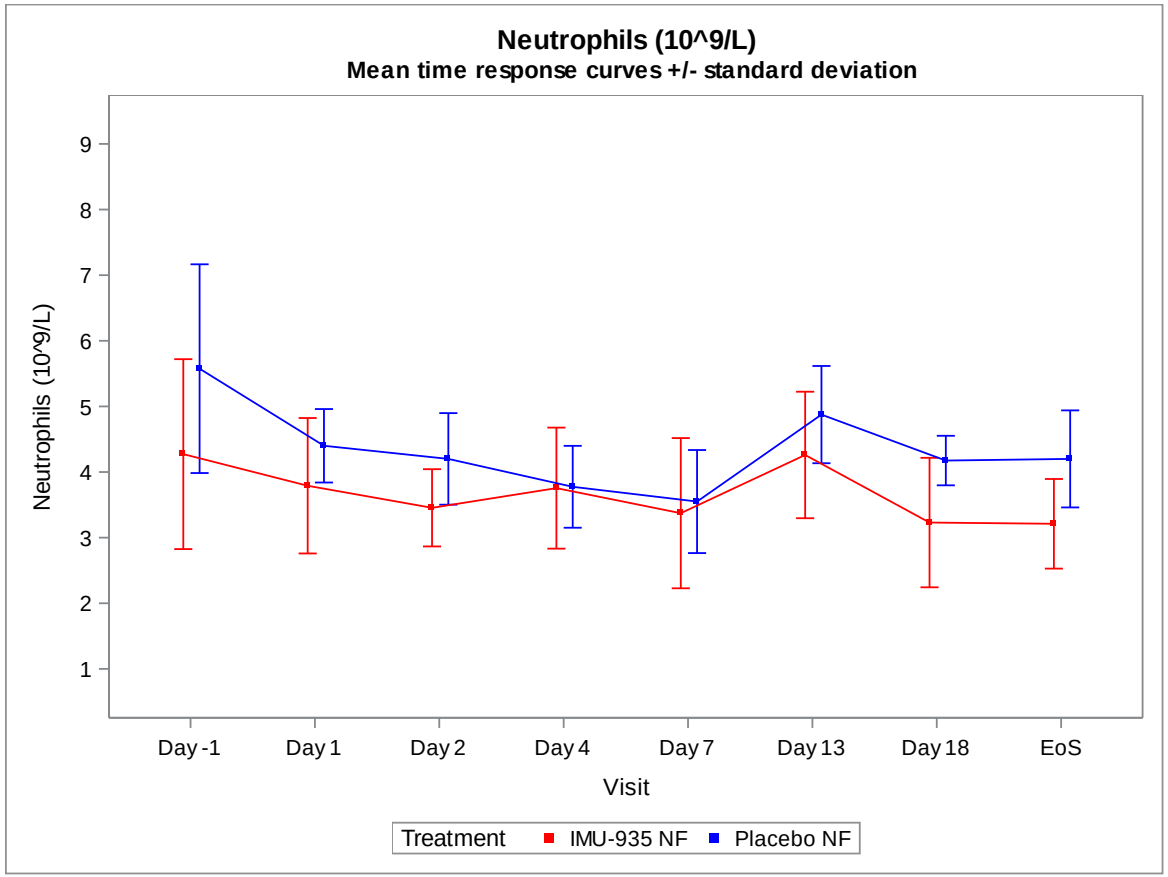
- Serious AEs (SAE)
  - None (N=0)
- Treatment discontinuations due to AEs
  - None (N=0)
- Moderate TEAEs
  - Placebo (N=1/4; 25%)
    - Constipation (related)
    - Animal bite, animal scratch and exacerbation of back pain (all unrelated)
  - 150 mg IMU-935 BID (N=1/11; 9%)
    - Catheter site reaction (unrelated)
- Severe TEAEs
  - None (N=0)
- Summary of laboratory variables
  - No trend for changes over time for any parameter
  - Shift tables showed no trend of individual changes beyond the normal range for any parameter
- TEAEs associated with laboratory abnormalities
  - None (N=0)
- TEAEs associated with vital signs
  - None (N=0)
- TEAEs associated with 12-lead ECGs
  - 150 mg IMU-935 QD (N=1)
    - PR prolongation

      Benign ECG finding in young healthy individuals
      (for full disclosure, more detailed information about this event is contained in the Extended Information section of this slide deck)

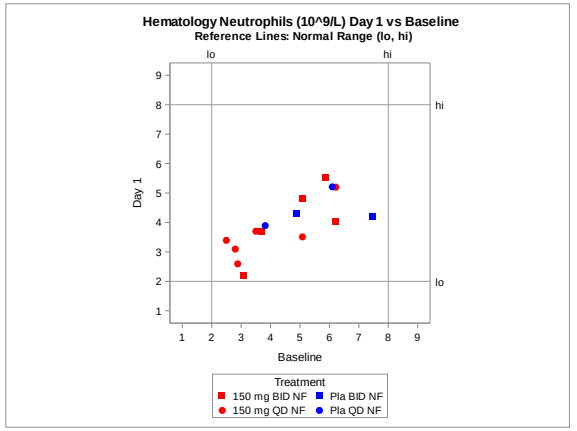
SAE: Serious Adverse Event; AE: Adverse Event; TEAE: Treatment-Emergent Adverse Event; ECG: electrocardiogram; QD: quaque die = once-daily; BID: bis in die = two times daily

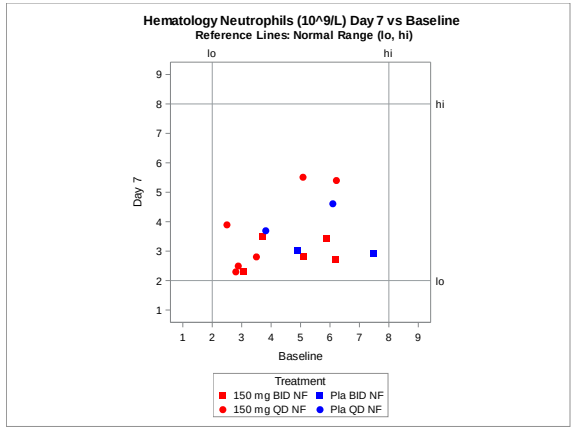
Laboratory Parameters: No Change in Neutrophils Compared to Placebo
Part B

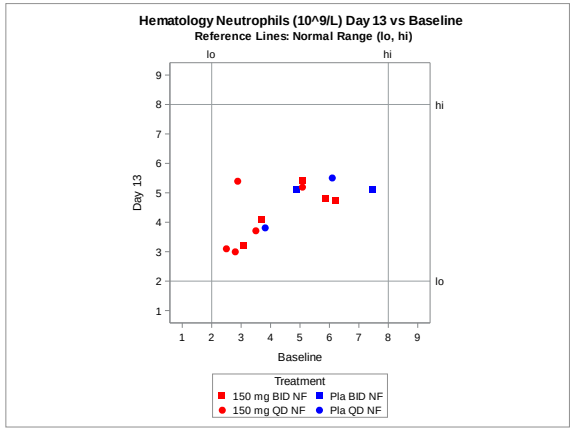
Laboratory Values Over Time
Hematology - Neutrophils

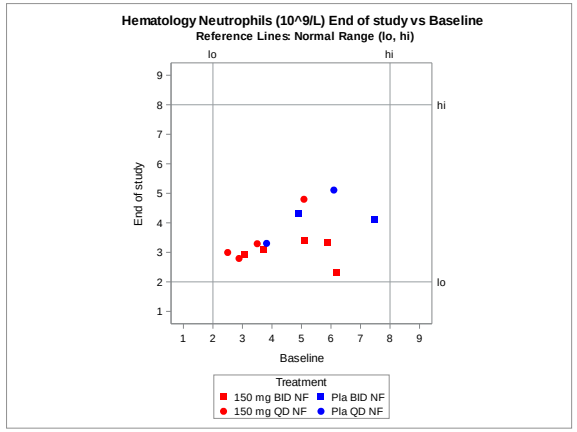


Individual Laboratory Values
Hematology - Neutrophils



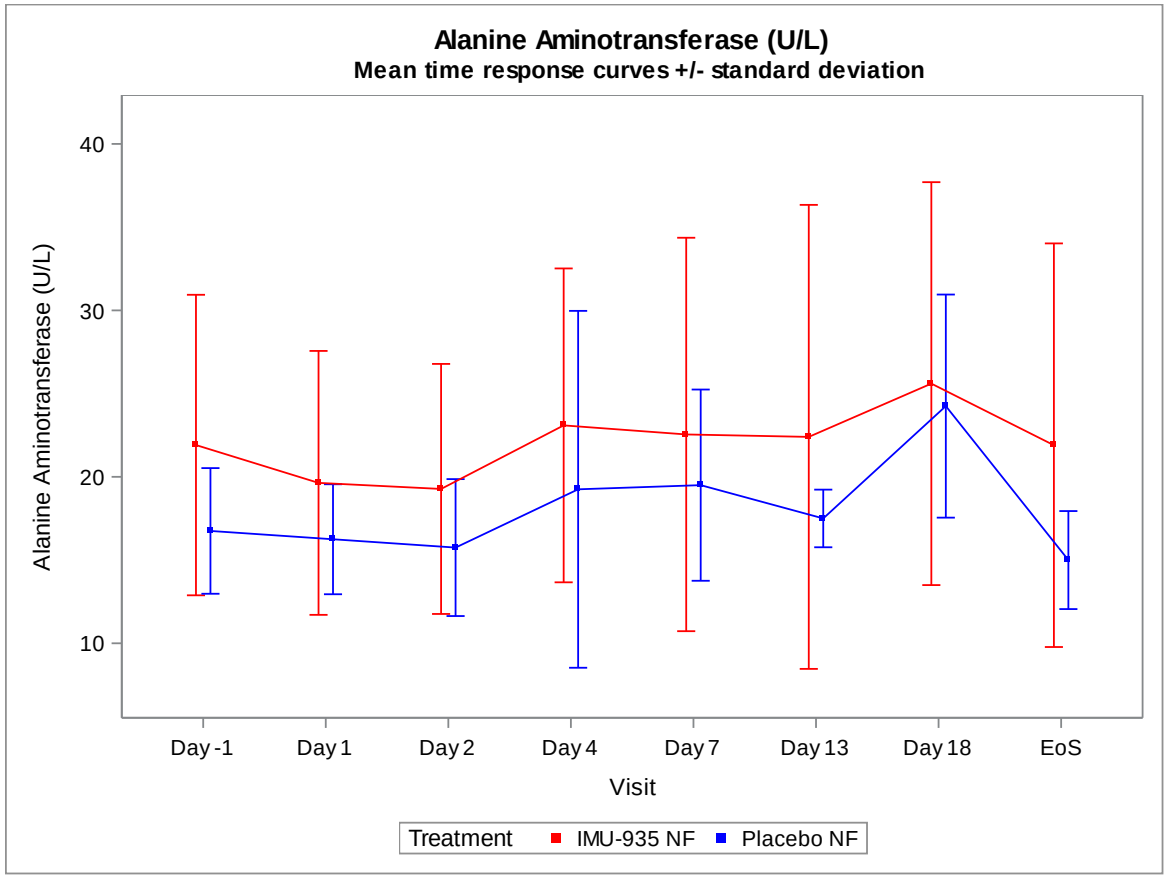




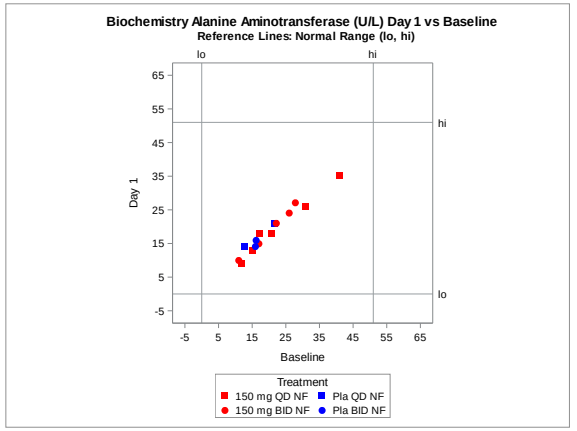


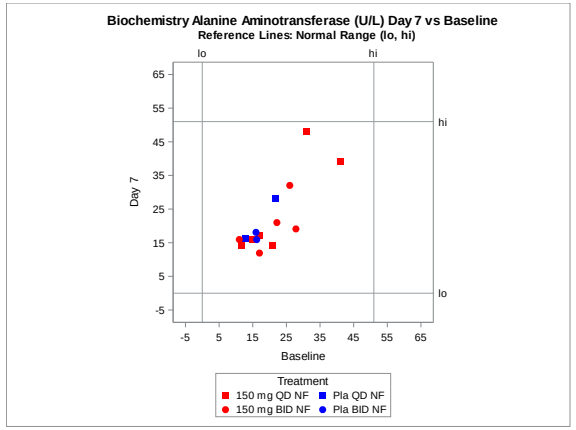
Laboratory Parameters: No Increase in ALT Compared to Placebo
Part B

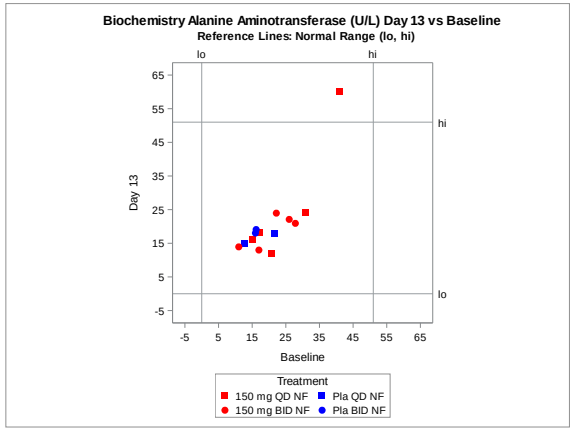
Laboratory Values Over Time
Biochemistry - ALT

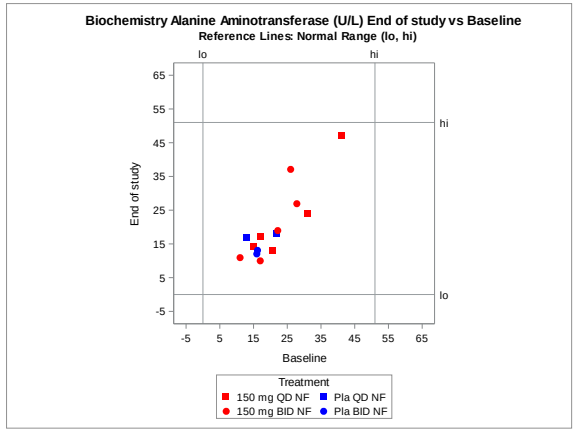


Individual Laboratory Values
Biochemistry - ALT





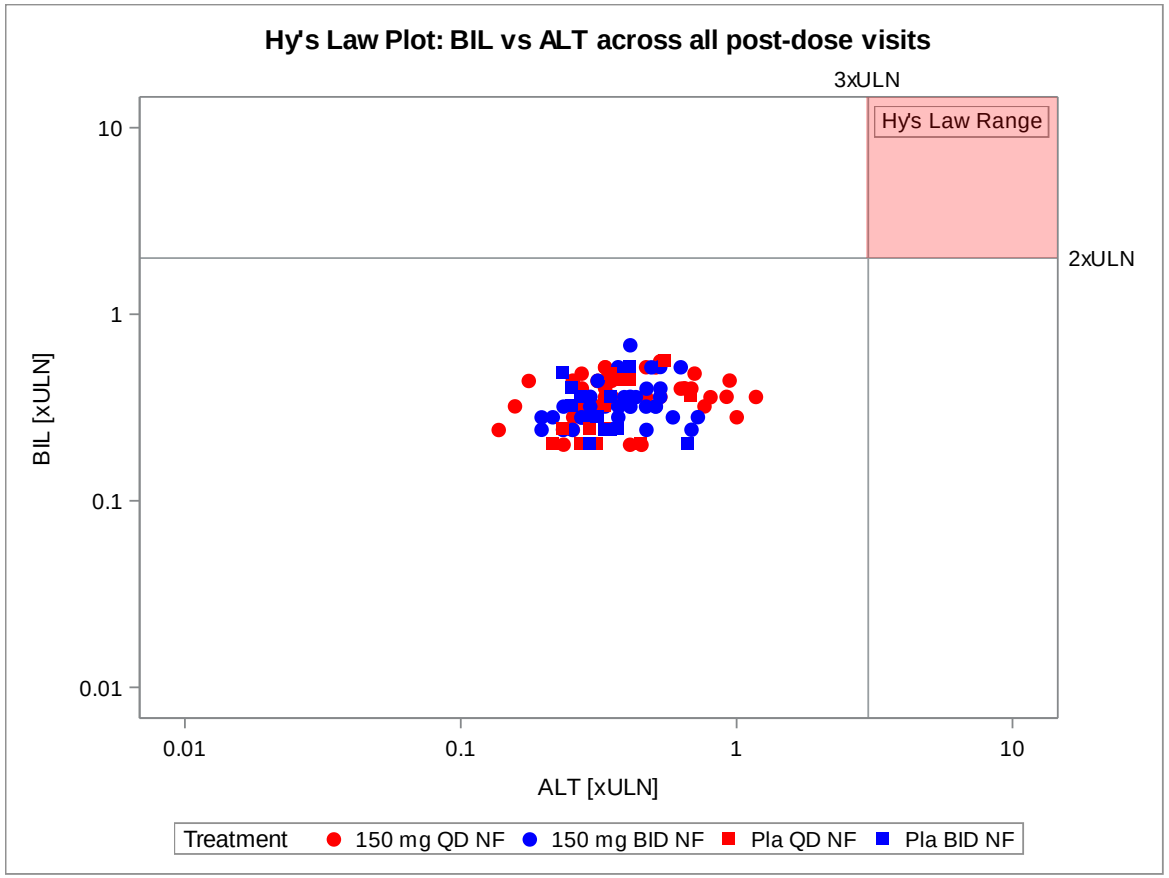




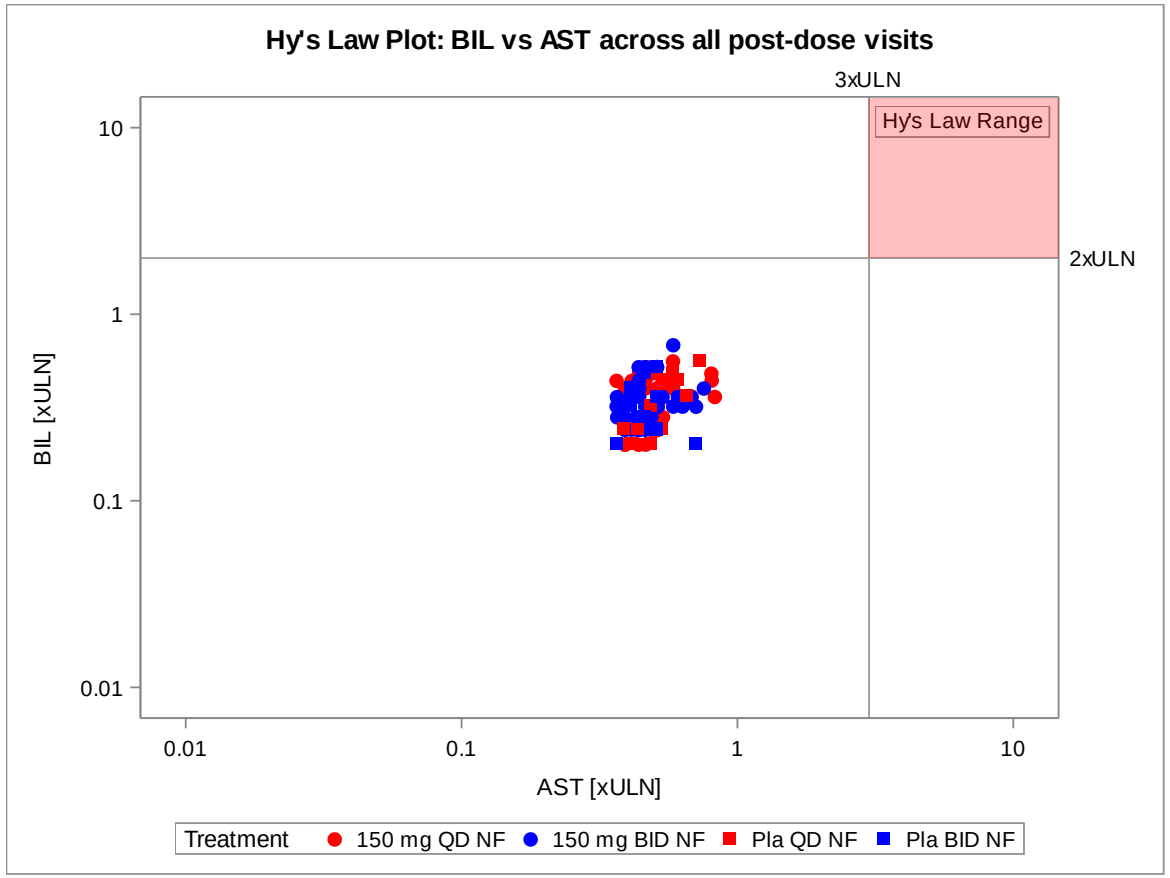
ALT: Alanine Aminotransferase

Laboratory Parameters: No Hy's Law Range Cases Observed
Part B

Bilirubin vs. ALT Showed No Evidence of DILI Potential



Bilirubin vs. AST Showed No Evidence of DILI Potential



ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase; DILI: drug-induced liver injury; BIL: Bilirubin; ULN: Upper Limit of Normal; Pla: Placebo

Conclusions

Part B: 14-Days Multiple Ascending Doses

- Multiple ascending doses of IMU-935 demonstrated a favorable safety, tolerability and pharmacokinetic profile.
- This allowed smooth transition from Part B (MAD) to Part C (28-day dosing in psoriasis patients) which is currently ongoing.

01

Phase 1 Clinical Trial of IMU-935

Trial Design and Status

Results Part A: Single Ascending Doses

Results Part B: Multiple Ascending Doses

Ongoing Part C in Psoriasis Patients

Ongoing First-in-Human Study
Part C: IMU-935 in Psoriasis Patients

Study Design

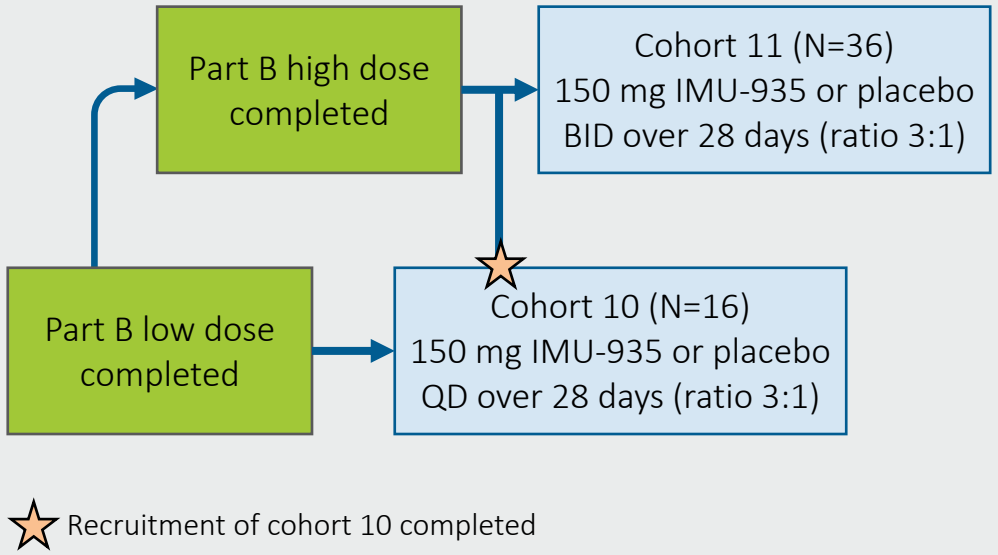
- Double-blind, placebo-controlled dose escalation study to evaluate safety, tolerability, pharmacodynamics and exploratory efficacy of IMU-935 in patients with moderate-to-severe psoriasis
- Psoriasis patients will receive 28 days of daily treatment
- Up to 52 psoriasis patients will be enrolled in 2 cohorts:
  - A cohort of 16 patients will receive a low dose of IMU-935 (150 mg QD) or placebo at a ratio of 3:1
  - A cohort of 36 patients will receive a high dose of IMU-935 (150 mg BID) or placebo at a ratio of 3:1
- Enrollment started on October 27, 2021

QD: quaque die = once-daily; BID: bis in die = two times daily

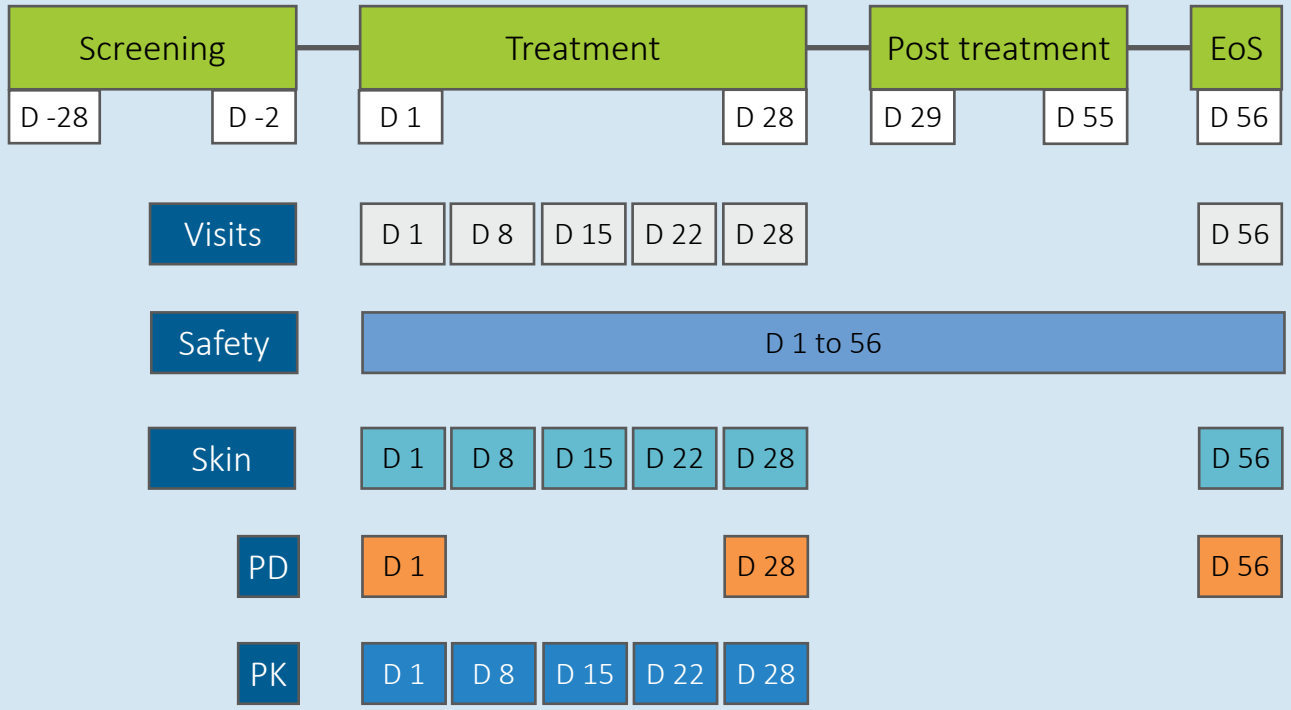
Ongoing First-in-Human Study

Part C: IMU-935 in Psoriasis Patients

Dose Escalation Scheme



Study Period



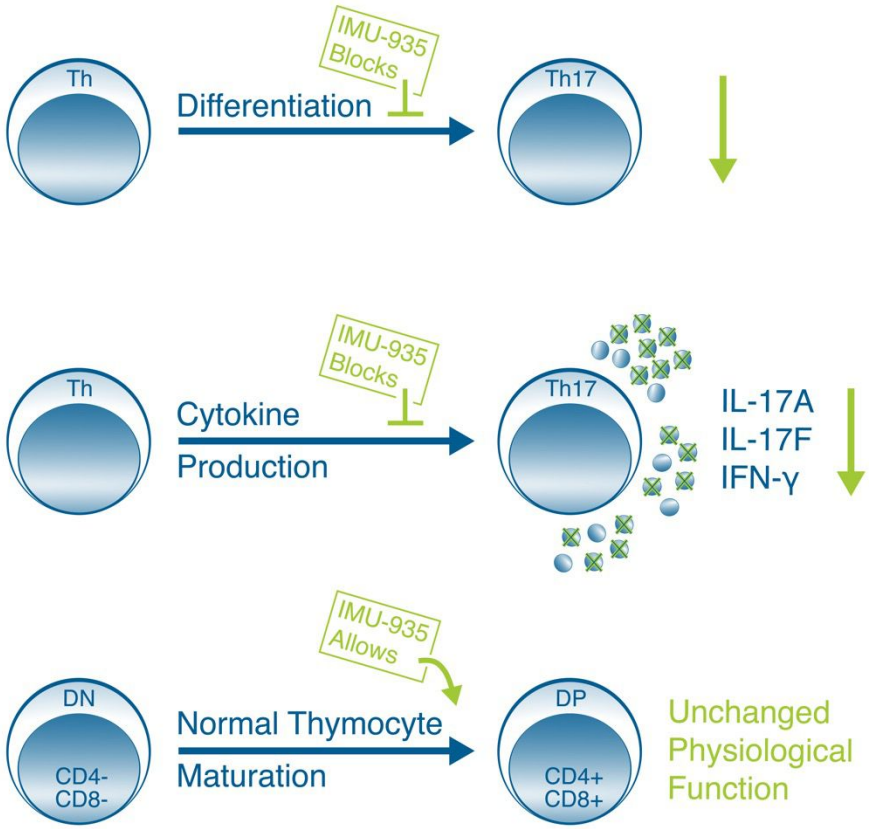
QD: quaque die = once-daily; BID: bis in die = two times daily; EoS: End of Study

02

IMU-935: An Oral IL-17 Inhibitor

Newly Obtained *In Vivo* Data

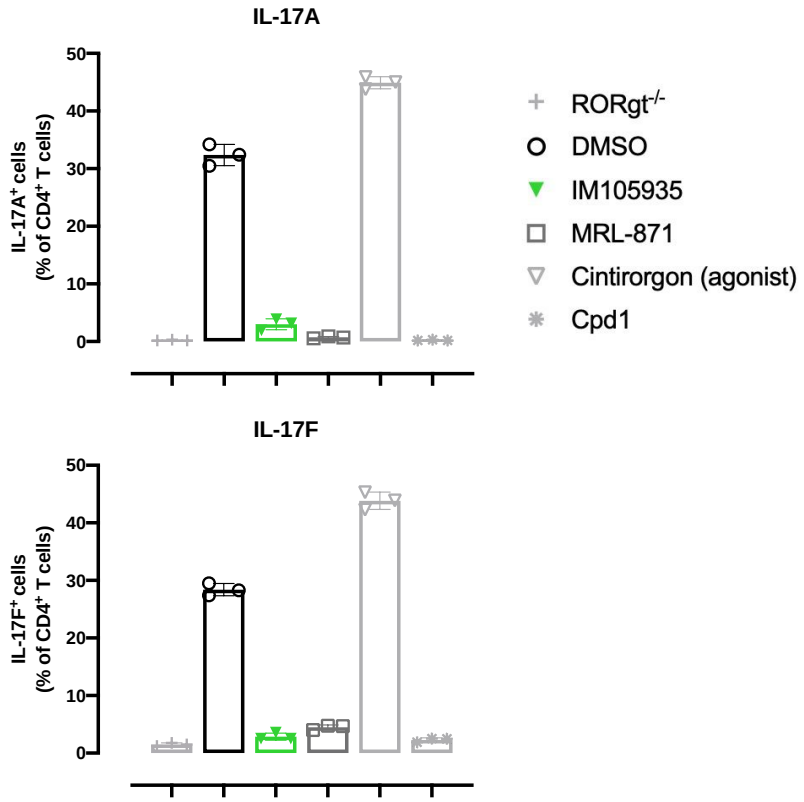
IMU-935 Selectively Inhibits Th17 Differentiation and IL-17 Secretion



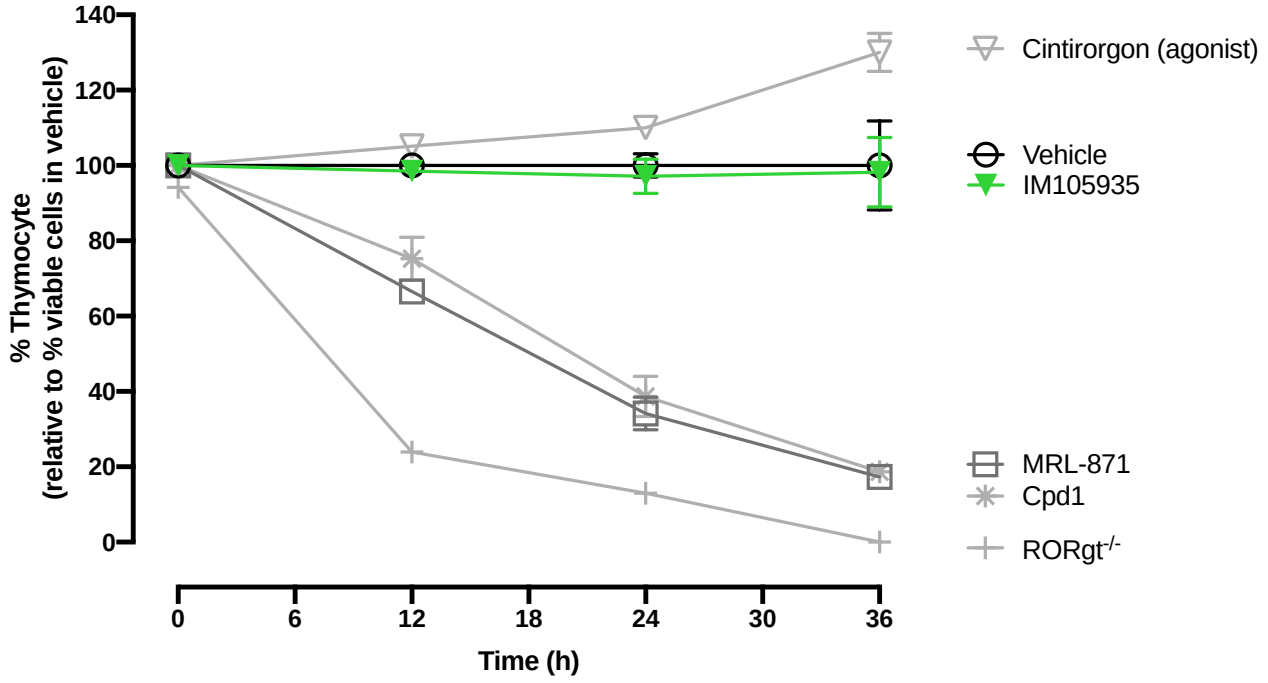
- The differentiation towards Th17 cells is inhibited by IMU-935
- The production of IL-17A and IL-17F is inhibited by IMU-935
- The physiological maturation of T cells within the thymus is **not affected by IMU-935**

Th: T helper; IL: interleukin; IFN: interferon; DN: double-negative; DP: double-positive; CD: cluster of differentiation

IMU-935's *in vitro* Selectivity on Th17 Suppression Confirmed, Well Differentiated to Other RORγt Inhibitors



Impact on Th17 differentiation at 500 nM



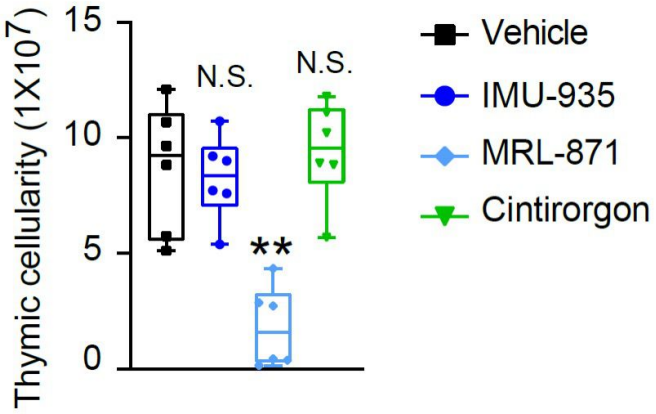
Impact on thymocyte viability at 1000 nM

Guo et al., 2016, Cell Reports (MRL-871), Guntermann et al., 2017, JCI Insight (Cpd1), Mahalingam et al., 2019, Clin Cancer Res. (Cintirorgon)

Immunic THERAPEUTICS

IMU-935 Allows Normal Thymocyte Maturation *in vivo*

Acute Model, 3 Days of Treatment



- IMU-935 (100 mg/kg BID), MRL-871 (100 mg/kg BID) and Cintirorgon (30 mg/kg BID) were tested for 3 days in C57BL/6j mice

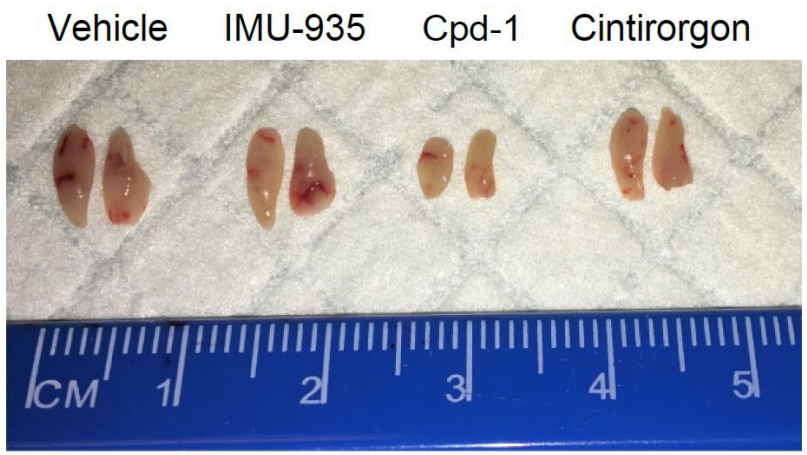
In contrast to MRL-871, **IMU-935 does not impact thymus size, thymocyte cell numbers or thymocyte maturation** in an acute mouse model.

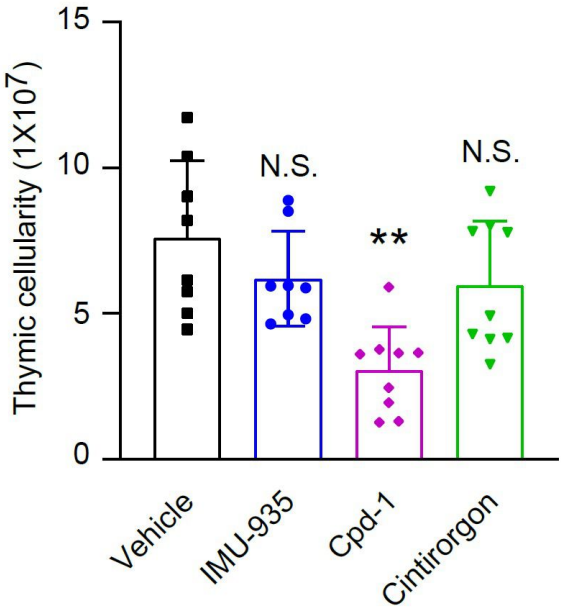
Guo et al., 2016, Cell Reports (MRL-871), Guntermann et al., 2017, JCI Insight (Cpd1), Mahalingam et al., 2019, Clin Cancer Res. (Cintirorgon)

Immunic THERAPEUTICS

IMU-935 Allows Normal Thymocyte Maturation *in vivo*

Chronic Model, 28 Days of Treatment





- C57BL/6j mice (male, 9wks, n=8-9 per group) were administrated with IMU-935 (100 mg/kg), Cpd1 (40 mg/kg), or Cintirorgon (30 mg/kg) for 4 weeks (BID)

In contrast to Cpd1, **IMU-935 does not impact thymus size, thymocyte cell numbers or thymocyte maturation** in a chronic mouse model.

Guo et al., 2016, Cell Reports (MRL-871), Guntermann et al., 2017, JCI Insight (Cpd1), Mahalingam et al., 2019, Clin Cancer Res. (Cintirorgon)

Immunic THERAPEUTICS

IMU-935 Has Shown a Favorable Safety Profile in Preclinical Studies

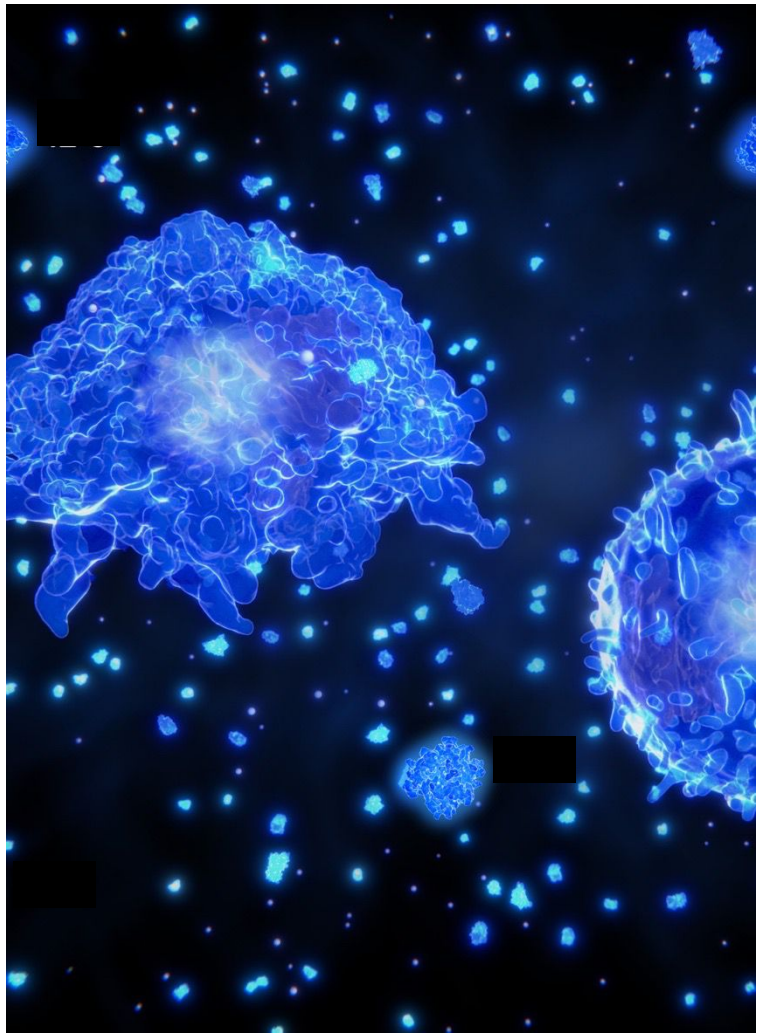
- **3-months tox studies** confirmed NOAEL seen in 28-day studies:
  - There were no IMU-935-related clinical observations, changes in body weight, food or water consumption, neurobehavioral exams, and clinical pathology parameters (urinalysis, hematology, coagulation, serum chemistry).
  - There were no drug-related observations in the gross pathological evaluation at scheduled termination or after recovery.
- **No changes in liver parameters or thymus have been observed.**
- **Data from preclinical safety studies and *in vivo* models for thymocyte maturation pave the way for IMU-935 to be a best-in-class oral IL-17 inhibitor.**

03

IMU-935: An Oral IL-17 Inhibitor

Summary

IMU-935: A Potentially Best-in-Class Oral IL-17 Inhibitor



- IMU-935 showed a very **favorable safety, tolerability and PK profile** in this phase 1 clinical trial with no serious adverse events seen in the SAD and MAD parts.
- In particular, IMU-935 was **safe and well-tolerated** in 14-day repeated oral dosing in healthy human subjects at doses expected to exceed required therapeutic dosing.
- IMU-935's outstanding **selectivity profile on Th17 over thymocyte development** was confirmed in an impressive fashion in a mouse model.
- IMU-935 is currently being tested in psoriasis patients with initial data expected in Q2/2022 – setting the stage for a potential **best-in-class oral** psoriasis therapy.
- IMU-935 may offer **extensive potential** beyond psoriasis in other autoimmune diseases.

Outlook: Multiple Value Inflection Points Expected in 2022

vidofludimus calcium (IMU-838)

- Phase 2 top-line data in ulcerative colitis expected to be available in Q2/2022

IMU-935

- Initial phase 1b psoriasis data expected to be available in Q2/2022
- Initial phase 1 CRPC data expected to be available in Q3/2022

IMU-856

- Unblinded SAD/MAD safety data in healthy volunteers expected to be available in Q3/2022

Immunic THERAPEUTICS

Thank You!

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