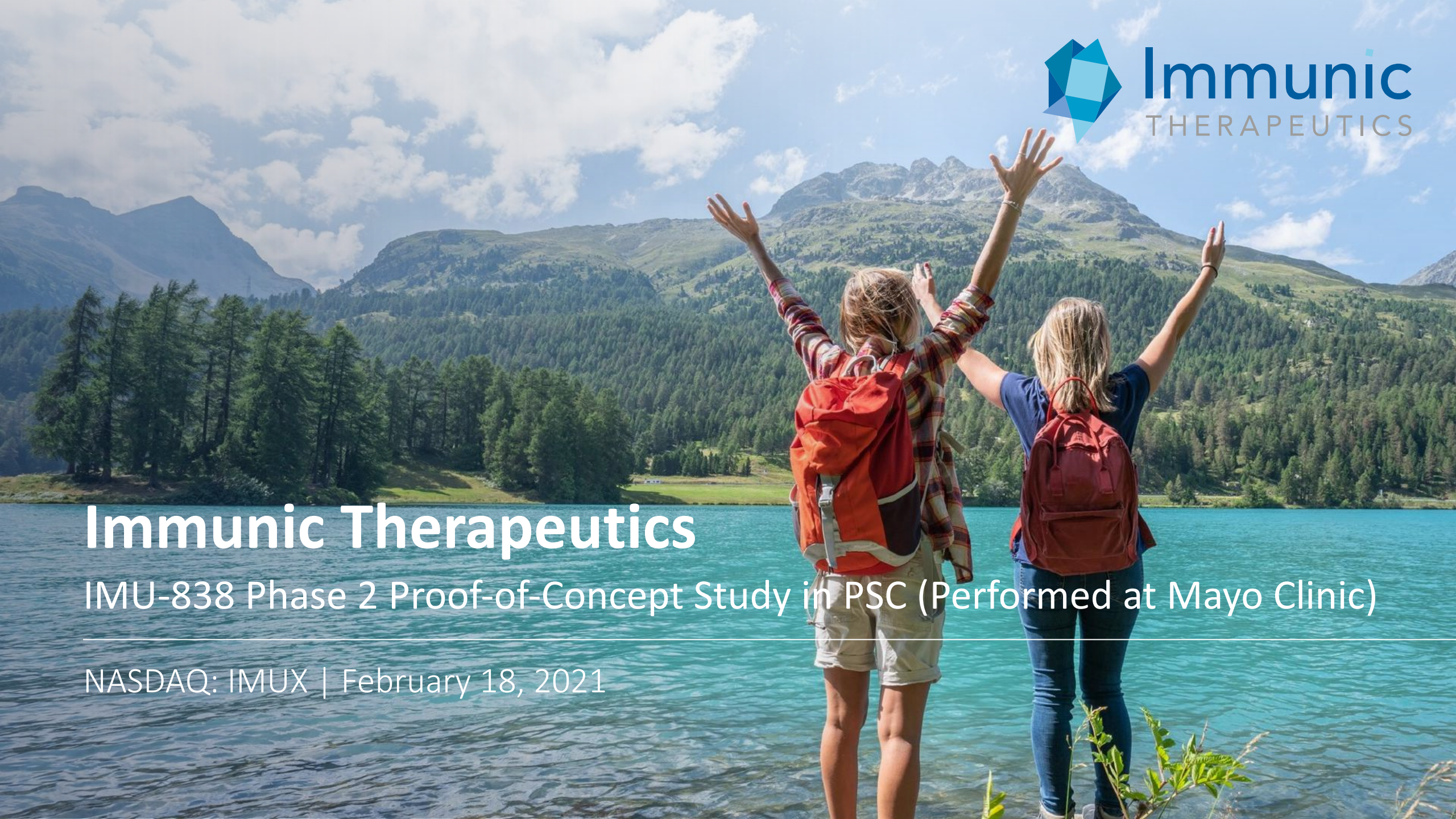

Immunic Therapeutics

IMU-838 Phase 2 Proof-of-Concept Study in PSC (Performed at Mayo Clinic)

NASDAQ: IMUX | February 18, 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	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3
IMU-838	Multiple Sclerosis	DHODH	■	■	■	■
	Ulcerative Colitis	DHODH	■	■	■	
	Crohn's Disease	DHODH	■	■		
	Primary Sclerosing Cholangitis	DHODH	■	■	■	Investigator-Sponsored Trial performed at Mayo Clinic / NIH
	COVID-19*	DHODH	■	■	■	■
IMU-935	Psoriasis	RORγt	■	■		
	Guillain-Barré Syndrome	RORγt	■	■		
IMU-856	Gastrointestinal Diseases	Intestinal Barrier Function	■	■		

■ Completed or ongoing ■ In preparation or planned

* Additional investigator-sponsored phase 2 clinical trial of IMU-838 in combination with oseltamivir in patients with moderate-to-severe COVID-19 ongoing in collaboration with the University Hospitals Coventry and Warwickshire NHS Trust, UK

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PSC: Disease, Epidemiology and Commercial Context

Rare Progressive Liver Disease With No Effective Treatment Currently Available

- Bile ducts in the liver become inflamed, narrow and prevent bile from flowing properly
- Exact cause and disease mechanism are still unknown, but an autoimmune mechanism may play a role
- Association with IBD, most often with ulcerative colitis and less commonly with Crohn's disease
- Other than liver transplantation, there are currently no approved therapies
- Estimated time from diagnosis of PSC to death or liver transplant has been shown to be less than 15 years[1]

Prevalence of PSC

- Orphan indication with high unmet medical need
- Approximately 30,000 Americans have PSC, although this number may be underestimated[2]
- Prevalence in the United States is approximately 1 to 6 cases per 100,000 people[3]
- PSC has a strong relationship with inflammatory bowel disease (IBD), which has a prevalence of 60-80% in patients with PSC in western countries[4]

The development of efficacious and safe therapies that prevent or delay the progression of liver fibrosis is the key unmet need for the treatment of PSC and represents a significant commercial opportunity.

[1] Goldberg, Gastroenterol Hepatol (N Y). 2016;12(2):127-129 [2] https://liverfoundation.org/caregivers https://liverfoundation.org/caregivers/
[3] https://www.hopkinsmedicine.org/gastroenterology_hepatology/_pdfs/liver/primary_sclerosing_cholangitis.pdf [4] Rossi RE et.al. . Eur J Gastroenterol Hepatol. 2016 Feb. 28:123-31

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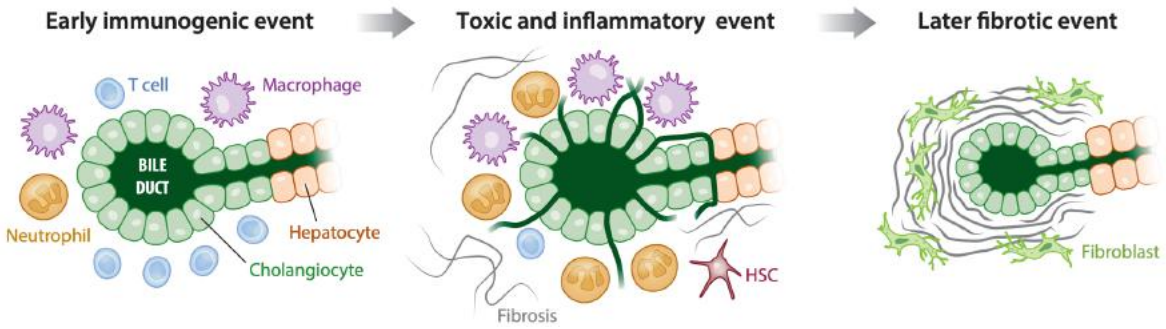
PSC: Novel Synergistic Approaches are Needed

"…anticholestatic treatments, however, are aimed to heal already injured biliary structures and do not address early immunological attacks as the cause of the disease. In the medium-term future, new treatments will have to be immunomodulatory."



"Potential synergistic anticholestatic treatment as a backbone therapy and additional immune-modulatory treatment designs may dominate earlier disease stages and phases, followed by bile acid toxicity–reducing, bile acid pool–reducing, and anti-inflammatory strategies."

Anticholestatic treatments aim to heal already injured biliary structures, but do not address early immunological attacks as the cause of the disease.

IMU-838 combines two promising approaches for the treatment of PSC in a one-pill-fits-all strategy.

Additional immune-modulatory treatment designs may dominate earlier disease stages, followed by reduction of bile acid toxicity, reduction of bile acid pool, and anti-inflammatory strategies.

Adapted from https://www.annualreviews.org/doi/10.1146/annurev-pharmtox-010818-021059

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IMU-838 in Primary Sclerosing Cholangitis (PSC)

Investigator-Sponsored Trial Performed at Mayo Clinic

IMU-838 for the Treatment of PSC

Top-Line Data Now Available

- Investigator-sponsored trial supported by a grant from the National Institutes of Health (NIH)
- Immunic provided the study medication
- Performed under an investigator IND from the FDA held by the Principal Investigator
- As per agreement between Immunic and Mayo Clinic:
  - Immunic gets access to limited top-line efficacy and safety data at the conclusion of the study
  - Additional and more complete data will be accessible by Immunic only at a later timepoint
  - Immunic is subject to certain restrictions regarding data publication before the full data is published by Mayo Clinic

IMU-838 in PSC: Phase 2 Proof-of-Concept Study

Principal Investigator

Elizabeth Carey, MD (Mayo Clinic)

Study Timelines

- Study started in August 2019
- Enrollment took place between July 2019 and September 2020, but almost all enrollment occurred in 2019 and early 2020
- The ongoing pandemic situation triggered the principal investigator's decision to terminate the study in late 2020

Investigator-Sponsored Trial Conducted at Two Mayo Clinic Sites

- Single-arm, open-label, exploratory study which planned to enroll 30 patients, aged 18 to 75 years
- Supported by National Institutes of Health (NIH) grant
- Study was performed at tertiary referral centers for PSC patients:
  - Mayo Clinic, Phoenix, Arizona (Elizabeth Carey, MD)
  - Mayo Clinic, Rochester, Minnesota (John E. Eaton, MD)
- Immunic provided the study medication
- Dosing: 30 mg of IMU-838 once daily for a period of 24 weeks
- Primary objective: change in serum alkaline phosphatase (ALP) at week 24, as compared to baseline
- Together with the investigators, Immunic determined to readout data of the 18 patients who were enrolled prior to the COVID-19 pandemic*

www.clinicaltrials.gov: NCT03722576

* During the COVID-19 pandemic, recruitment for this study was hampered, as patients with PSC are at a high risk of COVID-19 infections and were advised to avoid travel and unnecessary social contacts such as those required to participate in a clinical trial.

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IMU-838 in PSC: Study Flow Chart

Enrollment

Lead-in dosing
15 mg
1 week

Treatment
30 mg
(6 months)

Patient benefit?

Inclusion Criteria

Male or female subject aged 18 to 75 years

Diagnosis of PSC consistent with the guidelines published by the AASLD.

All subjects must have an elevated serum alkaline phosphatase (ALP) of at least 1.5 times upper limit of normal (ULN) at baseline plus cholangiographic evidence of PSC (magnetic resonance imaging, endoscopic retrograde cholangiography, or direct cholangiography).

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Study Population and Treatment Discontinuations

- Study planned to enroll 30 patients
- Study screened 27 PSC patients
  - 5 patients were screen failures (4 patients did not have ALP elevated of at least 1.5 times ULN, and 1 patient had an excluded condition)
  - 4 patients (in particular during the pandemic period) withdrew consent before receiving any treatment
  - **18 patients** started treatment of once daily 30mg IMU-838 (intent-to-treat population, ITT, n=18)
  - Of these 18 patients, 7 patients discontinued before week 24, and only **11 patients** completed 24-week IMU-838 treatment (per protocol population, PP, n=11)

Treatment Discontinuations	n=7
During Week 1	1
After Week 2	1
After Week 4	1
After Week 8	1
After Week 12	1
After Week 16	1
After Week 20	1

Patients prematurely discontinued treatment for different reasons:

- 4 patients withdrew consent or were lost to follow-up (mainly during the pandemic period),
- 1 patient was discontinued due to investigator decision, and
- 2 patients were discontinued due to adverse events (n=1 for liver enzyme elevation, presumed disease exacerbation, n=1 for abdominal pain).

ALP: alkaline phosphatase; ULN: upper limit of normal

Baseline Characteristics

	PP population (n=11)	ITT population (n=18)
Enrolled Site, n (%)		
Mayo Arizona	3 (27.3%)	9 (50.0%)
Mayo Rochester	8 (72.7%)	9 (50.0%)
Age at Enrollment		
Mean (SD)	48.1 (16.7)	45.7 (15.2)
Median (IQR)	41 (33, 66)	40 (32, 60)
Range	26.0, 69.7	26.0, 69.7
Gender, n (%)		
Male	5 (45.5%)	7 (38.9%)
Female	6 (54.5%)	11 (61.1%)
Race, n (%)		
White	11 (100.0%)	18 (100.0%)
Ethnicity, n (%)		
Not Hispanic or Latino	11 (100.0%)	17 (94.4%)
Hispanic or Latino	0 (0.0%)	1 (5.6%)
Crohn's Disease or Ulcerative Colitis, n (%)		
No	5 (45.5%)	6 (33.3%)
Yes	6 (54.5%)	12 (66.7%)
ALP at Baseline, IU/L		
Mean (SD)	386.2 (147.3)	366.1 (130.4)
Median (IQR)	361 (228, 507)	340 (261, 451)
Range	219.0, 661.0	215.0, 661.0
Total Bilirubin at Baseline, mg/dL		
Mean (SD)	0.9 (0.5)	0.8 (0.5)
Median (IQR)	1 (1, 1)	1 (1, 1)
Range	0.3, 2.1	0.3, 2.1

SD: standard deviation; IQR: interquartile range; ALP: alkaline phosphatase; PP: per-protocol; ITT: intend-to-treat

IMU-838 in Primary Sclerosing Cholangitis (PSC)

Efficacy

Primary Objective: Change in Serum Alkaline Phosphatase

The Primary Objective Was to Determine Whether IMU-838 Reduces Serum ALP in Adult Patients Diagnosed With PSC

Definition of the primary objective:

- Patients who achieve a reduction of ALP at week 24
  - greater or equal to 25%, as compared to baseline,
  - while the AST increase at week 24 is no more than 33%, as compared to baseline.

	Positive Outcome N (%)	95% CI
ALP Reduction ≥25% and AST Increase ≤33% Between Baseline and Week 24 (ITT, N=18)	3/18 (16.7%)	3.6%, 41.4%
ALP Reduction ≥25% and AST Increase ≤33% Between Baseline and Week 24 (PP, N=11)	**3/11 (27.3%)**	**6.0%, 61.0%**

ALP: alkaline phosphatase; AST: aspartate aminotransferase; PP: per-protocol; ITT: intend-to-treat, CI: confidence interval

Study Results: Statistically Significant Reduction in Serum ALP

IMU-838's Reduction in Serum ALP Levels Compares Well to Other Medications in Development for PSC

	IMU-838	norUDCA[1]	OCA[1]	Cilofexor[1]
Administration	Oral	Oral	Oral	Oral
Daily Dose	30 mg QD	1500 mg QD	5 to 10 mg QD	(30 and) 100 mg QD
Endpoint ("Positive Outcome" in %)	ALP reduction >=25% **and** AST increase <= 33% at week 24	≥ 25% ALP reduction	≥ 25% ALP reduction	≥ 25% ALP reduction
Treatment Duration	24 weeks	12 weeks	24 weeks	12 weeks
Number of Patients With a "Positive Outcome" in %	**27%***	**na**	**na**	**5% for 30 mg and 35% for 100 mg**

[1] Gerussi et al., Annals of Hepatology 19 (2020) 5-16
ALP: alkaline phosphatase; AST: aspartate aminotransferase; QD: quaque die = once-daily
*ALP reduction (PP, LS means)

Quantitative Change in Serum Alkaline Phosphatase

The Primary Objective Was to Determine Whether IMU-838 Reduces Serum ALP in Adult Patients Diagnosed With PSC

- Time from baseline: calculated as continuous variable and treated as the primary predictor using a random intercept model which was adjusted for age at baseline and gender
  - **ALP value statistically significantly (p=0.041) decreased** by an average of 5.76 IU/L every 30 days (95% CI: -11.29, -0.23; statistical model) in the PP population (N=11)
  - Not statistically significant in the ITT analysis (p=0.578; N=18)

	Estimate of Change Every 30 Days (95% CI)	p-value
ALP Change Between Baseline and Week 24 (ITT, N=18)	-2.11 (-9.62, 5.40)	0.578
ALP Change Between Baseline and Week 24 (PP, N=11)	**-5.76 (-11.29, -0.23)**	**0.041**

Model adjusted for age at baseline and gender

ALP: alkaline phosphatase; AST: aspartate aminotransferase; PP: per-protocol; ITT: intend-to-treat, CI: confidence interval

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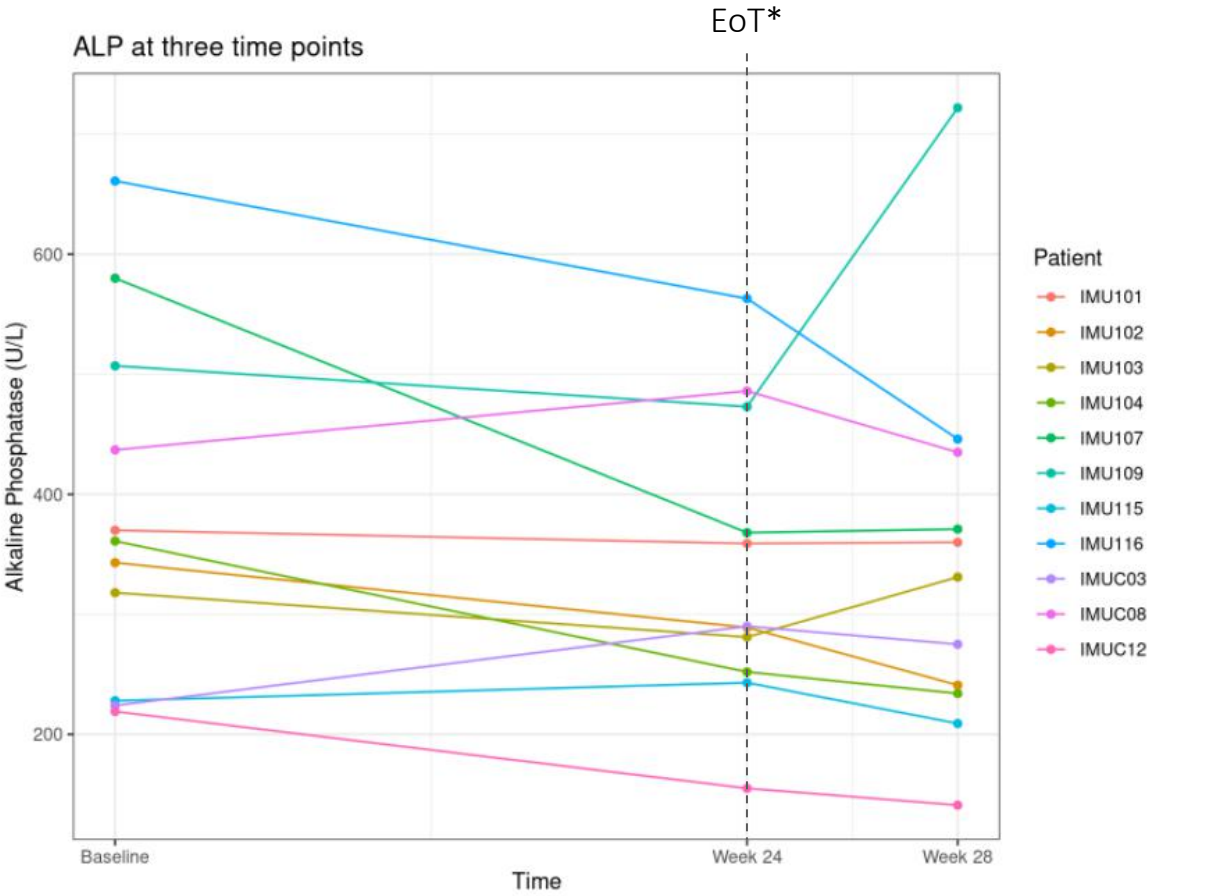
Individual ALP Changes Over Treatment Period



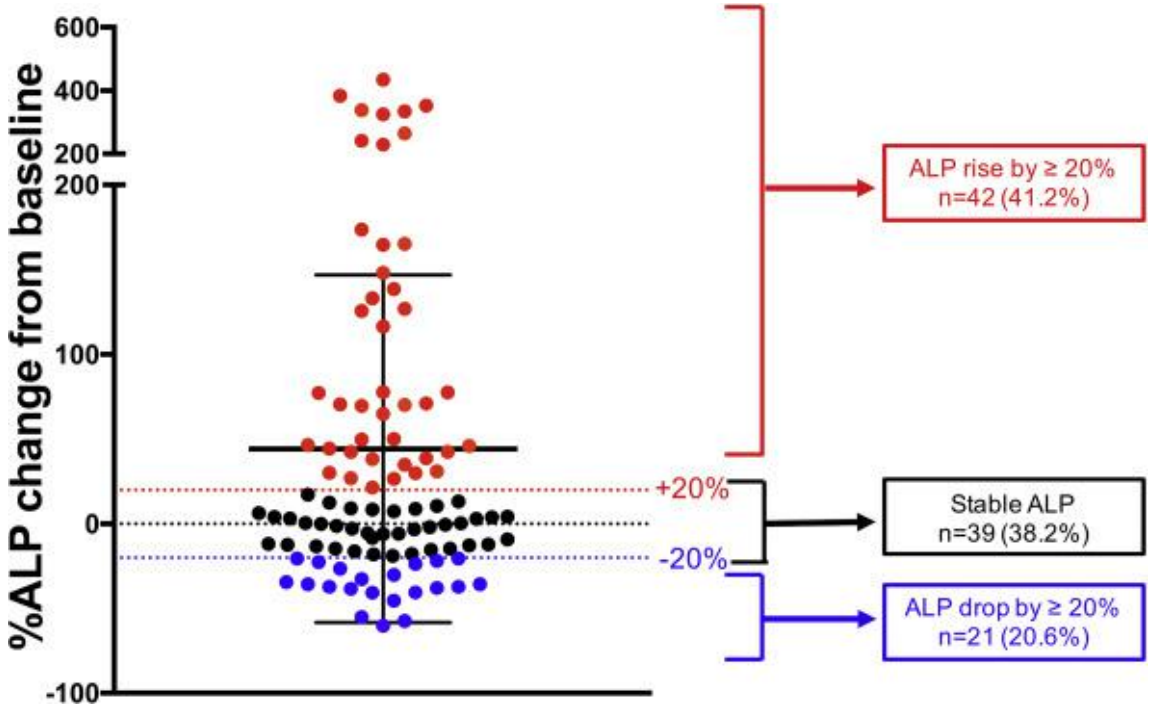
- Consistent individual pattern of a stable decrease in ALP values between baseline and Week 24 (24-week treatment period)
- While the decrease in ALP values was moderate, no patient of the PP population showed an increase of more than 20% of ALP at Week 24, as compared to baseline
- After treatment cessation at Week 24, a total of 2 patients showed a strong rebound effect at Week 28

ALP: alkaline phosphatase, Treatment period between baseline and Week 24. Follow-up period (without treatment) between Week 24 and Week 28, Per Protocol (PP) Population (n=11)
*EoT: End of Treatment

Example of Variability of Alkaline Phosphatase in PSC

Longitudinal Analysis of Vedolizumab in PSC-IBD

Vedolizumab, n=102; median treatment duration, 412 days



Almost half of the patients showed a progression by more than 20% in alkaline phosphatase

Serum levels of alkaline phosphatase decreased by more than 20% in only 20.6% of patients

Lynch et al. Effects of Vedolizumab in Patients With Primary Sclerosing Cholangitis and Inflammatory Bowel Diseases. Clin Gastroenterol Hepatol. 2020 Jan;18(1):179-187

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Secondary Objective: Absence of Increase of Other Liver-Related Biochemical Parameters

The Study Found That Other Liver-Related Biochemical Parameters Remained Stable Over the Treatment Period and No Signals for Worsening Were Observed

Biochemical Parameter		Baseline	W2	W4	W8	W12	W16	W20	W24
AST	ITT	78.5 (7.7)	79.1 (7.5)	79.6 (7.3)	80.8 (7.0)	82.0 (6.8)	83.1 (6.9)	84.3 (7.0)	85.4 (7.3)
	PP	77.1 (9.2)	77.7 (9.1)	78.2 (9.0)	79.4 (8.7)	80.5 (8.6)	81.6 (8.6)	82.8 (8.6)	83.9 (8.7)
ALT	ITT	110.5 (14.1)	111.0 (13.8)	111.4 (13.6)	112.3 (13.2)	113.1 (13.1)	114.0 (13.1)	114.9 (13.3)	115.7 (13.7)
	PP	107.6 (10.4)	108.0 (10.2)	108.4 (10.0)	109.2 (9.7)	110.0 (9.5)	110.8 (9.4)	111.6 (9.5)	112.3 (9.6)
Total Bilirubin	ITT	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)
	PP	0.8 (0.2)	0.8 (0.2)	0.8 (0.2)	0.9 (0.2)	0.9 (0.2)	0.9 (0.2)	0.9 (0.2)	0.9 (0.2)
Direct Bilirubin	ITT	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)
	PP	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)	0.4 (0.1)
Indirect Bilirubin	ITT	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)	0.5 (0.0)
	PP	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)	0.5 (0.1)

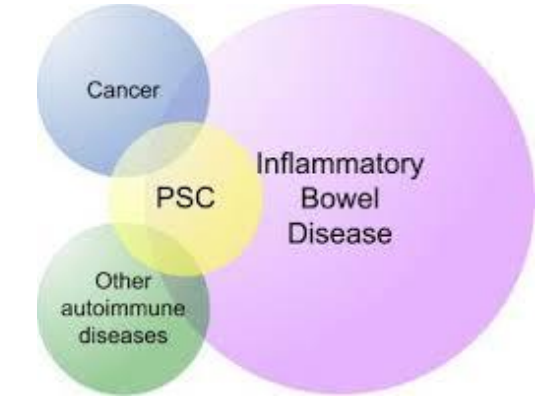
Mean (standard error) of liver-related biochemical parameters from baseline to Week 24 (W24, last potential treatment)
None of the above-listed biochemical parameters had shown a statistically significant change when evaluated as continuous variable
ALT: alanine aminotransferase; AST: aspartate aminotransferase; PP: per-protocol population; ITT: intend-to-treat population; W: week

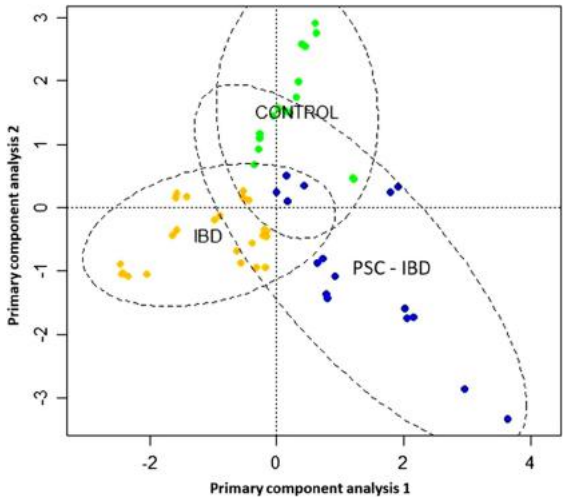
IMU-838 in Primary Sclerosing Cholangitis (PSC)

Patients with Existing Comorbidity: IBD Assessments

PSC and Ulcerative Colitis

Overlap and Differences in Epidemiology and Biology





- Whereas PSC occurs in about 5% of patients with inflammatory bowel disease (IBD), approximately 70% of patients with PSC have IBD[1]
- The gut-adherent microbiota in patients with PSC-IBD and IBD without PSC are significantly different[2]

[1] Maurice JB, Thorburn D. Precision medicine in primary sclerosing cholangitis. J Dig Dis. 2019 Jul;20(7):346-356
[2] Quraishi et al. Probing the microbiota in PSC: the gut adherent microbiota of PSC-IBD is distinct to that of IBD and controls. Hepatology 2014, Vol. 60, p. 267A

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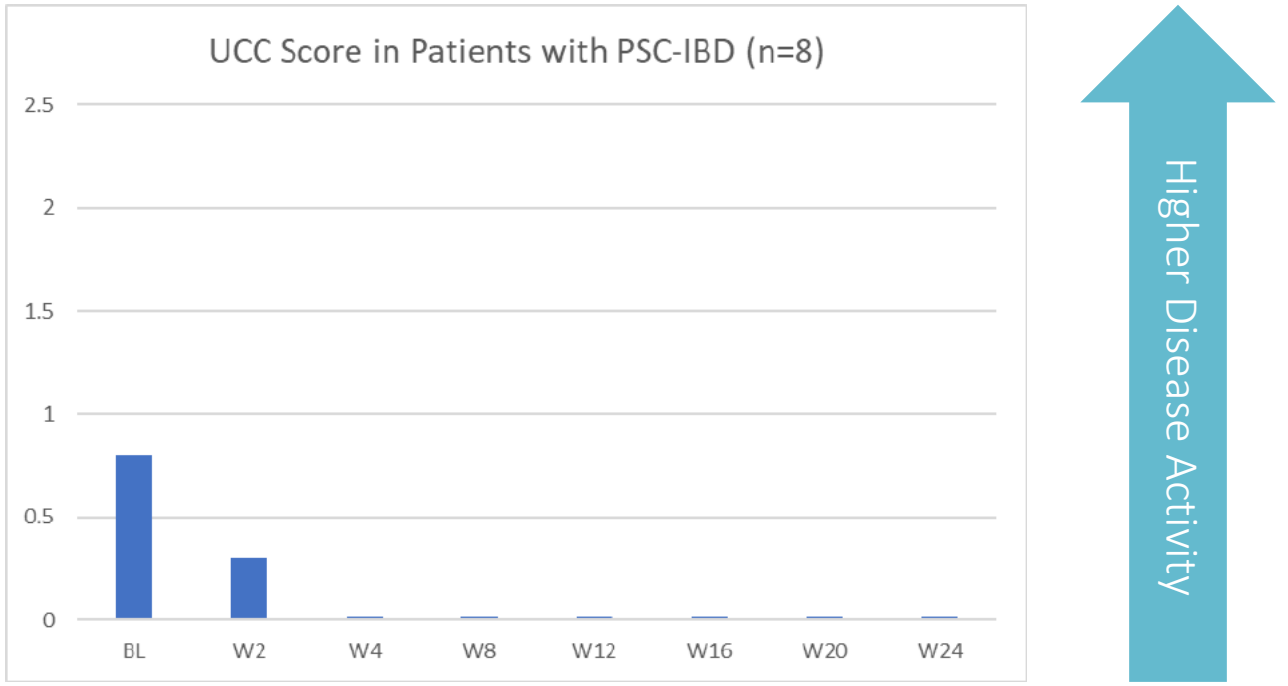
Ulcerative Colitis Clinical (UCC) Score

Physician Assessment of Ulcerative Colitis Activity

The UCC score, a modification and simplification of the well-known Mayo Score, consists of four items:

- stool frequency,
- rectal bleeding,
- subject's functional assessment, and
- physician's global assessment.

Scores Range From 0 to 12 Points, With Higher Scores Meaning Higher Colitis-Related Active Disease



Mean of UCC Score of patients with comorbidity PSC-IBD

Between baseline (BL) up to end of treatment at Week (W) 24

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Short Inflammatory Bowel Disease Questionnaire (SIBDQ)

Patient-Reported Questionnaire for Health-Related Quality of Life

The SIBDQ consists of questions scored in four domains:

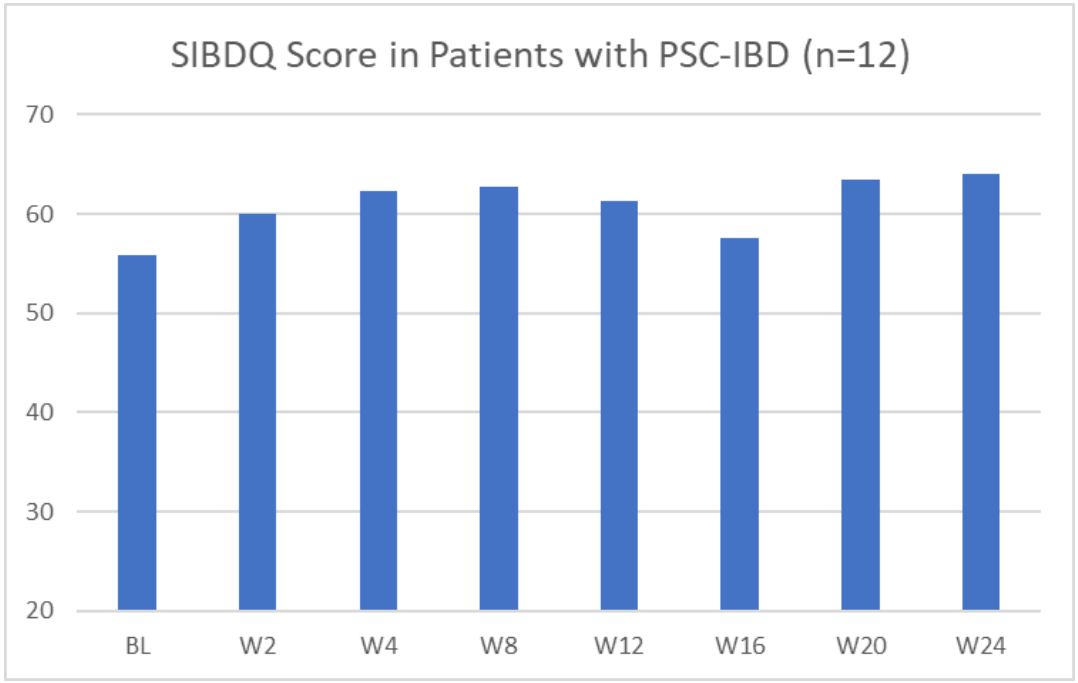
- bowel symptoms,
- emotional health,
- systemic systems, and
- social function.

Respondents are asked to provide a rating from 1 to 7 on quality-of-life measures during the last two weeks.

Typical SIBDQ scores: [1]

- Remission 50-64
- Mild relapse 35-50
- Moderate relapse 22-35
- Severe relapse 15-30

Questionnaire Provides a Score Ranging From 10 (Lowest Score) to 70 (Highest Score)



Mean of SIBDQ Score of patients with comorbidity PSC-IBD

Between baseline (BL) up to end of treatment at Week (W) 24

[1] Jowett et al. The short inflammatory bowel disease questionnaire (SIBDQ) is reliable and responsive to clinically important change in UC. Gastroenterology 2001 Vol120 (5) S1, p. A273-A274

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Summary of PSC-IBD Assessments

- Open-label trial using 30 mg IMU-838 once daily for 24 weeks in patients with PSC-IBD comorbidity allows exploratory investigation of IBD disease assessments by physicians and patients
- Patient numbers are limited and several post-baseline data close to Week 24 are missing
- Despite these limitations, the results of IBD symptoms and quality of life assessments are encouraging

IBD: inflammatory bowel disease with its main forms ulcerative colitis and Crohn's disease

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IMU-838 in Primary Sclerosing Cholangitis (PSC)

Safety

Study Results: Safety

IMU-838's Favorable Safety and Tolerability Profile Was Confirmed in This Patient Population

- **SAE:** There were no SAE or on-study deaths.
- **Treatment Emergent Adverse Events:**
  - A total 36 AE were reported in 12 of the 18 patients that received any dose of IMU-838:
    - 2 patients had one AE
    - 1 patient had two AE
    - 6 patients had 3 AE
    - 2 patients had 4 AE
    - 1 patient had 6 AE
- **Severity:** The majority of the AE was grade 1 (n=33) and only 3 AE were grade 2.
- **Relatedness:** Only 4 AE were possibly, probably or definitely attributed to the study drug by the investigators (n=1 ALP increased, n=1 fever, n=1 hematuria, n=1 liver enzymes worsened) while all the other 32 AE were not attributed to the study drug.

SAE: serious adverse events; AE: adverse events, ALP: alkaline phosphatase

IMU-838 in Primary Sclerosing Cholangitis (PSC)

Summary and Outlook

IMU-838 in PSC: Summary

Investigator-Sponsored Trial Performed at Mayo Clinic

- Highly underserved patient population with only a small number of cases worldwide and no treatment option currently available
- Feasibility study to explore activity of IMU-838 in PSC patients based on biochemical parameters
- Study enrollment and assessment being hampered by the high rate of treatment discontinuations during the COVID-19 pandemic makes the analysis of the biochemical changes and the assessment of the clinical relevance of the observations difficult

Encouraging Results Regarding Biochemical Parameters and Safety

- Primary objective achieved in 27.3% (3/11) of the PP patients, as compared to baseline (ALP reduction ≥25% and AST increase ≤33%)
- Observed signal for ALP similar to other drugs currently in development for PSC, however, the study results are limited due to the number of patients who completed the full 24-week treatment period
- None of the patients who reached Week 24 had an increase of more than 20% of ALP, as compared to baseline
- IMU-838 found to lead to a statistically significant reduction of serum ALP over time in the PP population, while no trend for increases in ALT, AST or bilirubin were observed
- The results of IBD symptoms and quality of life assessments in the evaluable patients are encouraging
- IMU-838's safety and tolerability profile confirmed in this patient population

ALP: alkaline phosphatase; AST: aspartate aminotransferase; ALT: alanine aminotransferase; PP: per-protocol; ITT: intend-to-treat

IMU-838 in PSC: Outlook

As an Orally Available DHODH Inhibitor With a Prominent Influence on Th17 Induced Inflammatory Processes, IMU-838 is a Promising Approach for the Treatment of PSC

- The encouraging results regarding biochemical parameters and safety suggest that IMU-838 merits further clinical testing in PSC
- Immunic is in discussions with investigators and leading clinical experts to further evaluate the data set and to explore potential next steps
- Immunic believes that dose optimization would be needed for potential future trials, which would also require assessment of pharmacokinetics in hepatic impaired patients

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Thank You!

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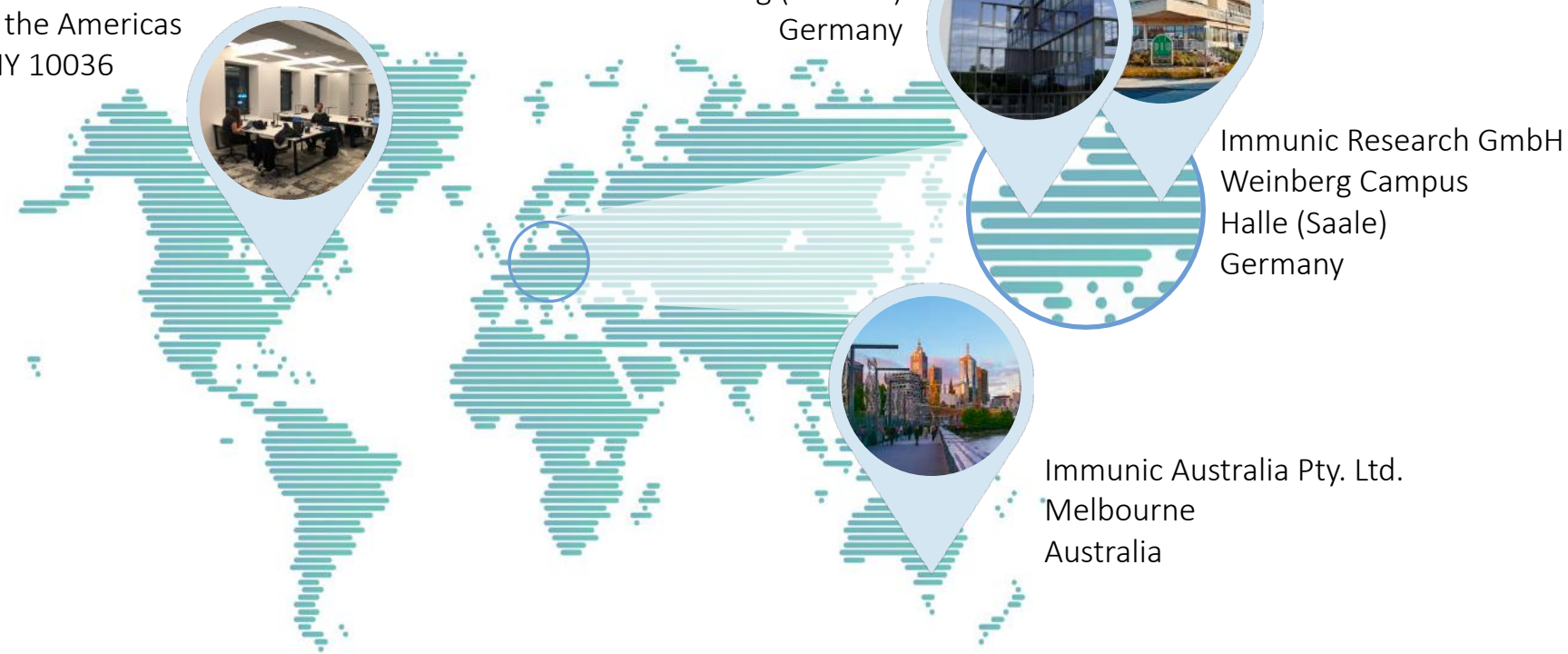

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