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INTEGRIS-PSC Topline Results

SEPTEMBER 26, 2023

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Today's Speakers

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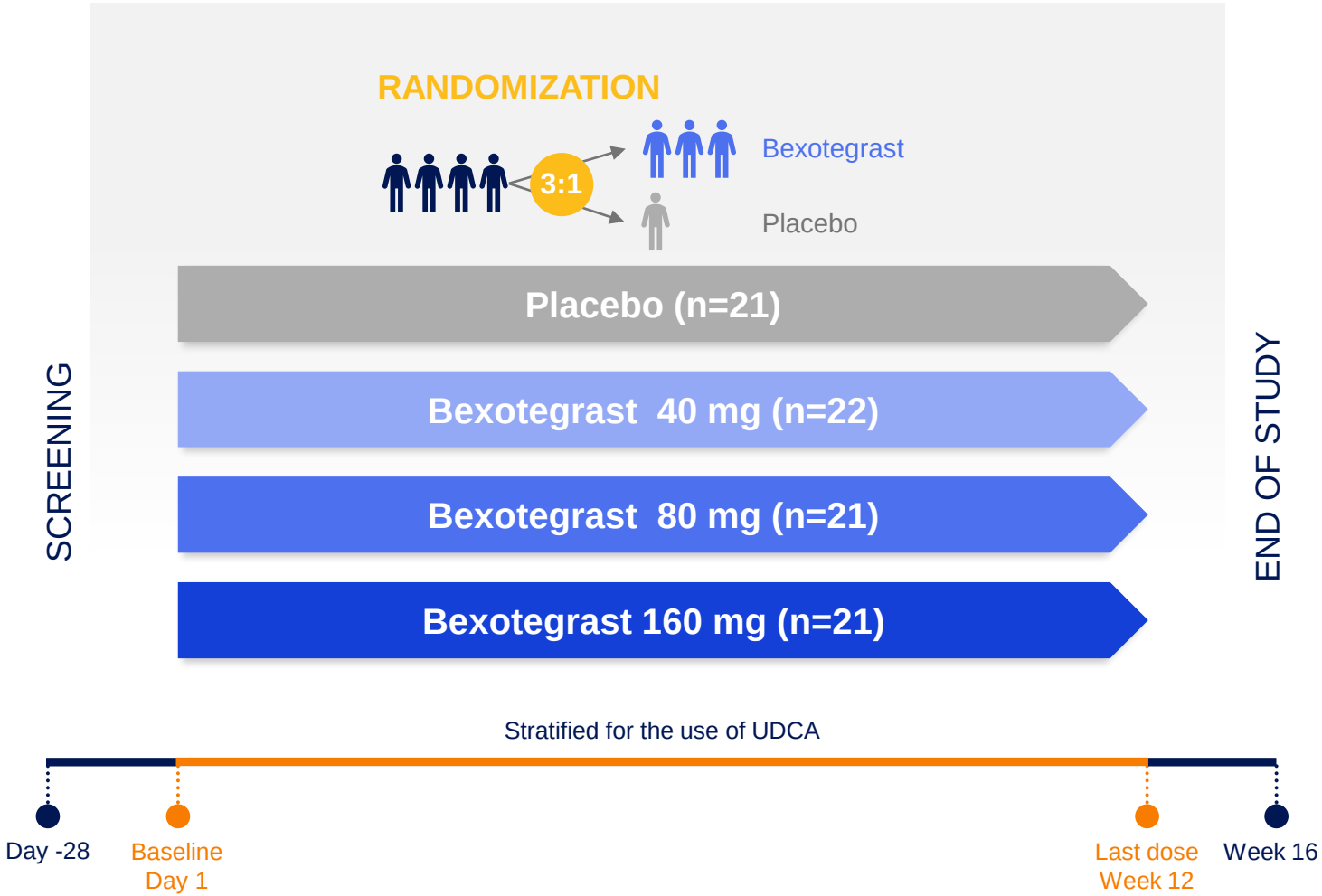
INTEGRIS-PSC Study Design and Objectives

First PSC Trial Enriched with Participants with Suspected Liver Fibrosis



PRIMARY AND SECONDARY ENDPOINTS

- Safety, tolerability, PK

EXPLORATORY ENDPOINTS

- Changes in liver fibrosis markers, ELF score and PRO-C3
- Changes in liver biochemistry
- Changes in liver imaging

INCLUSION CRITERIA

- Suspected moderate/severe fibrosis defined by at least one criterion:
  - ELF ≥ 7.7
  - TE ≥ 8 but ≤ 14.4 kPa
  - MRE ≥ 2.4 but ≤ 4.9 kPa
  - Historical biopsy

UDCA = Ursodeoxycholic acid ; TE = Transient elastography; ELF = enhanced liver fibrosis; MRE = magnetic resonance elastography

INTEGRIS-PSC – Key Findings

Bexotegrast was Well Tolerated Over 12 Weeks of Treatment in Participants with PSC

- Adverse events rates were comparable to placebo with all drug-related TEAEs mild or moderate in severity
- Low rate of discontinuation due to AEs and no treatment-related severe or serious AEs
- Patients with IBD experienced no clinically-relevant changes in IBD symptoms
- Bexotegrast total and unbound plasma concentrations increased with dose

Bexotegrast Demonstrated Antifibrotic Activity in a PSC Population with Suspected Moderate to Severe Liver Fibrosis

- All doses reduced ELF scores relative to placebo with a statistically significant difference for 160 mg
  - 160 mg achieved statistical significance at Week 12 across all components of the ELF score (TIMP-1, PIIINP, HA)
- All doses reduced collagen synthesis (PRO-C3) relative to placebo with statistical significance for the 160 mg dose

Additional Key Supportive Findings

- MRI imaging analysis suggests improved hepatocyte function and bile flow relative to placebo at Week 12
- Liver biochemistry markers, including ALP, were improved relative to placebo at Week 12
- Dose dependent reduction in itch, with statistical significance at the 160 mg dose relative to placebo at Week 12

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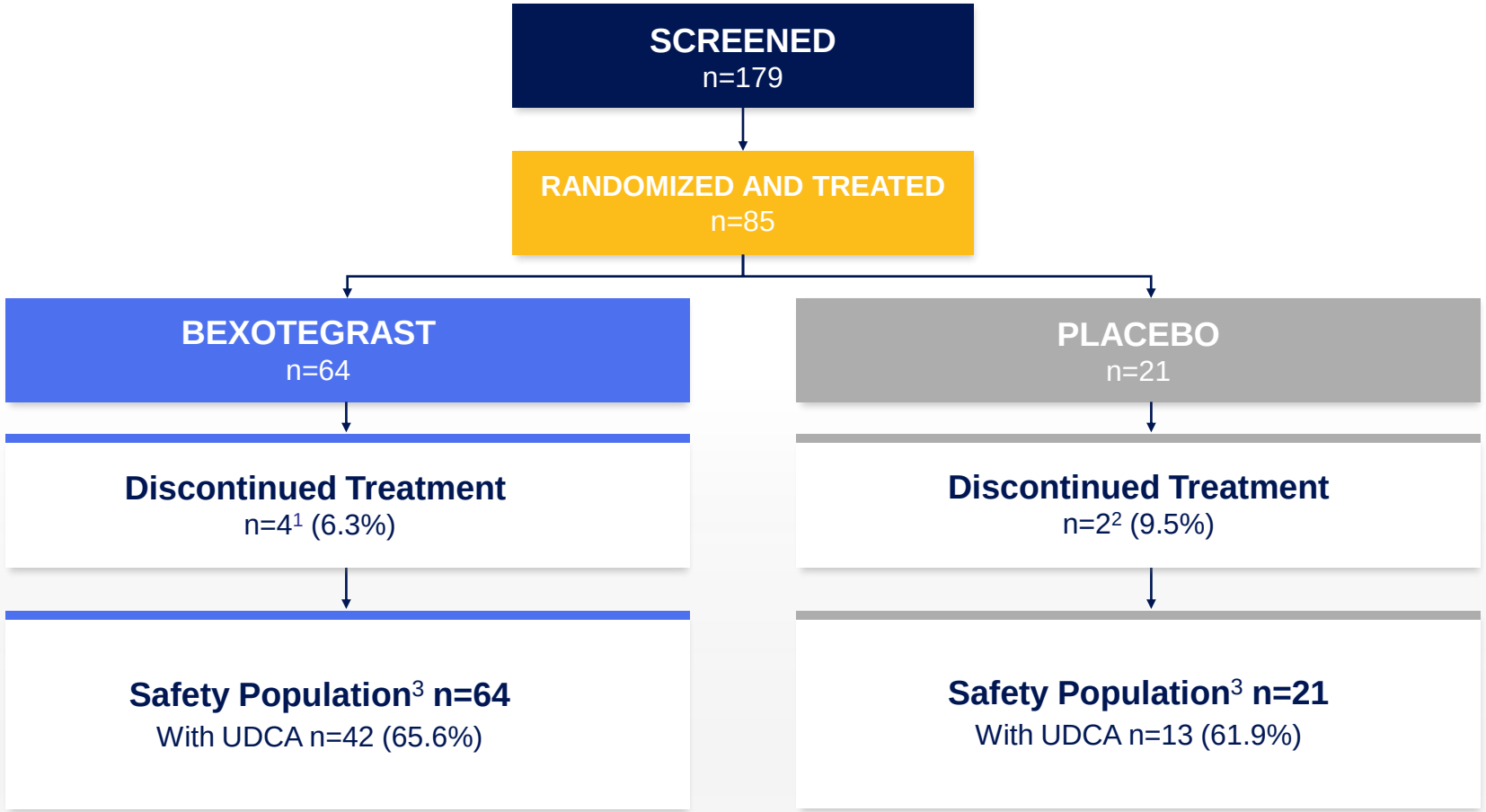
TIMP-1:Tissue inhibitor of metalloproteinases-1; HA: Hyaluronic acid ; PIIINP: Procollagen III, N-terminal propeptide

INTEGRIS-PSC – Participant Disposition



1 – Adverse Event (n=3; 40 mg, 80 mg, 160 mg) Protocol Deviation (n=1; 40 mg); 2 – Adverse Event (n=2); 3 – Safety population is the key population for both analysis of safety and efficacy

UDCA = Ursodeoxycholic acid

INTEGRIS-PSC – Baseline Demographics

Characteristic	Bexotegrast 40mg (n=24)*	Bexotegrast 80mg (n=20)*	Bexotegrast 160mg (n=20)*	Bexotegrast All (n=64)	Placebo (n=21)
Male sex, n (%)	17 (70.8)	16 (80.0)	14 (70.0)	47 (73.4)	17 (81.0)
Age (yr), mean (SD)	46.9 (15.06)	40.5 (15.32)	45.1 (12.65)	44.3 (14.46)	45.6 (12.48)
Race, n (%)					
White	20 (83.3)	16 (80.0)	18 (90.0)	54 (84.4)	18 (85.7)
Black	2 (8.3)	2 (10.0)	1 (5.0)	5 (7.8)	1 (4.8)
Asian	2 (8.3)	1 (5.0)	1 (5.0)	4 (6.3)	1 (4.8)
Other / Not Reported / Unknown	0	1 (5.0)	0	1 (1.6)	1 (4.8)
Time since diagnosis of PSC (yr), mean (SD)	11.1 (8.15)	8.3 (7.97)	7.8 (6.78)	9.2 (7.72)	10.0 (7.95)
Concomitant UDCA use, n (%)	14 (58.3)	15 (75.0)	13 (65.0)	42 (65.6)	13 (61.9)
IBD, n (%)	18 (75.0)	12 (60.0)	11 (55.0)	41 (64.0)	12 (57.1)
Ulcerative colitis	11 (45.8)	6 (30.0)	7 (35.0)	24 (37.5)	7 (33.3)
Crohn's disease	6 (25.0)	4 (20.0)	2 (10.0)	12 (18.8)	4 (19.0)
IBD Other	3 (12.5)	2 (10.0)	2 (10.0)	7 (10.9)	1 (4.8)
Partial Mayo Score, mean (SD)	0.7 (1.08)	1.6 (2.54)	1.1 (1.27)	1.1 (1.70)	0.7 (1.56)
Itch NRS, mean (SD)	1.8 (2.54)	2.1 (2.63)	1.4 (1.50)	1.7 (2.27)	1.1 (1.58)

Duration since diagnosis at screening is calculated from the first reported date for preferred terms of PSC.
Partial Mayo score only reported for those with active IBD at Baseline
BMI = Body Mass Index; IBD= inflammatory bowel diseases; NRS= numerical Rating scale;
SD = Standard deviation

* Two participants (80 mg and 160mg) were dispensed incorrect number of tablets and provided incorrect dosing instructions for the full treatment period due to an error at a single site. The participants' daily dose corresponded to a ≤40 mg dose. These 2 participants are grouped in the 40 mg dose group for all summaries.

INTEGRIS-PSC – Baseline Disease Activity Markers

	Bexotegrast 40mg (n=24)	Bexotegrast 80mg (n=20)	Bexotegrast 160mg (n=20)	Bexotegrast All (n=64)	Placebo (n=21)
Serum Liver tests, mean (SD)					
Alkaline phosphatase (U/L)	315.1 (140.26)	199.2 (81.03)	273.8 (165.63)	266.0 (140.68)	259.7 (185.76)
Alanine aminotransferase (U/L)	91.5 (62.08)	67.6 (63.15)	98.4 (73.11)	86.2 (66.25)	67.5 (49.19)
Aspartate aminotransferase (U/L)	67.2 (49.34)	46.4 (30.12)	69.0 (39.62)	61.3 (41.70)	48.8 (30.57)
Total Bilirubin (mg/dL)	0.66 (0.307)	0.79 (0.493)	0.88 (0.396)	0.77 (0.405)	0.84 (0.357)
Direct bilirubin (mg/dL)	0.27 (0.164)	0.26 (0.188)	0.31 (0.166)	0.28 (0.171)	0.30 (0.189)
Markers of Fibrosis, mean (SD)					
ELF Score	9.6 (0.77)	9.2 (1.01)	9.4 (0.79)	9.4 (0.86)	9.2 (1.08)
PRO-C3 (ng/mL)	49.96 (13.844)	48.84 (42.790)	46.12 (11.670)	48.39 (25.904)	43.24 (10.828)
Transient Elastography (kPa), mean (SD)	10.1 (2.62)	9.1 (2.99)	8.2 (3.16)	9.2 (2.98)	8.5 (2.86)

ELF: Enhanced Liver Fibrosis; PROC-C3: neo-epitope pro-peptide of type III collagen formation.
PRO-C3 quantified using Roche COBAS platform (assay reports approximately 2x higher concentrations than previous generation PRO-C3 ELISA)

INTEGRIS-PSC – Safety Summary

AE, n (%) of Participants Reporting	Bexotegrast 40mg (n=24)	Bexotegrast 80mg (n=20)	Bexotegrast 160mg (n=20)	Bexotegrast All (n=64)	Placebo (n=21)
TEAE	10 (41.7)	16 (80.0)	15 (75.0)	41 (64.1)	16 (76.2)
Related to study drug	1 (4.2)	6 (30.0)	4 (20.0)	11 (17.2)	7 (33.3)
Serious TEAE	1 (4.2)	1 (5.0)	0	2 (3.1)	0
Related to study drug	0	0	0	0	0
TEAE of CTCAE Grade 3 or Higher	1 (4.2)	2 (10.0)	1 (5.0)	4 (6.3)	3 (14.3)
Related to study drug	0	0	0	0	2 (9.5)
TEAE Leading to Interruption of Study Drug	1 (4.2)[1]	0	0	1 (1.6)[1]	0
TEAE Leading to Withdrawal of Study Drug	1 (4.2)[2]	1 (5.0)[3]	1 (5.0)[4]	3 (4.7)[2,3,4]	2 (9.5)[5,6]
TEAE Leading to Early Termination from Study	0	0	1 (5.0)[4]	1 (1.6)[4]	0
TEAE Leading to Death	0	0	0	0	0

1 – chills/fatigue/nausea/pyrexia/vomiting; 2 – COVID-19; 3 –Hepatic enzyme increase/Pruritus ; 4 – Fatigue; 5- cardiomegaly/dyspnoea/malaise; 6 - headache

AE = Adverse Event; TEAE = Treatment Emergent Adverse Event; SAE = Serious Adverse Events. Adverse events coded using MedDRA v. 24.0.
TEAE is defined as any AE starting (or worsening) on or after the date of first dose.

INTEGRIS-PSC – Most Frequent TEAEs

TEAE, n (%) of Participants Reporting	Bexotegrast 40mg (n=24)	Bexotegrast 80mg (n=20)	Bexotegrast 160mg (n=20)	Bexotegrast All (n=64)	Placebo (n=21)
Most frequent TEAEs (n ≥ 3 in at least one arm)					
Pruritus[1]	2 (8.3)	4 (20.0)	3 (15.0)	9 (14.1)	5 (23.8)
Fatigue	3 (12.5)	2 (10.0)	4 (20.0)	9 (14.1)	2 (9.5)
Headache	1 (4.2)	2 (10.0)	3 (15.0)	6 (9.4)	4 (19.0)
Nausea	1 (4.2)	2 (10.0)	3 (15.0)	6 (9.4)	0
COVID-19	2 (8.3)	1 (5.0)	0	3 (4.7)	3 (14.3)
Frequent bowel movements	0	3 (15.0)	0	3 (4.7)	3 (14.3)
Cholangitis	0	1 (5.0)	1 (5.0)	2 (3.1)	3 (14.3)

1- Pruritus includes preferred terms for pruritus and cholestatic pruritus

TEAE = Treatment Emergent Adverse Event; Adverse events coded using MedDRA version 24.0.
TEAE is defined as any AE starting (or worsening) on or after the date of first dose

INTEGRIS-PSC – Serious Adverse Events

No SAEs were Related to Study Drug

Treatment Group	SAE Preferred Term	Standard Toxicity Grade	Treatment Related	Any alternative cause or confounding factors?	Action Taken	Outcome
40 mg	Cholecystitis / Abdominal pain / Pancreatitis	Grade 3 (all) (Severe)	No	ERCP (post-procedure)	Hospitalization; **Event in follow-up Period (3-4 weeks post last dose)**	Recovered / Resolved
80 mg	Cholangitis	Grade 3 (Severe)	No	No [1]	Hospitalization; Dose not changed	Recovered / Resolved

1 – Patient has medical history of cholangitis.

SAE = Serious Adverse Events. Adverse events coded using MedDRA version 24.0.

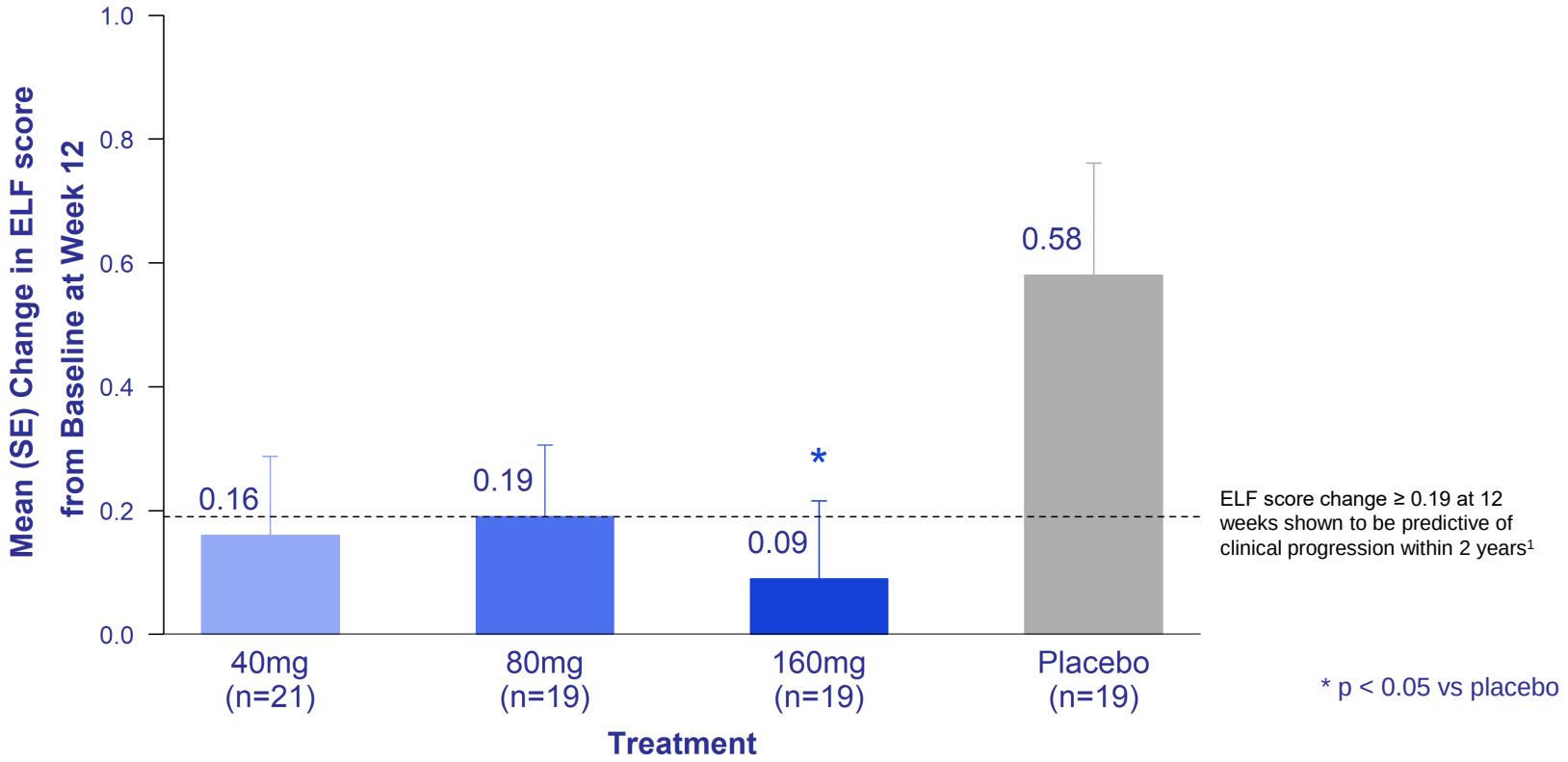
INTEGRIS-PSC – TEAEs Leading to Withdrawal of Study Drug

Treatment Group	AE Preferred Term (s)	Standard Toxicity Grade	Treatment Related	Any alternative cause or confounding factors?	Action Taken	Outcome
40 mg	COVID-19 / Nasal congestion / Dyspnoea	Grade 1 (Mild)	No	COVID-19	Drug withdrawn	Recovered / Resolved
80 mg	Hepatic enzyme increased / Pruritus	Grade 1 (Mild)	Yes	Variation in PSC / Aggravation of PSC	Drug withdrawn	Recovered / Resolved
160 mg	Fatigue	Grade 2 (Moderate)	Yes	No	Drug withdrawn	Recovered / Resolved
Placebo	Dyspnoea / Malaise / Cardiomegaly	Grade 2 (Moderate) / Grade 3 (Severe) / Grade 1 (Mild)	Yes	No	Drug withdrawn	Recovered / Resolved
Placebo	Headache	Grade 1 (Mild)	Yes	Fasting before drug administration	Drug withdrawn	Recovered / Resolved

TEAE = Treatment Emergent Adverse Event; Adverse events coded using MedDRA version 24.0.
TEAE is defined as any AE starting (or worsening) on or after the date of first dose

ELF Score – Change from Baseline at Week 12

Safety Population



Bexotegrast reduced ELF relative to placebo at all doses with statistical significance at the 160 mg dose

160 mg dose demonstrated an 84% reduction relative to placebo

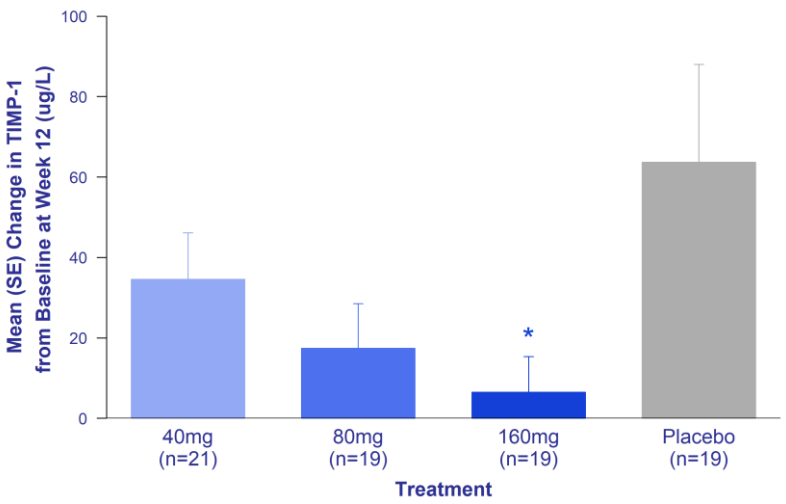
ELF: enhanced liver fibrosis score; All participants had baseline ELF ≥ 7.7 (moderate to severe liver fibrosis)[2]

[1]Hepatology 2019 69(2):684-698 [2]Hepatology 2015 62(1):188-197

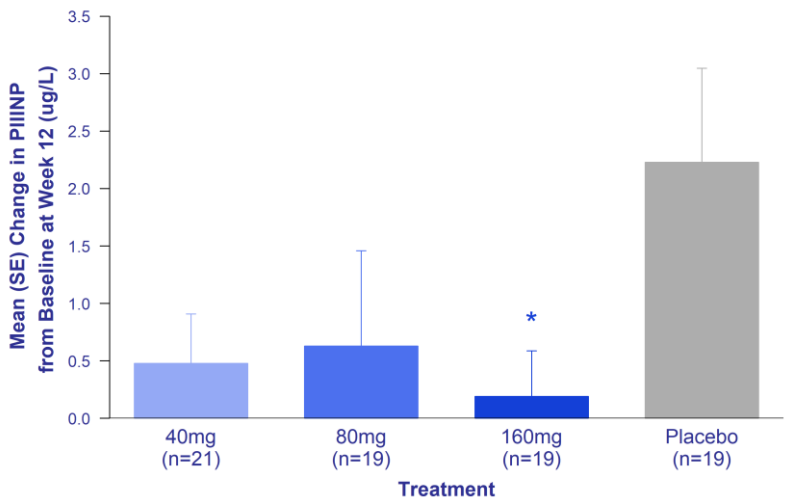
ELF Score Components - Change from Baseline at Week 12

Safety Population

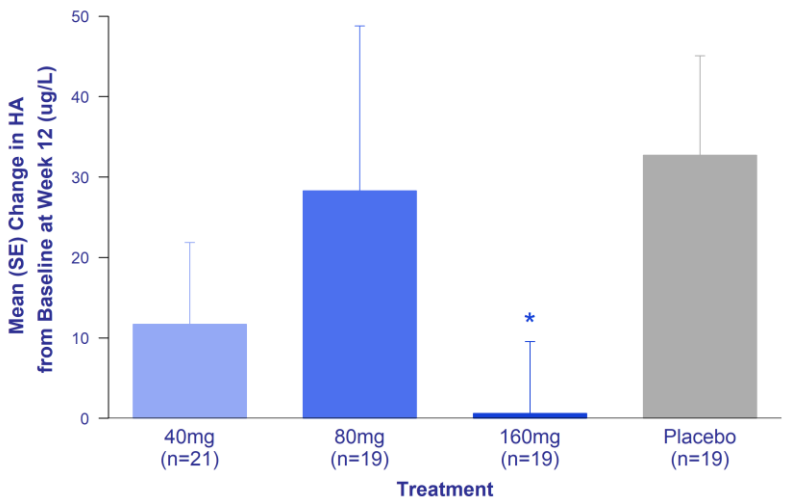
TIMP-1



PIIINP



HA



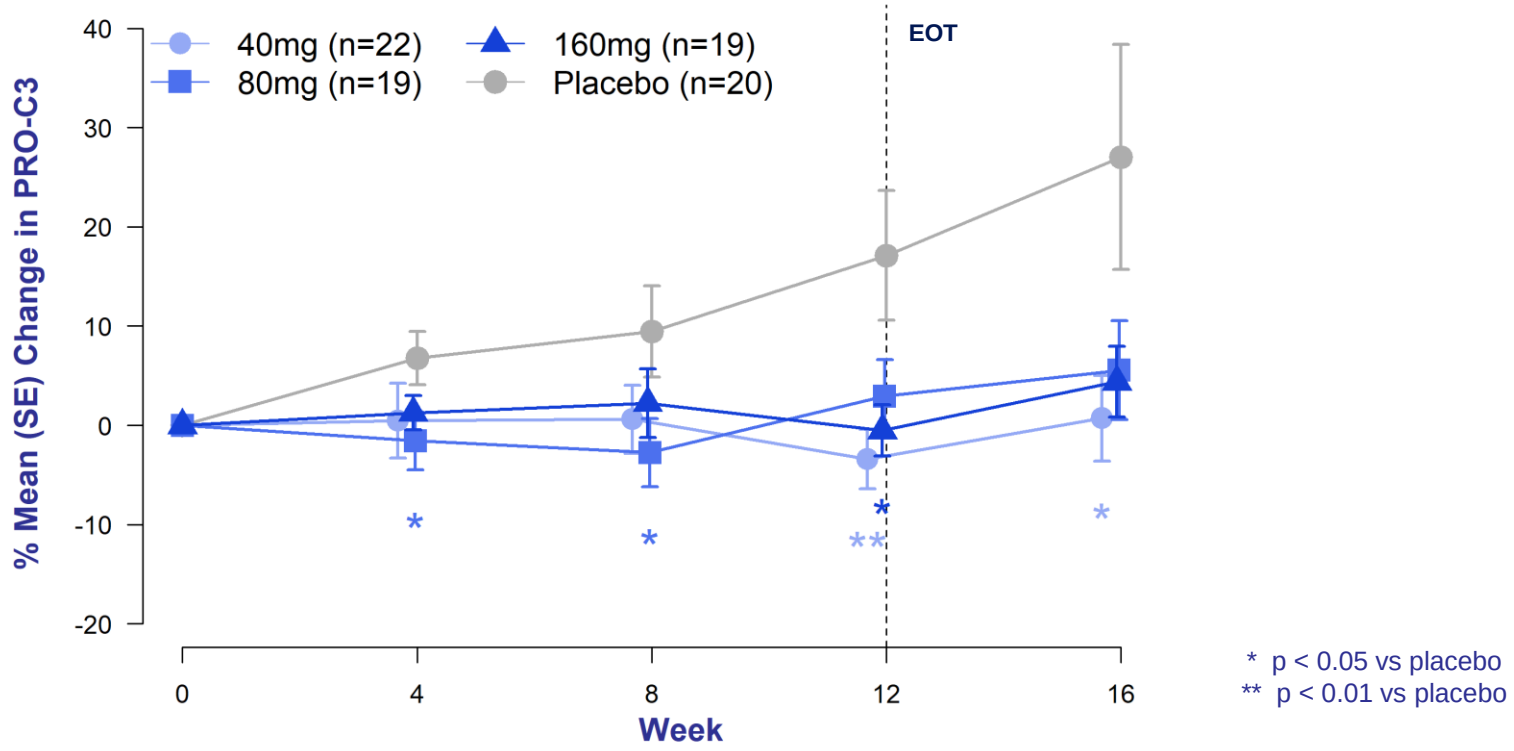
* $p < 0.05$ vs placebo

Bexotegrast 160 mg demonstrated statistically significant reductions of all three ELF score components relative to placebo

TIMP-1:Tissue inhibitor of metalloproteinases-1; HA: Hyaluronic acid ; PIIINP: Procollagen III, N-terminal propeptide

PRO-C3 - Percent Change from Baseline

Safety Population

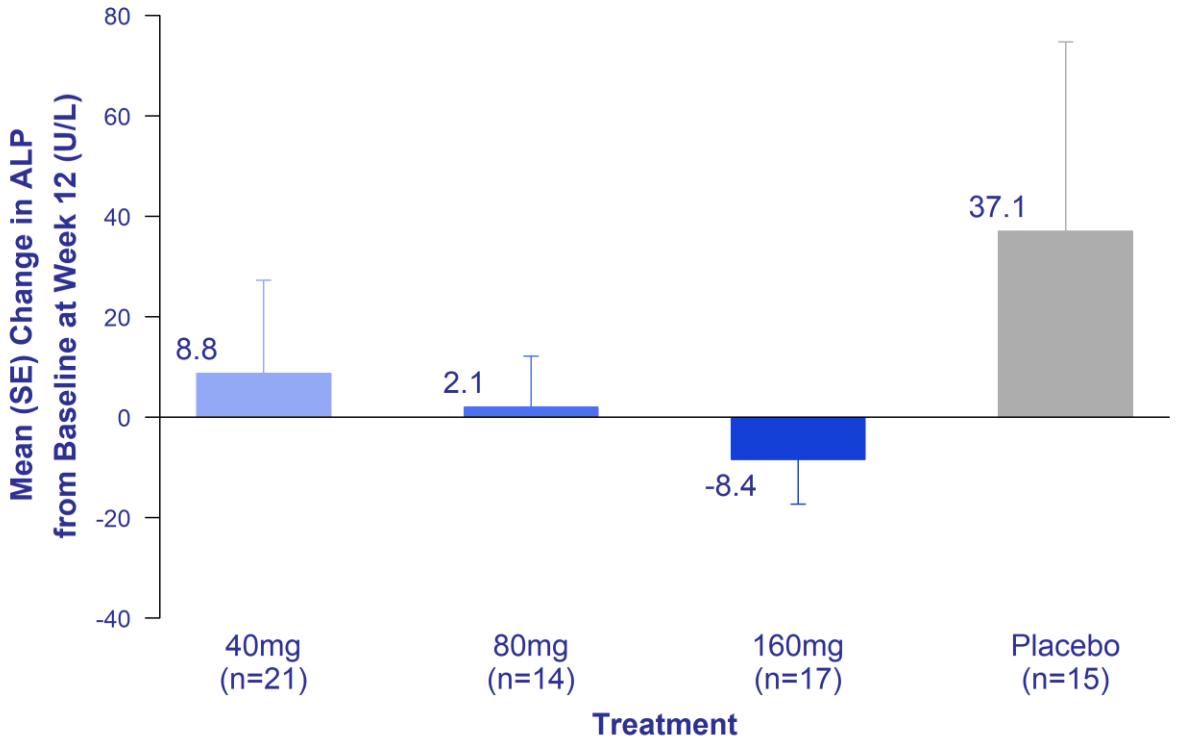


All doses reduced collagen synthesis (PRO-C3) relative to placebo with statistical significance at Week 12 for 40 mg and 160 mg doses

PROC-C3: neo-epitope pro-peptide of type III collagen formation
Only participates with both a baseline and post baseline are summarized

ALP – Change from Baseline at Week 12

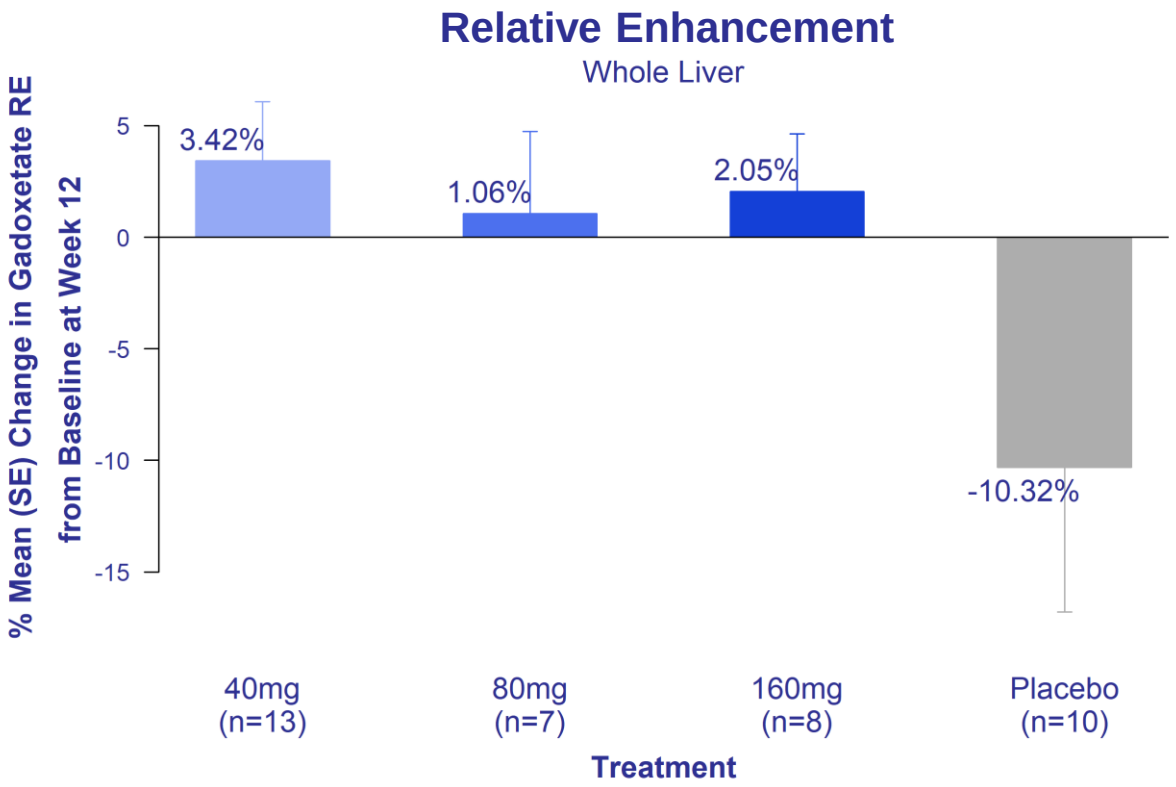
Safety Population – Participants with ALP > ULN at Baseline

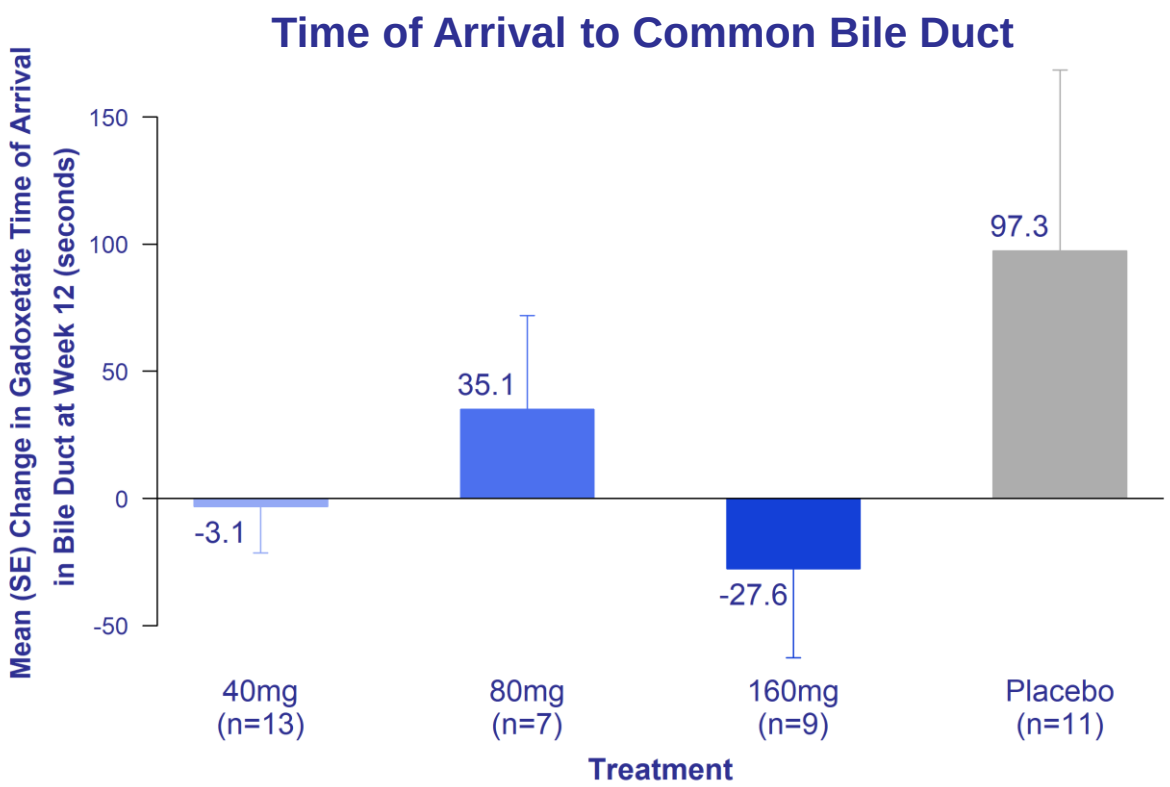


Bexotegrast showed a dose-dependent trend of reduction in ALP relative to placebo

MRI Parameters – Change from Baseline at Week 12

Sub Study Safety Population





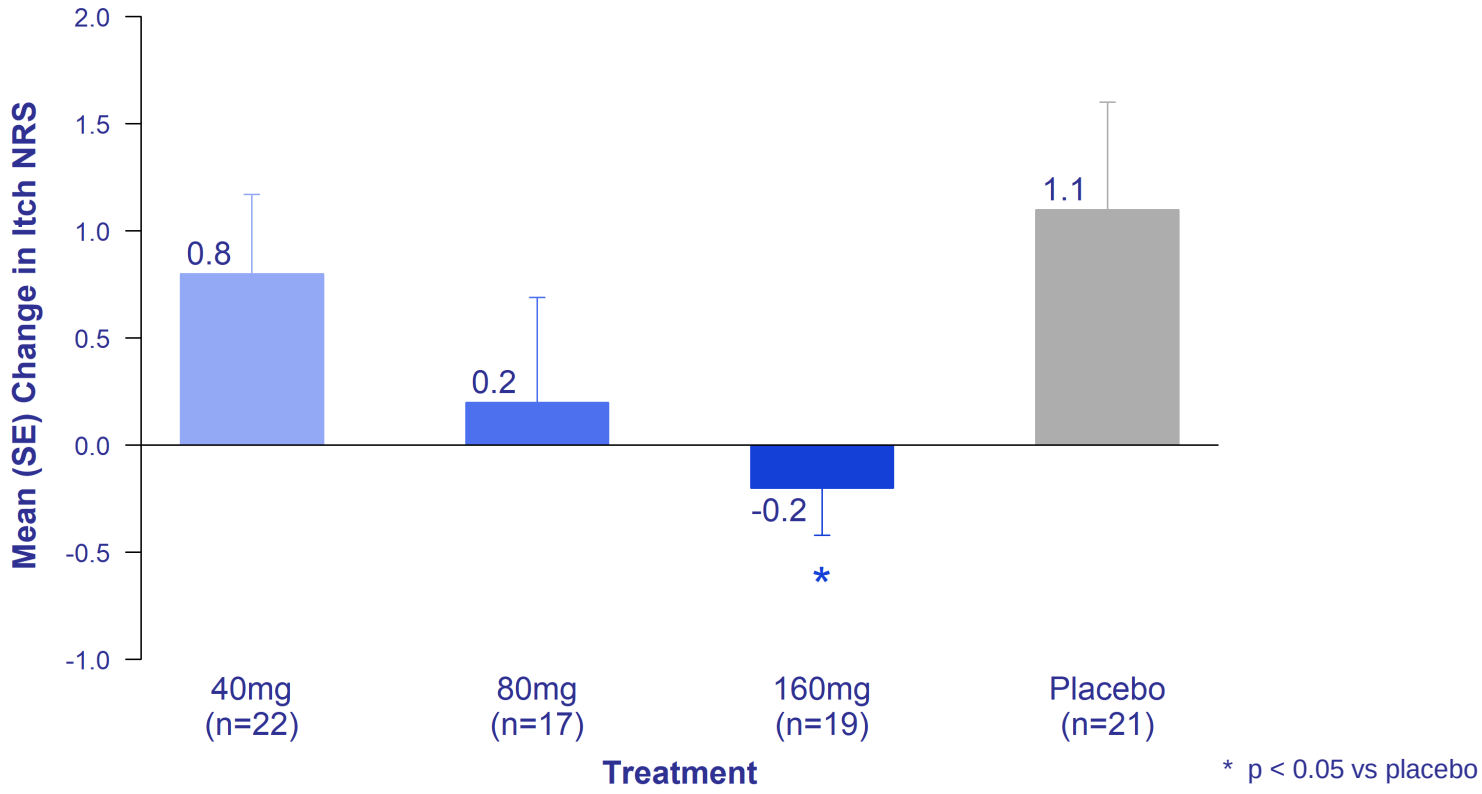
All doses showed an increase in relative enhancement compared to a reduction in placebo, suggesting improved hepatocyte function

All doses reduced time of arrival to the common bile duct compared to placebo, suggesting improved bile flow

Relative enhancement (RE), using the contrast agent gadoxetate, is a measure of hepatocyte function. Time of arrival of gadoxetate to bile duct is a measure of biliary flow.
MRI was an optional sub study to main study

Itch Numerical Rating Scale – Change from Baseline at Week 12

Safety Population



* p < 0.05 vs placebo

Bexotegrast showed dose-dependent reductions in itch relative to placebo with statistical significance for the 160 mg dose

NRS: Numerical Rating scale; Itch NRS is a patient reported outcome which assesses severity of itch, over the last 24 hours, on a scale of 0 (no itch) to 10 (Worst imaginable itching)

INTEGRIS-PSC – Summary and Next Steps

- Bexotegrast demonstrated a favorable safety and tolerability profile in a PSC patient population with suspected moderate to severe liver fibrosis
- Bexotegrast showed antifibrotic activity (ELF and PRO-C3) with statistically significant differences relative to placebo observed at Week 12 for the 160 mg dose
- Liver biochemistry and imaging parameters were improved relative to placebo at Week 12
- Dose dependent changes in Itch Numerical Rating Scale at Week 12 with statistical significance for the 160 mg dose
- 320 mg 12-week data expected in Q1 2024 with 24-week 320 mg data mid 2024

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Gideon Hirschfield, FRCP, Ph.D.

Lily and Terry Horner Chair in Autoimmune Liver Disease,
University of Toronto

Bexotegrast – A Potentially Broadly Applicable Antifibrotic

Growing Evidence that Localized TGF-β Inhibition has Potential as Backbone Antifibrotic

- TGF-β inhibition is a potent antifibrotic pathway, but systemic toxicity has challenged drug development
- Tissue-specific TGF-β inhibition avoids systemic toxicity while maintaining the antifibrotic effect

Bexotegrast Continues to Demonstrate a Favorable Safety and Tolerability Profile

- Well tolerated in over 600 participants across multiple different patient populations
- No drug-related serious adverse events observed to date across all trials

Bexotegrast Shows Potential to Treat Fibrotic Diseases Across Multiple Organ Systems

- Clear antifibrotic effect across multiple organ systems and indications
- Effect has been observed across multiple exploratory endpoints and biomarkers
- Bexotegrast is positioned to expand into multiple indications across pulmonary and liver fibrosis

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Question and Answer Session