

EASL 2024 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Effect of obeticholic acid on reduction and normalization of alanine aminotransferase and aspartate aminotransferase in the phase 3 POISE trial in primary biliary cholangitis	Gish	Poster FRI-023
Evaluation of aspartate aminotransferase to platelet ratio index and fibrosis-4 index stabilization in the phase 3 POISE trial of obeticholic acid for the treatment of primary biliary cholangitis	Bonder	Poster FRI-030
Stabilization of enhanced liver fibrosis and liver stiffness measures in the open-label extension of the phase 3 POISE trial of obeticholic acid for the treatment of primary biliary cholangitis	Gish	Poster FRI-015
Association of elevated liver biochemistries and clinical outcomes within strata of alkaline phosphatase levels in patients with primary biliary cholangitis	Victor	Poster FRI-008
Time to initiation of the second-line therapy obeticholic acid in patients with primary biliary cholangitis	Kumar	Poster THU-110
Obeticholic acid normalizes inflammatory biomarkers in patients with primary biliary cholangitis	Jones	Poster THU-132
Combined effect of obeticholic acid and bezafibrate in patients with primary biliary cholangitis and inadequate response or intolerance to ursodeoxycholic acid: 6-month results form a Phase 2 trial	Jones	Poster LBP-027
INT-787		
Farnesoid X receptor agonist INT-787 exhibits high intestinal localization	Burkey	Poster THU-316
Farnesoid X receptor agonist INT-787 protects human liver organoids from alcohol-induced injury	De Franco	Poster TOP-313
NASH		
Final results from the phase 3 REGENERATE trial evaluating the effects of obeticholic acid in patients with pre-cirrhotic fibrosis due to metabolic dysfunction-associated steatohepatitis	Sanyal	Poster LBP-036

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Intercept Presentations	First Author	Presentation Type & Number
PBC		
Metabolic Outcomes and Key Efficacy Data from a Phase 2 Trial Evaluating Combination Obeticholic Acid and Bezafibrate in Patients With Primary Biliary Cholangitis	Bonder	Oral 155
Effect of Obeticholic Acid on APRI Score in Patients at Higher Risk for Fibrosis, as Determined by Higher Baseline Fibrosis-4 Score and Liver Stiffness: Subanalysis of the Phase 3 POISE Trial in Primary Biliary Cholangitis	Bonder	Oral 156
Effect of Obeticholic Acid on Normalization of Alanine Aminotransferase and Aspartate Aminotransferase: Sub-Analysis of the Phase 3 Poise Trial in Primary Biliary Cholangitis	Gish	Oral 632
Safety Analysis of the Current US Prescribing Information-Indicated Population From the HEROES Study of Obeticholic Acid in Patients With Primary Biliary Cholangitis	Hirshfield	Poster 1582
Hepatic Events in Patients With Primary Biliary Cholangitis Treated With Obeticholic Acid: 7 Years of Post-Marketing Experience	Levy	Poster 1598
NASH		
Final Results from the Phase 3 REGENERATE Trial Evaluating the Effects of Obeticholic Acid in Patients with Pre-Cirrhotic Fibrosis due to Nonalcoholic Steatohepatitis	Sanyal	Oral 1057e

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AASLD 2023 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Effect of obeticholic acid on prognostic thresholds of gamma-glutamyl transferase and alkaline phosphatase levels: sub-analysis of the phase 3 POISE trial in primary biliary cholangitis	Bonder	Poster 4545-C
United States (US) prevalence of diagnosed primary biliary cholangitis: 41 per 100,000 adults with wide regional variability	Buchanan-Peart	Poster 4588-C
Correlations between fibrosis scoring systems and transient elastography in the phase 3 POISE study of obeticholic acid in primary biliary cholangitis	Gish	Poster 4540-C
The challenge of confirmatory trials in rare disease: lessons learned from the COBALT trial in primary biliary cholangitis	Kowdley	Poster 4578-C
Clinical trial and real-world outcomes in patients with primary biliary cholangitis treated with obeticholic acid per current US label	Kowdley	Poster 4538-C
Combined effect of obeticholic acid and bezafibrate in patients with primary biliary cholangitis and inadequate response to or intolerance of ursodeoxycholic acid: results from two phase 2 clinical trials	Levy	Poster 5019-C
NASH		
Analysis of Hispanic/Latinx vs non-Hispanic/Latinx subgroups from the REGENERATE trial of obeticholic acid for the treatment of nonalcoholic steatohepatitis	Abdelmalek	Poster 2444-C
Effect of concomitant glucagon-like peptide-1 receptor agonists from the REGENERATE trial of obeticholic acid for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis	Kowdley	Poster 2451-C
Topline results from the REVERSE trial of obeticholic acid in patients with compensated cirrhosis due to nonalcoholic steatohepatitis	Ratziu	Poster 2473-C
INT-787		
A phase 2a, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, efficacy, and pharmacokinetics of INT-787 in subjects with severe alcohol-associated hepatitis: study design, objectives, and novel assessments	Capozza	Poster 3503-C

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EASL 2023 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Modulation of alkaline phosphatase levels by obeticholic acid in clinical trials and cultured human hepatocytes	Bonder	Poster WED-267
Risk of death, liver transplant or hepatic decompensation in primary biliary cholangitis increases with increased duration and degree beyond established clinical thresholds for hepatic biomarkers and fibrosis scores	Kowdley	Poster WED-268
Fibrosis-4 score less than 2.67 and normal gamma-glutamyl transferase levels are associated with high negative predictive value for high-risk of liver stiffness in patients with primary biliary cholangitis	Bonder	Poster FRI-500
Results from a planned interim analysis of a randomized, double-blind, active-controlled trial evaluating the effects of obeticholic acid and bezafibrate on serum biomarkers in primary biliary cholangitis	Hejda	Oral OS-046
NASH		
Incidence and risk of dyslipidemia and hyperglycemia in a phase 3 study of obeticholic acid for the treatment of nonalcoholic steatohepatitis	Abdelmalek	Poster FRI-467
Incidence and median times to onset and resolution of pruritus adverse events in a phase 3 study of obeticholic acid in patients with nonalcoholic steatohepatitis	Younossi	Poster FRI-516
Significant dose-dependent reduction in liver stiffness using transient elastography in a phase 3 randomized placebo-controlled trial of obeticholic acid over 48 months in patients with pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis	Loomba	Poster TOP-074
Evaluation of noninvasive tests to identify precirrhotic fibrosis due to NASH in patients screened for the phase 3 REGENERATE and REVERSE studies of obeticholic acid	Loomba	Poster LBP-26

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Intercept Presentations	First Author	Presentation Type & Number
<i>NASH</i>		
Real-world study examining clinical characteristics and comorbidities of patients with advanced liver fibrosis due to non-alcoholic steatohepatitis (NASH)	Bertoia	Poster 1575
Obeticholic acid treatment of fibrosis due to nonalcoholic steatohepatitis reduces incidence of diarrhea but increases constipation: An analysis based on adverse events from the REGENERATE Trial	Walters	Poster 1603
New safety and efficacy analyses from the REGENERATE trial of obeticholic acid for the treatment of nonalcoholic steatohepatitis	Rinella	Oral 451

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AASLD 2022 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
<i>PBC</i>		
Results of the HEROES Study: Treatment Efficacy of Obeticholic Acid on Hepatic Real-World Outcomes in Patients with Primary Biliary Cholangitis	Brookhart	Oral 223
Efficacy of Obeticholic Acid (OCA) vs Placebo and External Controls (EC) on Clinical Outcomes in Primary Biliary Cholangitis (PBC)	Kowdley	Poster 5032
<i>NASH</i>		
Topline Results from a New Analysis of the REGENERATE Trial of Obeticholic Acid for the Treatment of Nonalcoholic Steatohepatitis	Sanyal	Oral 5008
<i>INT-787</i>		
The Novel FXR Agonist INT-787 Shows Higher Efficacy as Well as Greater Hepatic and Ileal Gene Modulation Than Obeticholic Acid in the Gubra-AMLN Mouse Model of Diet-Induced and Biopsy-Confirmed Nonalcoholic Steatohepatitis	Adorini	Poster 2514
Safety, Tolerability, and Pharmacokinetics of Oral INT-787, a Novel Modified Bile Acid FXR Agonist, in Healthy Volunteers	Capozza	Poster 4758

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EASL 2022 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
<i>PBC</i>		
Real-world prevalence of pruritus with obeticholic acid: a systematic literature review and meta-analysis	Horne	Poster THU439
Analyses of obeticholic acid treatment retention in UK patients based on medicine delivery data	Gibbons	Poster THU438
Long-term obeticholic acid (OCA) for primary biliary cholangitis (PBC) in a clinical trial improved event free survival (death, liver transplant and hepatic decompensation) compared to external controls from the GLOBAL PBC real-world database	Murillo Perez	Poster THU484
Proportion of time and degree to which liver biochemistries are out-of-range predicts time to first occurrence of negative hepatic outcomes in people with primary biliary cholangitis	Ritter	Poster THU478

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DDW 2022 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
<i>PBC</i>		
Patients with Primary Biliary Cholangitis Treated with Long-term Obeticholic Acid in a Trial-setting Demonstrate Better Event-free Survival Outcomes than External Controls from the GLOBAL PBC and UK-PBC Study Groups	Murillo Perez	Poster Su1357
Duration and Degree of Alkaline Phosphatase Elevation is Associated with Significantly Increased Risk of Death, Liver Transplant and Hepatic Decompensation in Patients with Primary Biliary Cholangitis	Ritter	Poster Su1347

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AASLD 2021 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Patients with Primary Biliary Cholangitis Treated with Long-Term Obeticholic Acid in a Trial-Setting Demonstrate Better Transplant-Free Survival Than External Controls from the Global PBC and UK-PBC Study Groups	Murillo Perez	Oral LO8
Expert Consensus Criteria and Practical Recommendations for PBC Care in the COVID-19 Era and Beyond	Berenguer	Poster 518
Results from a Retrospective, Observational, Multicenter Study of Patients with Primary Biliary Cholangitis Treated with Obeticholic Acid in Real Life in Italy (O-REAL)	Alvaro	Poster 1300
NASH		
A Phase 3, Double-blind, Randomized, Multicenter Study of Obeticholic Acid in Patients with Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH): Study Design and Baseline Patient Characteristics of the REVERSE Trial	Ratziu	Poster 1898
Minimizing Variability and Increasing Concordance for NASH Histological Scoring in NASH Clinical Trials	Sanyal	Poster 1620

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EASL 2021 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Effectiveness of Obeticholic Acid in Patients with Primary Biliary Cholangitis Stratified by Biochemical Marker Status in the Real-world Setting in the United States	Gish	Poster PO-254
Incidence of Hepatic Outcomes in Patients with Cirrhosis Due to Primary Biliary Cholangitis: A Population-based Epidemiology Study	Titievsky	Poster PO-1664
NASH		
Incidence Rates of Select Outcomes Among Patients with Non-alcoholic Steatohepatitis (NASH) and Evidence of Fibrosis or Cirrhosis	Bertoia	Oral OS-1780
Aminotransferase Improvements in Patients with Non-alcoholic Steatohepatitis are Associated with Fibrosis Regression in the REGENERATE Study	Rinella	Poster PO-2290
Comorbidity and Healthcare Utilization Burden of Patients Diagnosed with Non-alcoholic Steatohepatitis Based on Fibrosis-4 Score Severity	Titievsky	Poster PO-1588
Incidence Rates of Hepatobiliary Outcomes Among Patients with Non-alcoholic Steatohepatitis Based on Fibrosis-4 Score Severity at Baseline	Titievsky	Poster PO-980

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AASLD 2020 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Long-Term Efficacy and Safety of Obeticholic Acid in Patients With PBC From the POISE Trial Grouped Biochemically by Risk of Disease Progression	Bowlus	Poster 1250
Long-Term Efficacy and Safety of Obeticholic Acid in Primary Biliary Cholangitis: Responder Analysis of Over 5 Years of Treatment in the POISE Trial	Hansen	Poster 1251
Real-World Effectiveness of Obeticholic Acid in Patients With Primary Biliary Cholangitis	Gish	Poster 1268
Primary Biliary Cholangitis: Patient Characteristics and the Healthcare Economic Burden in the United States	Gish	Poster 1259
NASH		
Noninvasive Assessments to Identify Patients With Advanced Fibrosis Due to NASH: Screened Population From the REGENERATE Trial	Boursier	Oral 0056
Evaluation of Obeticholic Acid Efficacy in Patients With NASH Who Were Monitored Using Noninvasive Tests: A Post Hoc Analysis of the REGENERATE Trial	Alkhoury	Oral 0070
Identification of Patients with Nonalcoholic Steatohepatitis (NASH) in an Electronic Health Record (EHR) Database	Bertoia	Poster 1599
FIB-4 and FibroScan Can Identify Patients With Nonalcoholic Fatty Liver Disease Who Are at Risk of Liver-Related Events: Results of a Longitudinal Analysis With Comparison with Liver Biopsy	Boursier	Poster 1589
Identification of Undiagnosed NASH: Development and Application of a Real-World Prediction Model	Kponee-Shovein	Poster 1520
A Fecal Microbiome Signature for NASH Based on Analysis of a REGENERATE Sub-Study Compared With Three Healthy Control Populations	Wu	Poster 1510
Predicted Long-Term Clinical Outcomes of Obeticholic Acid (OCA) for the Treatment of Patients with Advanced Fibrosis Without Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH) Compared to Standard of Care in the USA	Barritt	Poster 1542
Characteristics and Care Patterns of Real-World Nonalcoholic Steatohepatitis (NASH) Patients With and Without Liver Biopsy	Esposito	Poster 1576
Economic Burden of NASH-Associated Cirrhosis: US Payer's Perspective	Mozaffari	Poster 1584

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EASL 2020 Intercept Congress Presentations

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PBC		
Durability of biochemical improvements through six years of open label treatment with obeticholic acid in patients with primary biliary cholangitis who did not achieve the POISE criteria	Hirschfield	Poster FRI146
Predicted risk of end stage liver disease utilizing the UK-PBC risk score with continued standard of care and subsequent addition of obeticholic acid for 60 Months in patients with primary biliary cholangitis	Jones	Poster THU114
Efficacy and tolerance of obeticholic acid in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid in real life: interim analysis of the OCARELIFE study	Leroy	Poster FRI180
NASH		
Obesity-specific health-related quality of life in patients with non-alcoholic steatohepatitis: results from the REGENERATE study	Younossi	Poster FRI080
Obeticholic acid (OCA) improves experimental non-invasive markers of non-alcoholic steatohepatitis and advanced fibrosis: a secondary analysis of the phase 3 regenerate study	Boursier	Oral AS075
Obeticholic acid improves hepatic fibroinflammation as assessed by multiparametric magnetic resonance imaging: interim results of the REGENERATE trial	Loomba	Poster FRI066
The burden of disease associated with non-alcoholic steatohepatitis patients under standard of care	Pais	Poster THU048
Noninvasive tests for assessing fibrosis in patients with non-alcoholic fatty liver disease: an evaluation of combining test results	Vick	Poster FRI009
Obeticholic acid demonstrates sustained improvements at month 24 in transaminases and non-invasive markers of fibrosis: results of a post hoc analysis from the interim analysis of the REGENERATE study	Loomba	Poster LBP-019

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DDW 2020 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Durability of Biochemical Improvements Through Six Years of Open-Label Treatment With Obeticholic Acid in Patients with PBC who Did Not Achieve the POISE Criteria	Hirschfield	Oral 687
Predicted Risk of End-Stage Liver Disease Utilising the UK-PBC Risk Score With Continued Standard of Care and Subsequent Addition of Obeticholic Acid for 60 Months in Patients With Primary Biliary Cholangitis	Jones	Poster Su1647
NASH		
Obeticholic acid (OCA) improves experimental noninvasive markers of NASH and advanced fibrosis: results of a secondary analysis from the month-18 interim analysis of the REGENERATE study	Boursier	Oral 334
Obeticholic Acid Improves Hepatic Fibroinflammation as Assessed by Multiparametric Magnetic Resonance Imaging: Interim Results of the REGENERATE Trial	Lomba	Poster Tu1665
Obeticholic Acid Improves Transaminases in Patients With Non-alcoholic Steatohepatitis: Results From the 18-Month Interim Analysis of the REGENERATE Study	Rinella	Poster Mo1448
Obesity-specific Health-related Quality of Life In Patients With Non-alcoholic Steatohepatitis: Results From the REGENERATE Study	Younossi	Oral 326

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AASLD 2019 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
Effects of Obeticholic Acid on APRI and GLOBE Score in Patients with Primary Biliary Cholangitis	Harms	Poster 1261
Durable Response in the Markers of Cholestasis Through 5 Years of Open-Label Extension Study of Obeticholic Acid in Primary Biliary Cholangitis	Nevens	Oral LO6
NASH		
Obeticholic acid (OCA) improves non-invasive markers of fibrosis in patients with non-alcoholic steatohepatitis (NASH): A secondary analysis of the phase 3 REGENERATE study	Anstee	Poster 1715
Obeticholic Acid Treatment in Patients with Non-Alcoholic Steatohepatitis: A Secondary Analysis of the REGENERATE Study Across Fibrosis Stages	Sanyal	Oral 0034
The impact of pruritus on patient-reported outcomes in patients with non-alcoholic steatohepatitis treated with obeticholic acid	Younossi	Oral 0056
Assessment of patient-reported outcomes in patients with NASH treated with obeticholic acid: Results from REGENERATE phase 3 clinical trial	Younossi	Poster 2324
Safety, Pharmacokinetics and Pharmacodynamics of Obeticholic Acid in Patients with Nonalcoholic Steatohepatitis and Fibrosis or Cirrhosis	Alkhoury	Poster 2294
The economic cost and health burden of non-alcoholic steatohepatitis in the EU5 countries	Newsome	Poster 0395
Long-Term Outcomes of Patients with Advanced Fibrosis due to Non-Alcoholic Steatohepatitis (NASH) at Risk of Progressing to Cirrhosis Under Standard of Care	Pais	Poster 1217

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EASL 2019 Intercept Congress Presentations

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<i>PBC</i>		
Long-Term Obeticholic Acid Treatment is Associated with Improvements in Collagen Morphometry in Patients with Primary Biliary Cholangitis	Kremer	Poster FRI-033
Long Term Assessment of the Effects of Obeticholic Acid in Patients with Primary Biliary Cholangitis on Immune and Inflammatory Markers	Hirschfield	Poster FRI-026
<i>NASH</i>		
Positive Results from REGENERATE: A Phase 3 International, Randomized, Placebo-Controlled Study Evaluating Obeticholic Acid Treatment for NASH	Younossi	Oral GS-06
Effect of Obeticholic Acid on Liver Function in Patients with Fibrosis due to NASH (Study 117: HepQuant Disease Severity Index in NASH)	Alkhoury	Poster LBP-18

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AASLD 2018 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
PBC		
From Guidelines to Uniform Pan-healthcare Professional Practice: Development of an International Consensus Care Pathway for the Diagnosis and Management of Primary Biliary Cholangitis	Hirschfield	Poster 1886
Hepatic Safety Overview of Obeticholic Acid for the Treatment of Patients with Primary Biliary Cholangitis	Pockros	Poster 1931
NASH		
Obeticholic Acid Was Safe and Well Tolerated in Patients with NASH and Compensated Cirrhosis: A Secondary Analysis of the CONTROL Study	Halegoua-De Marzio	Oral 0071
CONTROL: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study Investigating the Effects of Obeticholic Acid and Atorvastatin Treatment on Lipoprotein Metabolism in Patients with Nonalcoholic Steatohepatitis	Pockros	Poster 1672
Efficacy and Safety of Obeticholic Acid in Patient with Nonalcoholic Steatohepatitis and Significant Fibrosis Using Endpoint Definitions and Populations Accepted for Registrational Studies	Neuschwander- Tetri	Poster 1673
Safety, Pharmacokinetics and Pharmacodynamics of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis	Alkhouri	Poster 1709

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EASL 2018 Intercept Congress Presentations

Intercept Presentations	First Author	Presentation Type & Number
Research		
Steroidal and non-steroidal FXR agonists elicit clinically-relevant lipoprotein profiles in mice with chimeric humanized livers	R. Papazyan	Oral PS-110
PBC		
Long-Term Obeticholic Acid (OCA) Treatment Associated with Reversal or Stabilization of Fibrosis/Cirrhosis in Patients with Primary Biliary Cholangitis (PBC)	C.L. Bowlus	Poster LBP-014
Change in Bilirubin with Obeticholic Acid Treatment in Primary Biliary Cholangitis Patients with High Baseline Bilirubin: A Retrospective Analysis of POISE, 201, and 202	G.M. Hirschfield	Poster 231
Durable Response in the Markers of Cholestasis through 36 Months of Open-Label Extension Study of Obeticholic Acid in Primary Biliary Cholangitis	M. Trauner	Poster 216
Independent Predictors of Primary Biliary Cholangitis (PBC) At High Risk for Progressive Course in the United States: Data from a Large-Real World Database	Z. Younossi	Poster 237
Primary Biliary Cholangitis in the U.S.: Real World Effectiveness of Obeticholic Acid in TARGET-PBC	C. Levy	Poster 224
Obeticholic acid response in primary biliary cholangitis associated with differential expression of antigen presentation, Wnt signalling and mRNA splicing	M. Seifi	Poster 191
Biliary Atresia		
Disease severity, obeticholic acid disposition and dose selection in patients with biliary atresia	J.E. Edwards	Poster 057
NASH		
Combined Administration of Obeticholic Acid (OCA) and GFT-505: Additive Histological Improvements in Mice with Diet-induced and Biopsy-confirmed Non-alcoholic Steatohepatitis (NASH)	J. Roth	Poster 479
Fibrosis involves increased fibroblast and hepatocyte collagen species, reflecting the interstitial and basement membrane matrix: Restoration of the local tissue milieu with FXR agonism	J. Roth	Poster 085
Treatment with obeticholic acid in patients with NASH does not show increased markers of liver toxicity based on evaluation of drug-induced serious hepatotoxicity (eDISH)	A. Sanyal	Poster 482

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