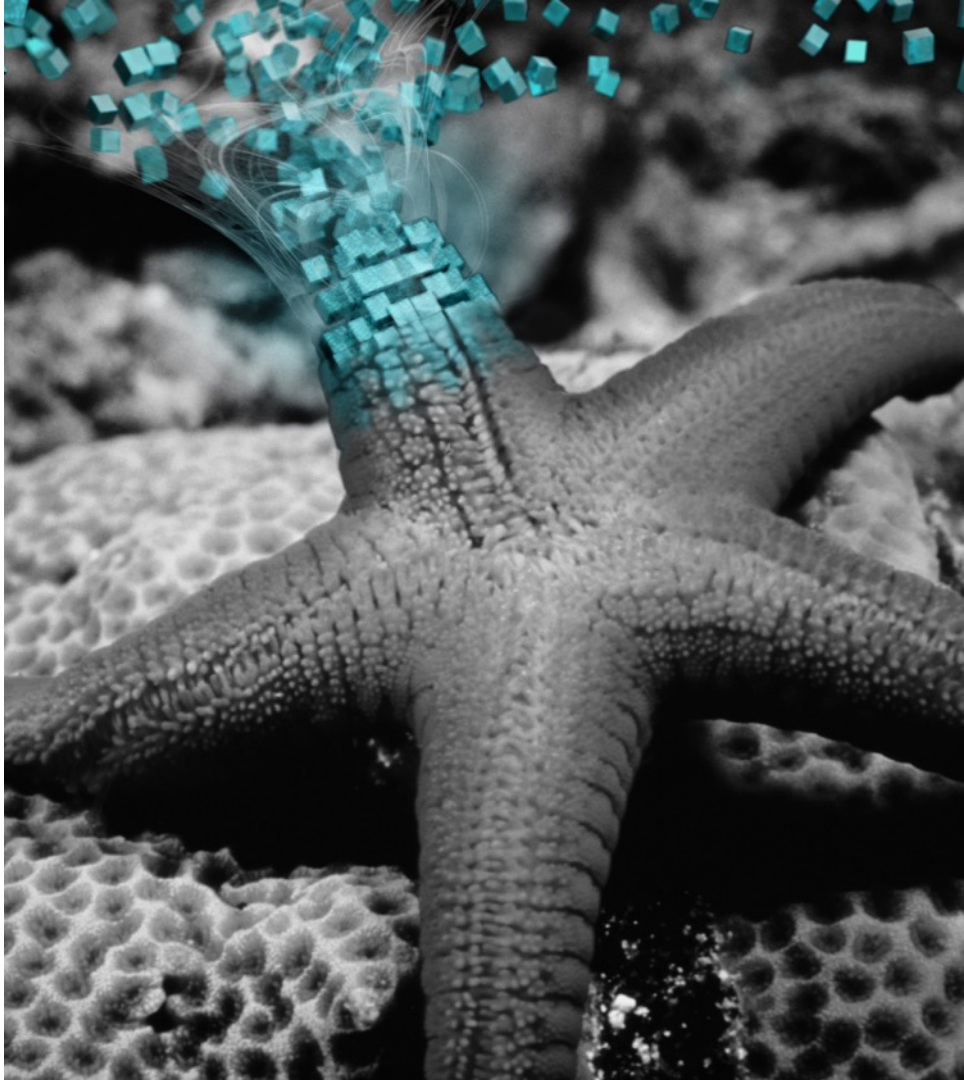
Intercept Pharmaceuticals

Corporate Presentation

May 2018



Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of Intercept's clinical trials, including its clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of Intercept's approved product, Ocaliva (obeticholic acid or "OCA"), the potential approval of OCA for indications other than primary biliary cholangitis ("PBC"), the timing and potential commercial success of OCA and any other product candidates Intercept may develop and Intercept's strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans, objectives of management and expected market growth.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "possible," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation, and Intercept undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by Intercept's management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by Intercept's forward-looking statements: Intercept's ability to successfully commercialize Ocaliva for PBC; Intercept's ability to maintain its regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel and other jurisdictions in which it has or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of Intercept's research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients or completing and timely reporting the results of its NASH or PBC clinical trials; Intercept's ability to timely and cost-effectively obtain regulatory approval of its product candidates, including OCA for NASH; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its products and product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings contained in the label of any of its products or product candidates; any potential side effects associated with Ocaliva for PBC or Intercept's product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate; Intercept's ability to maintain its relationships with, and the performance of, third-party vendors upon whom it is substantially dependent, including contract research organizations for its clinical trials and its third-party suppliers and manufacturers; Intercept's ability to identify, develop and commercialize its products and product candidates; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates; Intercept's ability to successfully commercialize its product candidates, if approved; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, Intercept's product candidates, which may be affected by the ability of patients and healthcare providers to obtain coverage or reimbursement from payors for its products and the extent to which such coverage or reimbursement is provided; Intercept's ability to establish and maintain an effective sales and marketing infrastructure directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; costs and outcomes relating to any securities, intellectual property, employment, product liability or other litigation; Intercept's ability to prevent system failures, data breaches or violations of data protection laws; Intercept's collaborators' election to pursue research, development and commercialization activities; Intercept's ability to attract and maintain collaborators with development, regulatory and commercialization expertise; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; Intercept's ability to acquire, license and invest in businesses, technologies, product candidates and products; Intercept's ability to attract and retain key personnel to manage its business effectively; Intercept's ability to manage the growth of its operations, infrastructure, personnel, systems and controls; Intercept's ability to obtain and maintain adequate insurance coverage; and the other risks and uncertainties identified in Intercept's periodic filings filed with the U.S. Securities and Exchange Commission, including Intercept's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and Annual Report on Form 10-K for the year ended December 31, 2017.

Focused on Progressive Non-Viral Liver Diseases

In a new age of liver disease treatment, Intercept is developing vital therapies to meet the high unmet medical need of those living with progressive non-viral liver diseases.

Brandi,
Living with PBC

Leading the Way in Progressive Non-Viral Liver Diseases

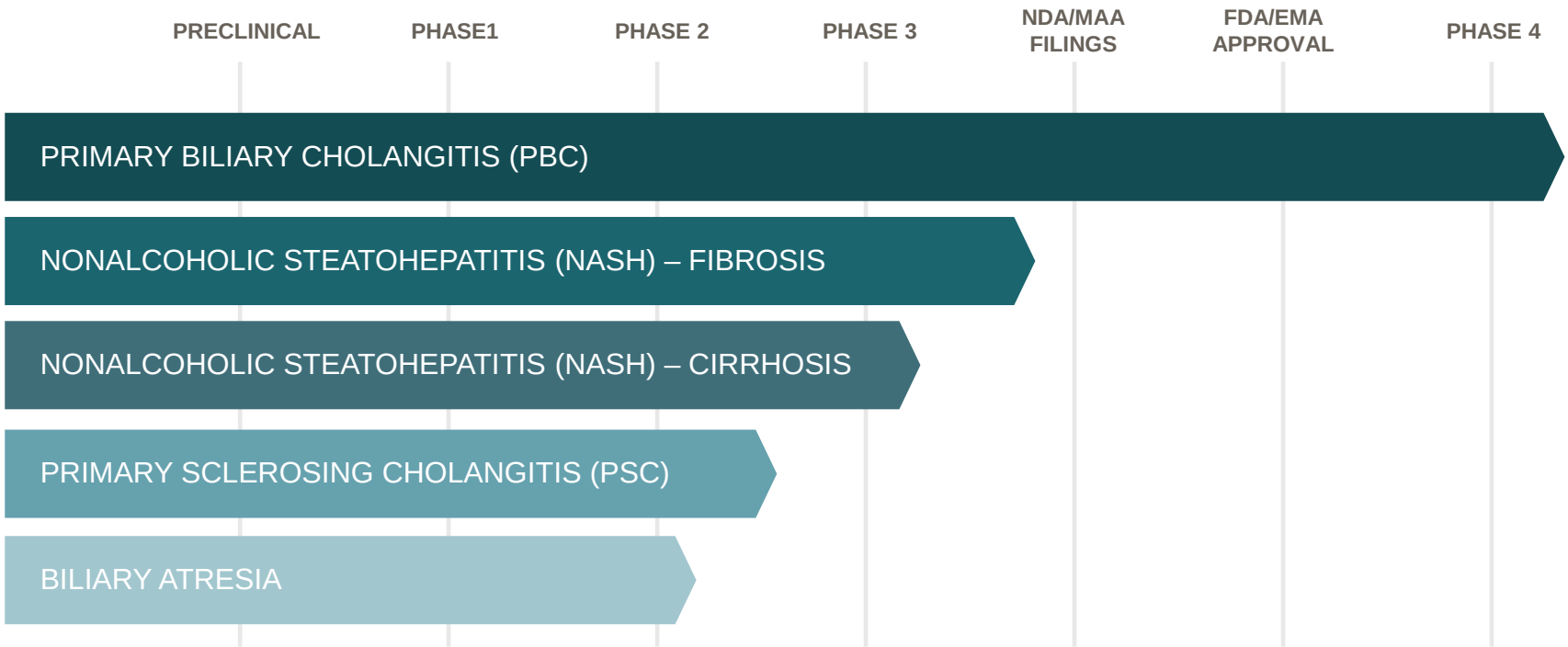
We believe we are well positioned to continue building a leading specialty focused business in progressive non-viral liver diseases with high unmet medical need:

- The Farnesoid X Receptor (FXR) represents a validated and novel scientific target with potential for therapeutic application across multiple liver and other diseases
- Commercial-stage biopharmaceutical company with global commercial organization and operations in the U.S., Europe and Canada
- Strong global launch of first drug approved in the U.S. for primary biliary cholangitis (PBC) in over 20 years
- Broad nonalcoholic steatohepatitis (NASH) clinical development program, supported by robust safety and efficacy data

Key Business Highlights At-A-Glance

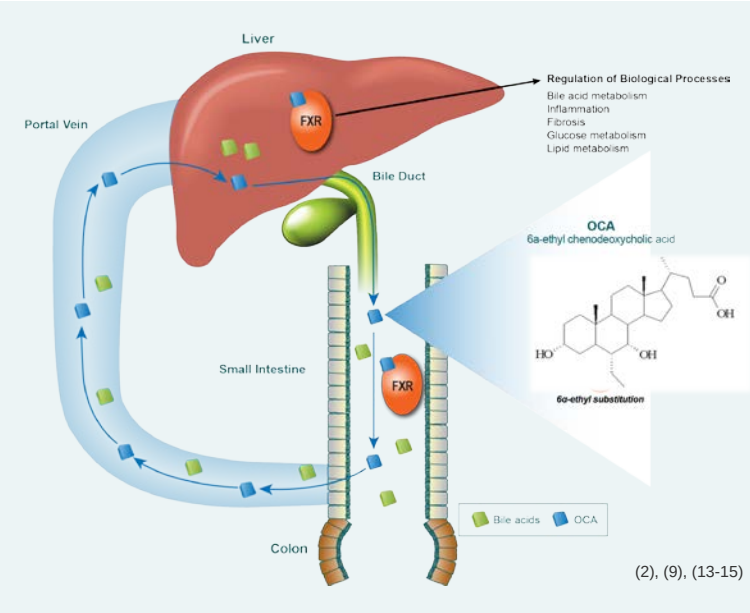
PBC: Ocaliva® (obeticholic acid) for PBC	✓ $129.2M in 2017 worldwide net sales and $35.2M in Q1 2018 worldwide net sales ✓ Ocaliva was approved for PBC in the U.S. in May 2016; conditionally approved in Europe in December 2016; and subsequently approved in other target markets, including Canada and Israel ✓ COBALT Phase 4 confirmatory outcomes trial ongoing ✓ U.S. label updated in February 2018
NASH: Significant Market Opportunity	✓ Leading NASH clinical development program – first NASH compound in development that FDA has designated as a Breakthrough Therapy ✓ Phase 3 REGENERATE trial studying obeticholic acid (OCA) in non-cirrhotic patients with liver fibrosis completed enrollment of interim analysis cohort in 2017, with top-line results expected 1H 2019 ✓ Phase 3 REVERSE trial studying OCA in patients with compensated cirrhosis
Additional Indications: PSC & BA	✓ Positive top-line results in Phase 2 AESOP trial studying OCA in patients with primary sclerosing cholangitis (PSC) reported in July 2017 ✓ Working to define regulatory path forward for OCA in PSC in 2018 ✓ Phase 2 study ongoing in biliary atresia (BA)

Obeticholic Acid Development Program in Non-Viral Liver Diseases



OCA Engages FXR Both in the Liver and Intestine

- In addition to a role in digestion and absorption, bile acids bind and activate dedicated receptors like FXR(1-3)
- FXR is a key regulator of multiple biological processes including bile acid metabolism, inflammation, and fibrosis(4-7)
- OCA is an analog of the bile acid chenodeoxycholic acid (CDCA), the natural FXR ligand, but ~100x more potent(8)
  - Due to OCA's bile acid-like properties, it circulates enterohepatically and thereby engages FXR in both the liver and intestine where FXR is highly expressed(9-11)
  - FXR engagement in the liver is believed to be critical to successfully treat pathologic injury due to progressive underlying disease(12)



(2), (9), (13-15)

1. Tortora GJ, et al. In: Tortora GJ, et al, ed. 2014. Principles of Anatomy and Physiology. 14th ed.
2. Silverthorn D, et al. The Digestive System. In: Silverthorn D, ed. 2016. Human Physiology: An Integrated Approach. 7th ed.
3. de Aguiar VTQ, et al. *Cell Metab.* 2013;17(5):657-669.
4. Eloranta JJ, et al. *Physiology.* 2008;23:286-295.
5. Modica S, et al. *Nucl Recept Signal*. 2010;e005.
6. Lefebvre P, et al. *Physiol Rev*. 2009;89(1):147-191.
7. Claudel T, et al. *Biochim Biophys Acta.* 2011;1812(8):867-878.
8. Pellicciari R, et al. *J Med Chem*. 2002;45(17):3569-3572.
9. Reshetnyak VI. *World J Gastroenterol*. 2013;19(42):7341-7360.
10. Seol W et al. *Mol Endocrinol*. 1995;9(1):72-85.
11. Forman BM, et al. *Cell*. 1995;81(5):687-693.
12. Xu JY, et al. *World J Gastroenterol*. 2014;20(37):13493–13500.
13. Greenberger NJ, et al. 2015. Harrison's Principles of Internal Medicine. 19th ed. New York, NY.
14. Halilbasic E, et al. *J Hepatol*. 2013;58(1):155-168.
15. Hylemon PB, et al. *J Lipid Res*. 2009;50(8):1509-1520.

Delivering Hope to People Living with PBC

Debbie,
Living with PBC

Intercept

Primary Biliary Cholangitis (PBC) Overview

Primarily a disease of women (**10:1**) that affects an estimated **1 in 1,000 women over the age of 40**[1]

One of the leading causes of **liver failure and transplant** in women[2]

Increased alkaline phosphatase (ALP) observed early in disease[3]

Hepatocellular damage marked by increases in **AST, ALT, GGT**

Elevation of bilirubin occurs with advanced disease

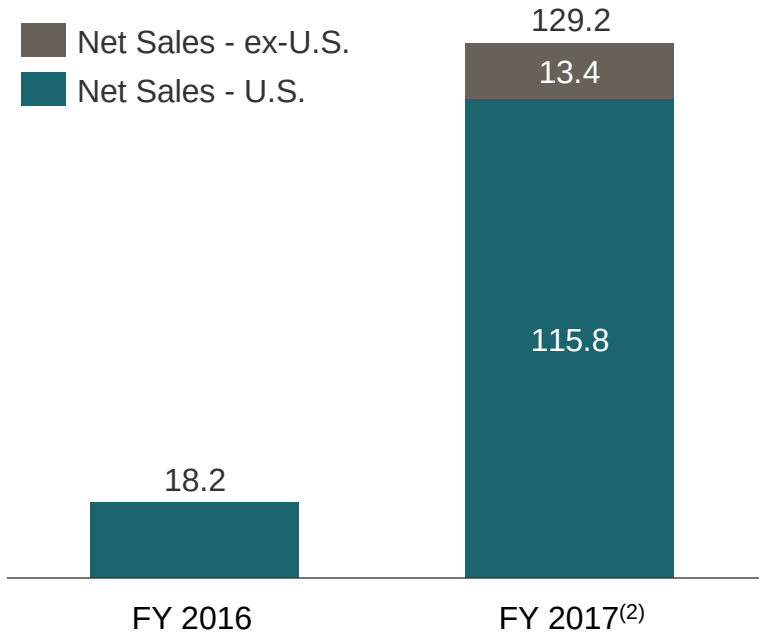
Within one year of a hepatic decompensation event, **death or liver transplant** occurs in **41% of ursodeoxycholic acid (UDCA) treated PBC patients**[4]

Proportion of **PBC patients removed from transplant waitlist** due to disease severity or mortality **increased nearly four-fold since the mid-1990s**[5]

1. Al-Harthy N, et al. *Hepat Med. 2012 Dec 4;4:61-71* & Poupon R. *J Hepatol*. 2010 May;52(5):745-58.
2. Lasker, et al. *Br J Health Psychol*. 2011;16(3):502-527.
3. Lammers WJ, et al. *Gastroenterology*. 2014 Dec;147(6):1338-49.
4. Harms MH, et al. *Hepatology*. 62(S1):244A.
5. Perumpail RB, et al. *Gastroenterology*. 2016;150(4):S1034.

FDA Approved Ocaliva in May 2016

- Granted accelerated approval for PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA
- Approval based on a reduction in ALP
- Launched in June 2016 in the U.S.
- Marketing Authorization from EMA in December 2016
- Subsequent approvals in other target markets, including Canada and Israel
- Approximately 120,000 patients in North America and Europe diagnosed and under physician care(1)



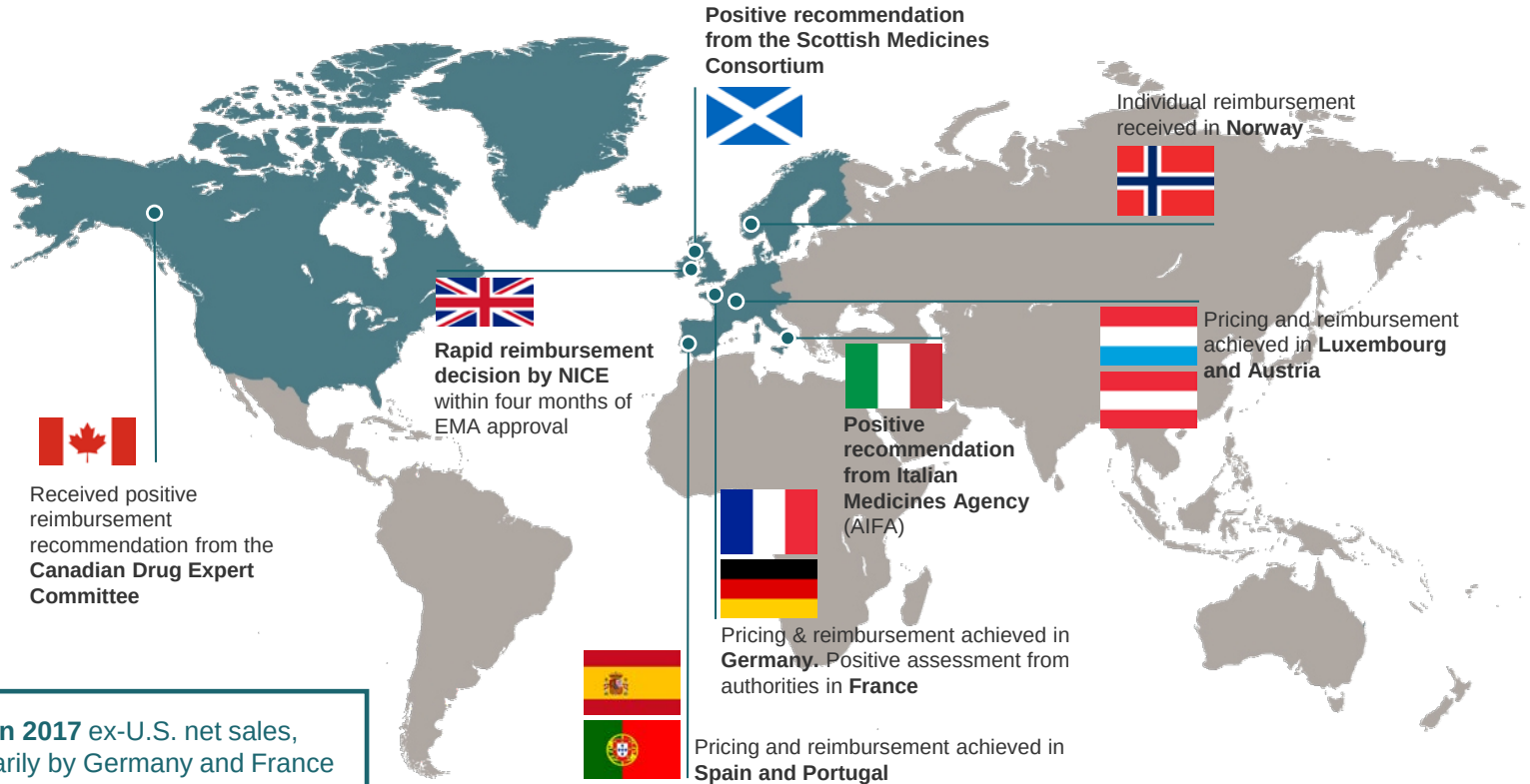
1. ICPT market research.
2. 2017 net sales includes the recognition of $4.1 million of previously deferred revenue as a result of the switch in Intercept's revenue recognition policy from the sell-through to the sell-in method.

Updated Ocaliva Label Reinforces Appropriate Dosing in PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis(1)

- In the post-marketing setting, adverse events have been reported in PBC patients with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment (which we believe represents a small proportion of the PBC population) when Ocaliva was dosed more frequently than recommended
  - In response, we undertook an evaluation of our post-marketing experience, including empaneling an independent Hepatic Adjudication Committee to look at our post-marketing experience
  - **We remain confident in Ocaliva's safety profile and the benefit it provides when used as directed in patients with PBC across the entirety of the disease spectrum**
- In February 2018, the Ocaliva label was revised to include a boxed warning specific to **PBC patients with Child-Pugh Class B or C or decompensated cirrhosis**
  - Reinforces the existing starting, titrating and maximum doses of Ocaliva for all patients, including those with Child-Pugh Class B or C or decompensated cirrhosis. **Recommended dosing remains unchanged across the patient population**
  - Underscores the importance of monitoring all patients for evidence of disease progression, as per standard of care

1. Please see the slide entitled "Ocaliva® (obeticholic acid) U.S. Important Safety Information".

Advancing Ocaliva's Global Commercial Footprint in PBC



$13.4M in 2017 ex-U.S. net sales, driven primarily by Germany and France

Pioneering the Way in NASH

This presentation is intended for investor purposes only and is not intended for promotional purposes.

Nonalcoholic Steatohepatitis (NASH) Overview

NASH affects **3-5%** of the U.S. population; NASH cases expected to **increase ~2x by 2030**[1]

Changes in the **lifestyle and diet** of the global population are fueling a **worldwide surge in obesity** and the **increasing prevalence of NAFLD and NASH**

Biopsy is the gold standard to diagnose and stage NASH today[2]

However, **non-invasive imaging** and/or combinations of **biochemical markers** are increasingly being used by HCPs to diagnose and stage NASH

Currently, there are no approved treatment options for NASH

As early as 2020, NASH is expected to surpass Hepatitis C as the **leading cause of liver transplants in the U.S.**[3]

Total direct costs of illness for NASH will continue to be **substantial** with the annual predicted economic burden of NASH with and without fibrosis estimated to be >$10B in the U.S. and major European markets[4]

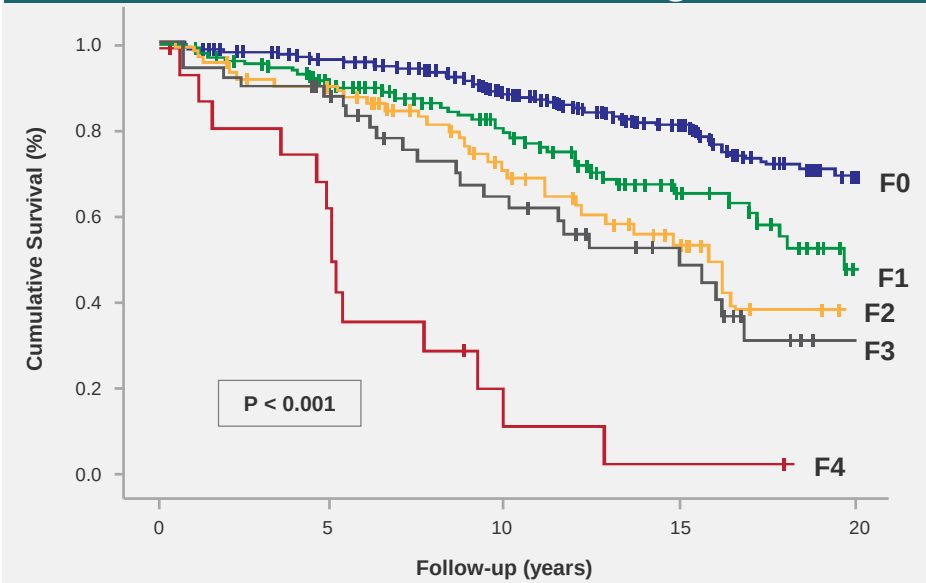
1. Estes C, et al. *Hepatology*. 2018;67:123–133.
2. EASL–EASD–EASO. *J Hepatol* 2016; 64:1388–1402 & Chalasani N, et al. *Hepatology. 2018 Jan;67(1):328-357.*
3. Charlton MR, et al. *Gastroenterology*. 2011;141;1249–1253.
4. Younossi ZM, et al. *Hepatology*. 2016;64:1577–1586.

Fibrosis is the Best Predictor of Overall Mortality in NASH

An estimated 40% of NASH patients in the U.S. have a fibrosis stage of F2 or higher[1]

NASH with advanced fibrosis carries the greatest risk of all-cause and liver-related mortality[2-4]

Survival Free of Liver Transplantation Based on Fibrosis stage[3]



1. Estes C, et al. *Hepatology*. 2018;67:123–133.
2. Dulai PS, et al. *Hepatology*. 2017;65:1557–1565.
3. Angulo P et al. *Gastroenterology*. 2015;149:389–397.
4. Hagström H, et al. *J Hepatol*. 2017;67:1265–1273.

OCA is the Only NASH Investigational Drug that has Suggested Efficacy on Key Histologic Parameters in a Well Controlled Phase 2 Trial[1]

Placebo-controlled randomized
Phase 2 FLINT trial included 200 paired biopsies over 72 weeks[2]

Primary endpoint met: decrease in NAFLD Activity Score (NAS) of at least two points with no increase in fibrosis score

OCA improved key components of NASH[3], including fibrosis, steatosis, lobular inflammation and hepatocellular ballooning[4]

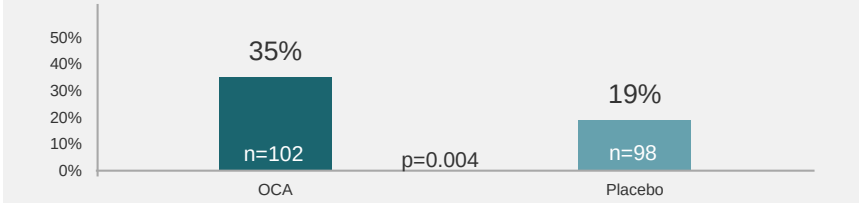
OCA was generally well tolerated

1. NASH remains an investigational indication for OCA and these findings must be confirmed in further studies.
2. FLINT trial published online in Tetri et al. The Lancet and Supplementary Appendix on November 7, 2014.
3. Secondary histological outcomes measures.
4. Despite these improvements in the individual histological features of NASH, the proportion of patients with resolution of NASH did not differ with statistical significance in patients treated with OCA compared with placebo.

OCA has Shown Preliminary Evidence of Efficacy on Both Approvable NASH Endpoints[1]

Published Analysis (Full Cohort)[2]

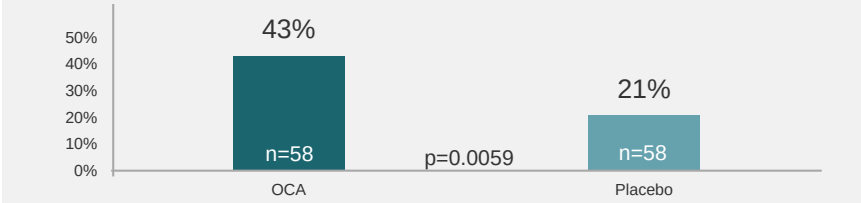
≥ 1 Stage Fibrosis Improvement



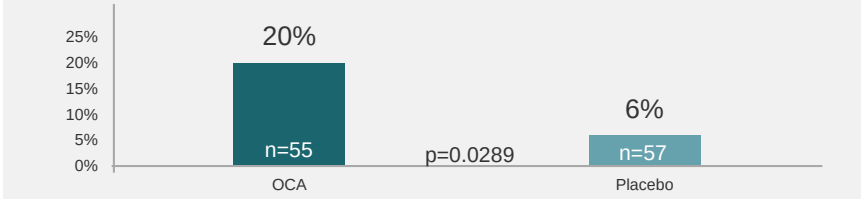
NASH Resolution[4]

Post-Hoc Analysis[3] (REGENERATE-matched cohort: F2 & F3 Fibrosis)

≥1 Stage Fibrosis Improvement w/o Worsening of NASH



NASH Resolution[5] w/o Worsening of Fibrosis



1. NASH remains an investigational indication for OCA and these findings must be confirmed in further studies.
2. Data from FLINT trial published online in Tetri et al. The Lancet and Supplementary Appendix on November 7, 2014; All p-values compared to placebo.
3. Retrospective analyses after the un-blinding of results can potentially introduce bias and regulatory authorities typically give greatest weight to results from pre-specified analyses as compared to retrospective analyses.
4. Secondary histological outcome. Showed improvement, although not statistically significant.
5. Defined as no increase in hepatocellular ballooning or lobular inflammation.

Our Leading NASH Development Program

REGENERATE

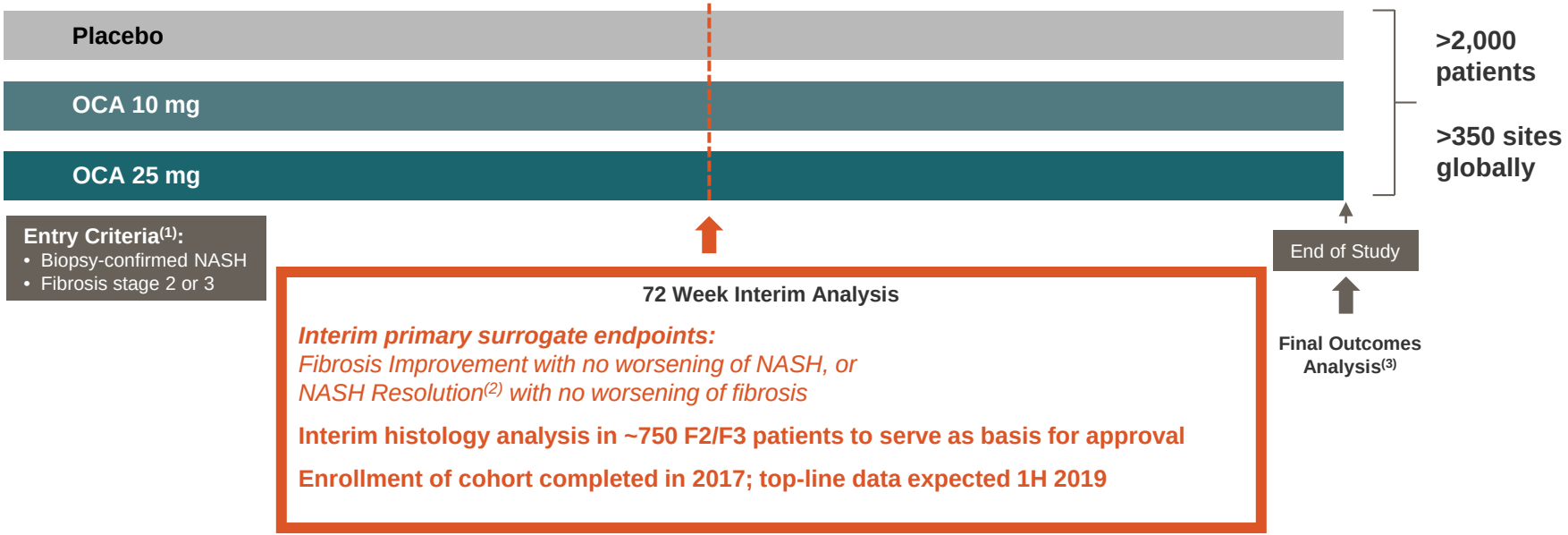
- Patients with advanced fibrosis (F2/F3) and high risk early fibrosis (F1 + metabolic syndrome)
- Pre-planned interim histology analysis on ~750 F2/F3 patients; Enrollment completed 2017; Top-line results expected 1H 2019
- Expected to support initial approval
- Targeting additional ~1,600 patients for outcomes

REVERSE

- Patients with compensated cirrhosis
- Target enrollment ~540 patients
- Targeted to support market access at launch and regulatory approval

Global Phase 3 REGENERATE Trial in NASH Fibrosis

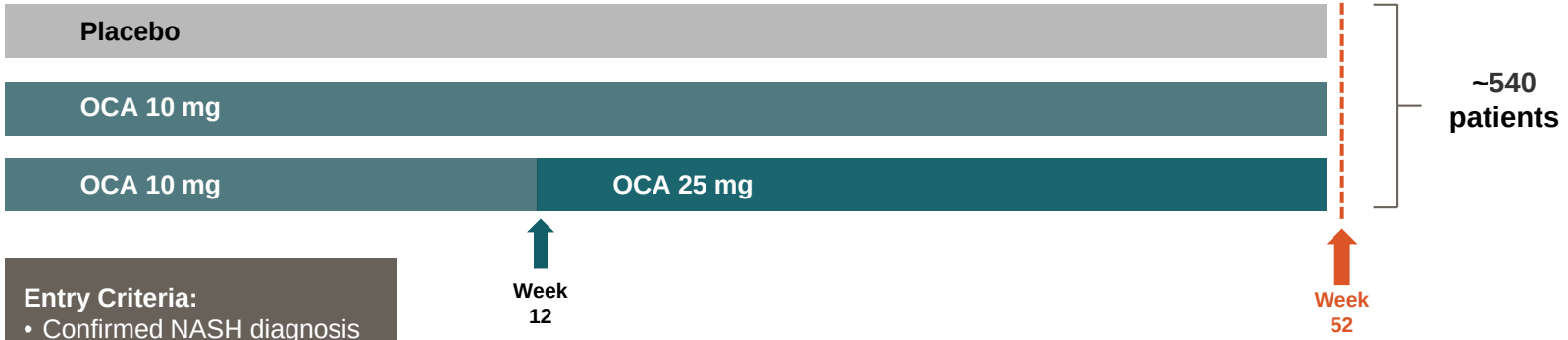
REGENERATE
NASH FIBROSIS STUDY



1. Exploratory group of NASH patients with stage 1 liver fibrosis with comorbid risk factors (defined as diabetes, obesity or active liver inflammation (ALT >1.5X ULN)) will also be enrolled, but not included in the primary endpoint analyses.
2. Hepatocyte ballooning score of 0 and residual or no inflammation ("objective definition").
3. EOS endpoint: Occurrence of pre-specified number of clinical events

Global Phase 3 REVERSE Trial in NASH Cirrhosis

REVERSE
NASH CIRRHOSIS STUDY



Entry Criteria:
- Confirmed NASH diagnosis
- Fibrosis stage 4 (compensated cirrhosis)

Primary surrogate endpoint:
Fibrosis improvement with no worsening of NASH

Trial currently enrolling with data targeted to support initial launch / approval

Advancing Research in Additional Indications

Intercept

Primary Sclerosing Cholangitis (PSC) Overview

Primarily a disease of **men (3:1)**[1]

Estimated **U.S. prevalence of ~40,000**, with similar numbers in Europe[2]

Increased ALP observed in disease

~70% of patients have concomitant IBD, primarily ulcerative colitis[3]

Often leads to **biliary obstructions and infections**, with risk of progression to **cholangiocarcinoma and liver cancer**

Autoimmune cholestatic liver disease with **high unmet need**

More **complicated and aggressive** than PBC

No approved treatment; UDCA is often used, but not recommended by AASLD[3]

1. Lindor KD, et al. ACG Clinical Guideline: Primary Sclerosing Cholangitis. *Am J Gastroenterol*. 2015 Apr;110:646-659.
2. Preliminary ICPT Market Research.
3. Chapman R, et al. Diagnosis and Management of Primary Sclerosing Cholangitis. *Hepatology*. 2010;51(2):660-678.

AESOP Phase 2 Trial Provided Proof of Concept for OCA in PSC – Working to Clarify Regulatory Path Forward in 2018[1]

OCA 5-10mg met the primary endpoint of alkaline phosphatase (ALP) reduction at 24 weeks

(U/L)	Placebo (N=25)	OCA 1.5-3 mg (N=25)	OCA 5-10 mg (N=26)
Mean Baseline ALP	563	423	429
LS[2] Mean Change from Baseline in ALP at Week 12	-53	-57	-135[3]
LS Mean Change from Baseline in ALP at Week 24	-27	-105	-110[3][4]
LS Mean % Change from Baseline in ALP at Week 24	+1%	-22%[3]	-22%[3]

In a post-hoc analysis, ALP reductions were observed with OCA regardless of treatment with UDCA. Patients receiving OCA monotherapy had greater reductions in ALP compared to patients who received OCA + UDCA[5]

	- UDCA			+ UDCA		
	Placebo	OCA 1.5-3 mg	OCA 5-10 mg	Placebo	OCA 1.5-3 mg	OCA 5-10 mg
LS Mean Percent Change from Baseline in ALP at Week 12	-5%	-12%	-30%	-1%	-1%	-16%
LS Mean Percent Change from Baseline in ALP at Week 24	-7%	-19%	-25%	19%	-15%	-14%

1. PSC remains an investigational indication for OCA and these findings must be confirmed in further studies. Pruritis was the most common adverse event observed in the AESOP trial in the OCA treatment groups.
2. Least Squares.
3. $p<0.05$.
4. The primary endpoint was the change in ALP relative to placebo at week 24 for the OCA 5-10 mg group.
5. Retrospective analyses after the un-blinding of results can potentially introduce bias and regulatory authorities typically give greatest weight to results from pre-specified analyses as compared to retrospective analyses.

Financial Summary

Intercept

Q1 2018 and Full Year 2017 Financial Results

	Quarter Ended 3/31/2018	Year Ended 12/31/2017
Product Revenue, net	**$35.2M**	**$129.2M**
Gross-to-Net Range	**10-15%**	**10-15%**
Cost of Sales	**$0.3M**	**$1.4M**
Interest Expense	**$7.5M**	**$29.3M**
Total Operating Expenses	**$111.4M**	**$466.6M**
Non-GAAP Adjusted Operating Expenses(1)	**$97.8M**	**$405.0M**
Cash Position(2)	**$326.1M**	**$414.9M**

1. "Non-GAAP Adjusted Operating Expenses" mean Intercept's Total Operating Expenses, as calculated and presented in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"), adjusted for the effects of two non-cash items: Stock-Based Compensation and Depreciation. Please see the slide entitled "Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses" for a reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses.
2. Consists of cash, cash equivalents and investment securities available for sale. Excludes net proceeds of approximately $261.4 million from a public offering and concurrent private placement of Intercept common stock completed in April 2018.

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses(1)

	Quarter Ended 3/31/2018	Year Ended 12/31/2017
Total Operating Expenses	**$111.4M**	**$466.6M**
Adjustments:		
Stock-Based Compensation	**$12.3M**	**$57.0M**
Depreciation	**$1.3M**	**$4.6M**
Non-GAAP Adjusted Operating Expenses	**$97.8M**	**$405.0M**

1. "Non-GAAP Adjusted Operating Expenses" is a financial measure that has not been prepared in accordance with GAAP. Accordingly, investors should consider Non-GAAP Adjusted Operating Expenses in addition to, but not as a substitute for, Total Operating Expenses that Intercept calculates and presents in accordance with GAAP. Among other things, Intercept's management uses Non-GAAP Adjusted Operating Expenses to establish budgets and operational goals and to manage Intercept's business. Other companies may define or use this measure in different ways. Intercept believes that the presentation of Non-GAAP Adjusted Operating Expenses provides investors and management with helpful supplemental information relating to operating performance and trends.

Ocaliva® (obeticholic acid) U.S. Important Safety Information

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

- **In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with Primary Biliary Cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.**
- **The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.**

Contraindications

OCALIVA is contraindicated in patients with complete biliary obstruction.

Warnings and Precautions

Hepatic Decompensation and Failure in Incorrectly-Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with decompensated cirrhosis or Child-Pugh B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy).

Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required. Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (e.g., gastroenteritis), may exacerbate the risk of hepatic decompensation. Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions. Discontinue OCALIVA in patients who develop complete biliary obstruction.

Liver-Related Adverse Reactions

Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage). Monitor patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions.

Severe Pruritus

Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Ocaliva® (obeticholic acid) U.S. Important Safety Information (continued)

Reduction in HDL-C

Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions

The most common adverse reactions from subjects taking OCALIVA were pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

Bile Acid Binding Resins

Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.

Warfarin

The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when coadministering OCALIVA and warfarin.

CYP1A2 Substrates with Narrow Therapeutic Index

Obeticholic acid, the active ingredient in OCALIVA, may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g. theophylline and tizanidine) is recommended when coadministered with OCALIVA.

Inhibitors of Bile Salt Efflux Pump

Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please see **Full Prescribing Information, including Boxed WARNING** and **Medication Guide** for OCALIVA.

To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Thank You

Bel,
Living with PBC

Intercept