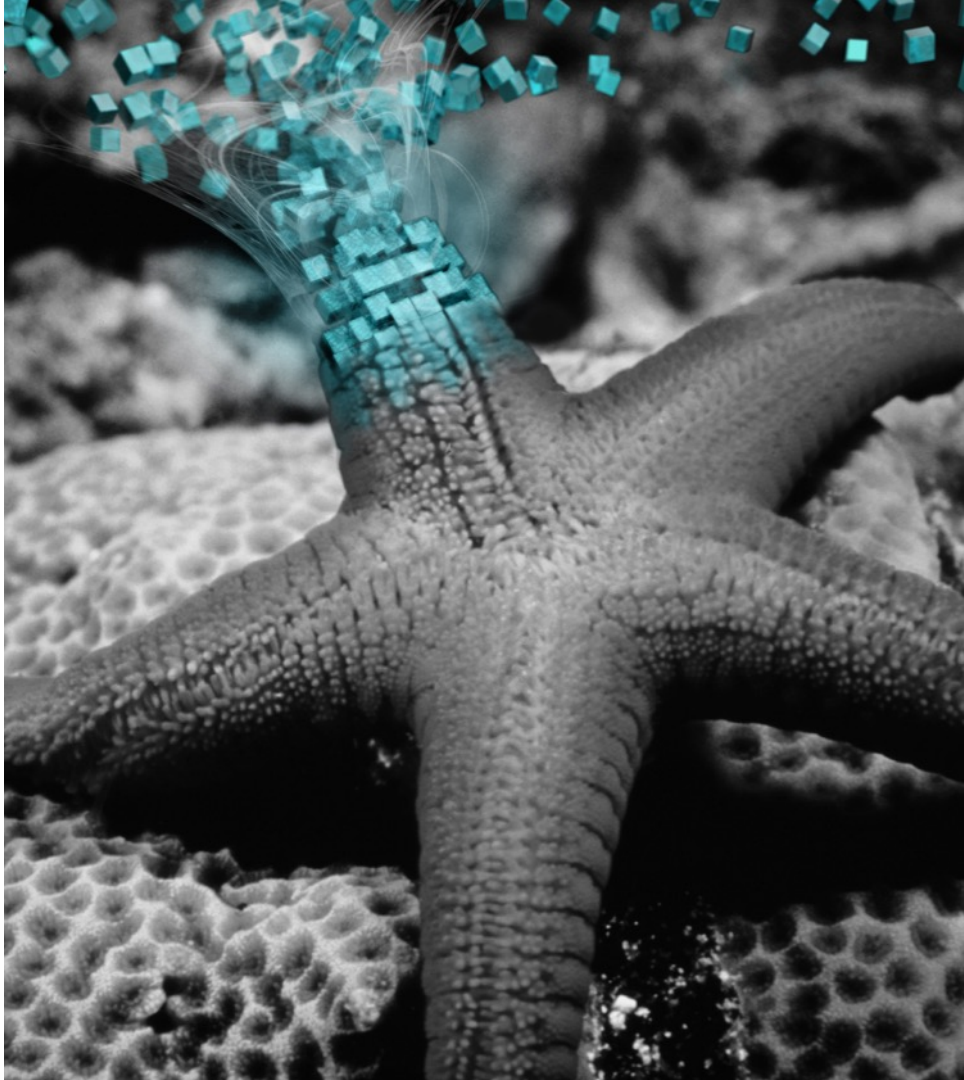
Intercept Pharmaceuticals

Q1 2020 Earnings Call Presentation

May 11, 2020

Intercept



Cautionary Note Regarding Forward-Looking Statements and Non-GAAP Financial Measures

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") for primary biliary cholangitis ("PBC"), and Intercept's product candidates, including OCA for liver fibrosis due to NASH, the timing and acceptance of Intercept's regulatory filings and potential approval of OCA for liver fibrosis due to NASH or any other indications in addition to 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 and objectives.

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: the impact of COVID-19, including any impact on Intercept's net sales, non-GAAP adjusted operating expenses or financial position, related quarantines and government actions, delays relating to Intercept's regulatory applications, disruptions relating to its ongoing clinical trials or involving its contract research organizations, study sites or other clinical partners, disruptions relating to Intercept's supply chain or involving its third-party manufacturers, distributors or other distribution partners, facility closures or other restrictions, and the extent and duration thereof; 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, Australia 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, retaining patients, meeting specific endpoints in the jurisdictions in which it intends to seek approval or completing and timely reporting the results of its NASH or PBC clinical trials; Intercept's ability to timely and cost-effectively file for and obtain regulatory approval of its product candidates, including the regulatory approval of its New Drug Application for liver fibrosis due to NASH; any advisory committee recommendation that Intercept's product candidates, including OCA for liver fibrosis due to NASH, should not be approved or approved only under certain conditions; any determination that the regulatory applications and subsequent information Intercept submits for its product candidates, including OCA for liver fibrosis due to NASH, do not contain adequate clinical or other data or meet applicable regulatory requirements for approval; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its products and product candidates, including OCA for liver fibrosis due to NASH, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), any risk mitigation programs such as a REMS, 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, OCA for liver fibrosis due to NASH or Intercept's other 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 establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom it is substantially dependent for, among other things, the manufacture and supply of its products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and its clinical trial activities; Intercept's ability to identify, develop and successfully commercialize its products and product candidates, including its ability to timely and successfully launch OCA for liver fibrosis due to NASH, if approved; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates, including its ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights; 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, OCA for liver fibrosis due to NASH or Intercept's other product candidates among physicians, patients and healthcare payors; the availability of adequate coverage and reimbursement from governmental and private healthcare payors for Intercept's products, including Ocaliva for PBC and, if approved, OCA for liver fibrosis due to NASH, and its ability to obtain adequate pricing for such products; Intercept's ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; Intercept's ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; Intercept's collaborators' election to pursue research, development and commercialization activities; Intercept's ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise; Intercept's need for and ability to generate or obtain additional financing; Intercept's estimates regarding future 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; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions, including the potential impact of Brexit; and the other risks and uncertainties identified in Intercept's periodic filings filed with the U.S. Securities and Exchange Commission, including Intercept's Annual Report on Form 10-K for the year ended December 31, 2019.

This presentation also presents non-GAAP adjusted operating expenses on a historical basis. For the periods presented, non-GAAP adjusted operating expenses exclude from total operating expenses, as calculated and presented in accordance with GAAP, the effects of two non-cash items: stock-based compensation and depreciation. 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 we calculate and present in accordance with GAAP. Among other things, our management uses non-GAAP adjusted operating expenses to establish budgets and operational goals and to manage our business. Other companies may define or use this measure in different ways. We believe that the presentation of non-GAAP adjusted operating expenses provides investors and management with helpful supplemental information relating to operating performance and trends. As of March 31, 2020, non-GAAP adjusted operating expenses no longer excluded from total operating expenses the effects of non-cash operating lease expense cost, and non-GAAP adjusted operating expenses for all periods included herein have been presented accordingly. A table reconciling non-GAAP adjusted operating expenses to total operating expenses for all historical periods presented is included in the Appendix under the heading "Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses".

Key Business Updates

As the global COVID-19 pandemic continues to evolve, Intercept remains committed to implementing measures intended to safeguard the health of our team and the patients we serve

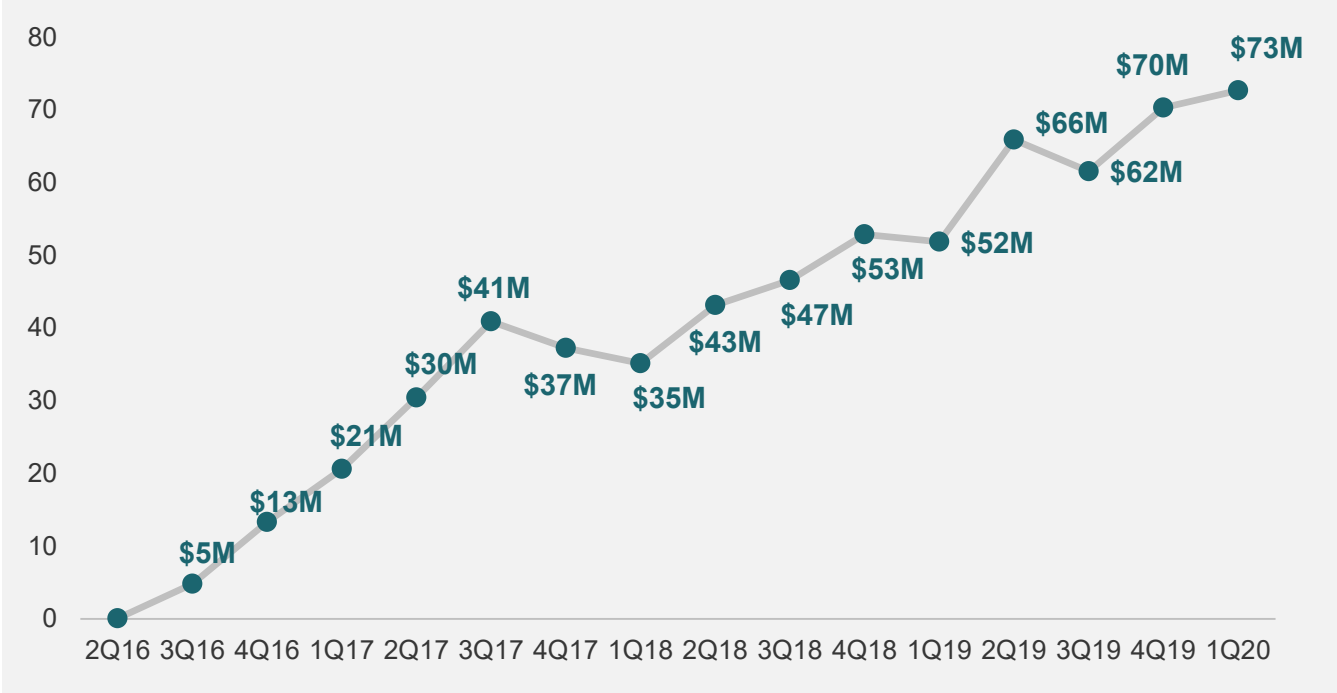
Working closely with FDA on our priority review application for OCA in liver fibrosis due to NASH; advisory committee meeting tentatively scheduled for June 9 and PDUFA on June 26

Prepared to launch OCA upon approval with a thoughtful and flexible plan

PBC business continued to perform well in the first quarter of 2020, with net sales of $72.7 million, representing 40% growth over prior year quarter

Continued Strong Commercial Performance for Ocaliva in PBC

Quarterly Worldwide Net Sales as of Q1 2020

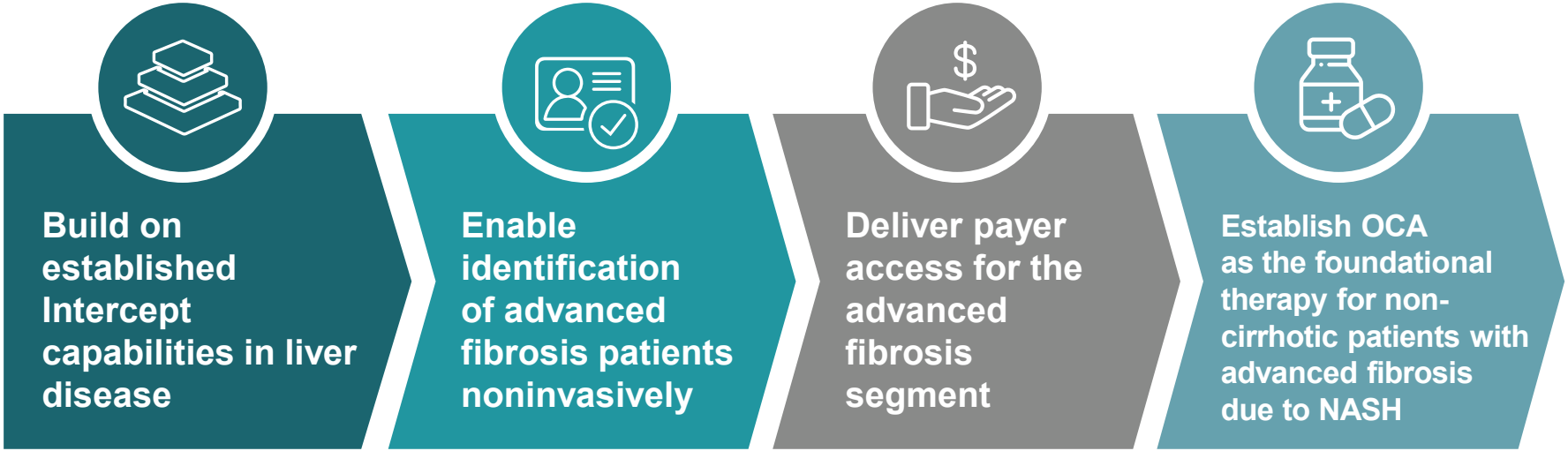


Q1 2020 Net Sales Overview

$50.8M in U.S.
net sales reflecting strong demand and total prescription growth

$21.9M in ex-U.S.
net sales driven by continued strong performance in key markets

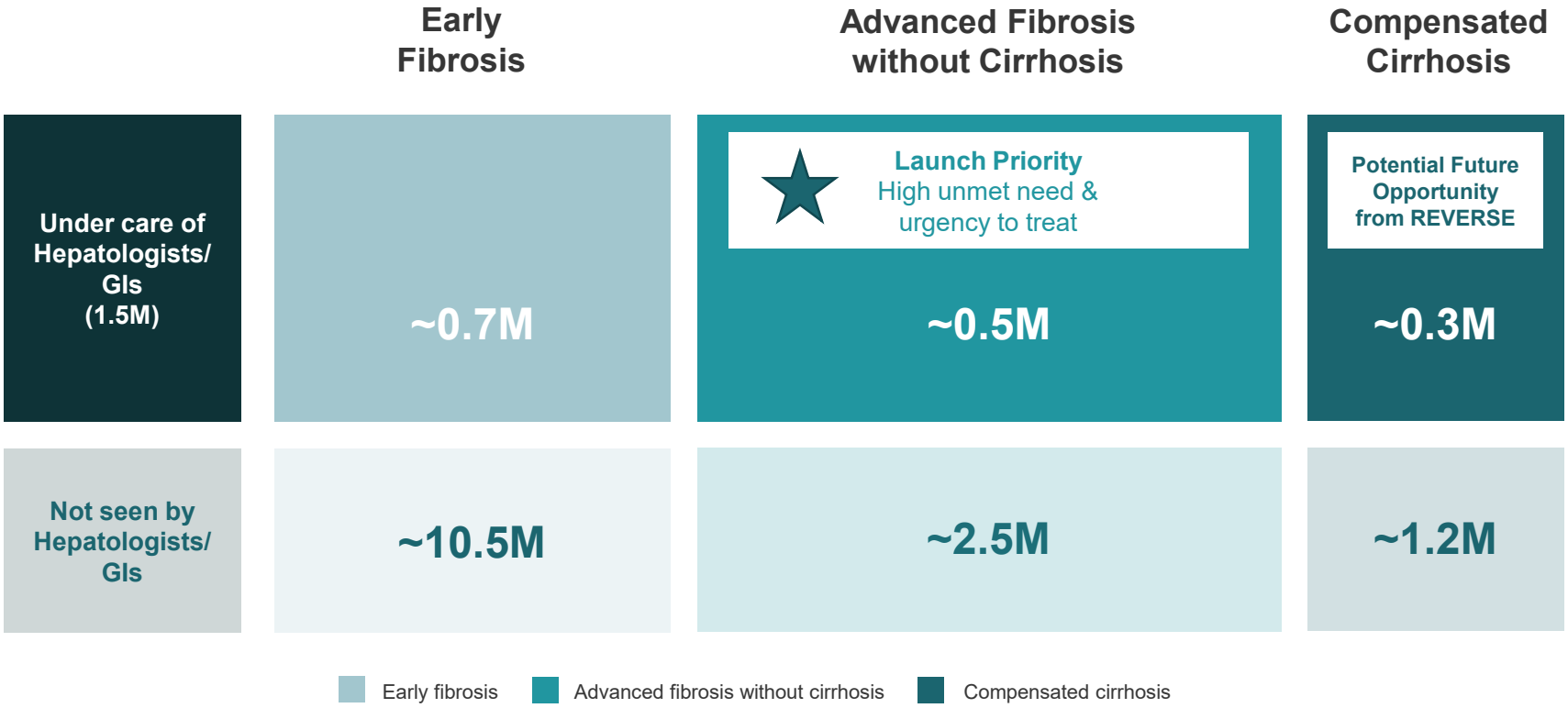
We Have a Focused NASH Launch Plan Based on Four Key Pillars



Launch strategy and commercial opportunity remains the same

Customer interaction model updated for COVID-19

Initial OCA Launch Will Focus on Subset of REGENERATE Population: Patients with Advanced Fibrosis Due to NASH Under Care of Hepatologists/Gastroenterologists



Reference: Estimates based upon Estes et al. *Hepatology* 2018;67(1)123-133; Adapted learnings from multiple studies and triangulated with medical claims & laboratory report data

Adjusting NASH Pre-Launch Activities in Response to COVID-19 Pandemic

- Payor discussions have continued virtually with minimal, if any, disruption
- Pulsing the physician community regularly through surveys and engagement
- Commercial efforts have become virtual, having some impact on education
- Assessing each geography and building the capability to assess our markets in real-time
- Flexible launch plan in place to address the dynamic market environment

Q1 2020 Financial Highlights

	Three Months Ended March 31,	
	2020	2019
Total revenue	$ 72.7M	$ 52.2M
Ocaliva net sales – U.S.	50.8M	38.0M
Ocaliva net sales – ex-U.S.	21.9M	13.8M
Licensing revenue	--	0.4M
GAAP operating expenses	156.1M	136.2M
Non-GAAP adjusted operating expenses (1)	142.9M	120.3M
Cost of sales	0.9M	0.6M
SG&A Expenses	98.6M	77.2M
R&D Expenses	56.7M	58.4M

(1) Refer to slide 10 for a reconciliation of non-GAAP adjusted operating expenses to total operating expenses

	3/31/20	12/31/19
Cash, cash equivalents, restricted cash & investment debt securities available for sale	$ 554.0M	$ 657.3M

Appendix

Non-GAAP Reconciliation

Reconciliation of Non-GAAP Adjusted Operating Expenses to Total Operating Expenses
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2020	**2019**
Total operating expenses	$ 156,097	$ 136,197
Adjustments:		
Stock-based compensation	12,473	14,897
Depreciation	764	996
Non-GAAP adjusted operating expenses	$ 142,860	$ 120,304

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.**

Indication

OCALIVA is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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). Patients who died due to liver-related complications generally had decompensated cirrhosis prior to treatment and were started on OCALIVA 5mg once daily, which is 7-fold greater than the once-weekly starting regimen in this population.

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.

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

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.

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 occurring in ≥5% of 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.