Alfasigma completes acquisition of Intercept Pharmaceuticals, Inc.

Bologna, Italy & Morristown, N.J., U.S. – November 8, 2023 – Alfasigma S.p.A. ("Alfasigma") and Intercept Pharmaceuticals, Inc. ("Intercept") announced today the completion of the acquisition of Intercept by Alfasigma through its wholly owned subsidiary Interstellar Acquisition Inc.

Following the completion of Alfasigma's successful tender offer to purchase all outstanding shares of common stock of Intercept for USD 19.00 per share, net to the seller thereof in cash, without interest, less any applicable withholding of taxes, Alfasigma acquired all remaining shares of common stock of Intercept through a merger pursuant to Section 251(h) of the General Corporation Law of the State of Delaware. As a result of the transaction, Intercept has become a wholly owned subsidiary of Alfasigma, and the common stock of Intercept has ceased to be traded on the NASDAQ Stock Market.

At the effective time of the merger, and subject to any perfected appraisal rights, all of the remaining shares of common stock of Intercept not purchased in the tender offer were converted into the right to receive the same USD 19.00 per share, net to the seller thereof in cash, without interest, less any applicable withholding of taxes.

With this transaction, Alfasigma adds Ocaliva to its portfolio, the only second-line treatment approved by the Food and Drug Administration (FDA) for primary biliary cholangitis (PBC), a progressive autoimmune disease affecting the liver. The deal will strengthen Alfasigma's pipeline, with the addition of a novel fixed-dose combination possibly establishing a new treatment paradigm for PBC.

Stefano Golinelli, Chairman of Alfasigma, commented: "At Alfasigma, the passion we have for Pharmaceuticals is in our DNA - and a driver for our ambitious international growth plans. Thus, we are delighted to announce the successful outcome of our tender offer for Intercept Pharmaceuticals, Inc. This transaction not only allows us to expand our portfolio with Ocaliva, a leading treatment against PBC, it is also central to strengthening our presence in the highly attractive US market. This deal represents an important opportunity for both companies, and certifies Alfasigma's commitment to our mission of improving people's health and quality of life".

Francesco Balestrieri, CEO of Alfasigma, added: "Today, we complete a transformational acquisition which strongly aligns with our strategy of building a solid presence in gastroenterology and hepatology, Alfasigma's core business areas. Intercept's leading product Ocaliva is the first and only FDA approved second line treatment for adult patients with PBC. Furthermore, Alfasigma will benefit from a strengthened innovation and R&D pipeline, including the addition of a novel fixed-dose combination of obeticholic acid and bezafibrate with potential to establish a new paradigm in the treatment of patients with PBC. This deal represents a significant progress in Alfasigma's international growth plan, and we look

forward to working with our colleagues at Intercept to provide innovative and effective treatment options for patients affected by severe liver diseases, and to growing our business in the United States".

Forward-looking statements

This press release may contain forward-looking statements by Alfasigma that involve risks and uncertainties and reflect Alfasigma's judgment as of the date of this press release. These forward-looking statements generally are identified by words such as "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Actual events or results may differ from Alfasigma's expectations due to risks and uncertainties inherent in Alfasigma's business, including, without limitation: litigation relating to the transaction; risks that the transaction disrupts the current plans and operations of Alfasigma or Intercept; the ability of Intercept to retain key personnel; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement of the transaction; Alfasigma's ability to achieve the growth prospects and synergies expected from the transaction, as well as delays, challenges and expenses associated with integrating Intercept with its existing businesses; legislative, regulatory and economic developments; and other risks described in Alfasigma's prior press releases. These forward-looking statements are made only as of the date hereof and Alfasigma disclaims any intent or obligation to update these forward looking statements after the date hereof, except as required by law.

About Alfasigma

Alfasigma is one of Italy's leading pharmaceutical companies with a strong international position. The Group has a worldwide presence in over 100 countries where about 3000 people work in research, development, production and distribution. In Italy, Alfasigma is a leader in the prescription products market where, in addition to its strong focus on gastro-intestinal products, it is present in several primary care therapeutic areas. It is popular with the consumer public for a number of nutraceuticals & food supplements that respond to different needs, and that are well known and deeply rooted in the Italian families experience. Its historical headquarters is in Bologna, to which is added Milan, while the production sites are: in Italy, in Pomezia (RM), Alanno (PE), Sermoneta (LT) and Trezzano Rosa (MI) and abroad in Tortosa in Spain and in Shreveport (Louisiana) in the United States. The R&D laboratories are in Pomezia and in the *Parco Scientifico Tecnologico Kilometro Rosso* in Bergamo. Alfasigma's mission is to improve people's health and quality of life by offering caregivers and healthcare personnel therapeutic solutions according to the highest standards of quality and safety.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare and serious liver diseases, including primary biliary cholangitis (PBC) and severe

alcohol-associated hepatitis (sAH). For more information, please visit www.interceptpharma.com or connect with the Company on Twitter and LinkedIn.

About Ocaliva® (obeticholic acid)
OCALIVA, a farnesoid X receptor (FXR) agonist, is indicated for the treatment of adult patients with primary biliary cholangitis (PBC)

- without cirrhosis or
- with compensated cirrhosis who do not have evidence of portal hypertension,

either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients 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.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- **Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis.**
- **OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension.**
- **Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension, or experience clinically significant hepatic adverse reactions while on treatment.**

Contraindications

OCALIVA is contraindicated in patients with:

- decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event

- compensated cirrhosis who have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)

- complete biliary obstruction

Warnings and Precautions

Hepatic Decompensation and Failure in PBC Patients with Cirrhosis
Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in PBC patients with cirrhosis, either compensated or decompensated. Among post-marketing cases reporting it, median time to hepatic decompensation (e.g., new onset ascites) was 4 months for patients with compensated cirrhosis; median time to a new decompensation event (e.g., hepatic encephalopathy) was 2.5 months for patients with decompensated cirrhosis.

Some of these cases occurred in patients with decompensated cirrhosis when they were treated with higher than the recommended dosage for that patient population; however, cases of hepatic decompensation and failure have continued to be reported in patients with decompensated cirrhosis even when they received the recommended dosage.

Hepatotoxicity was observed in the OCALIVA clinical trials. A dose-response relationship was observed for the occurrence of hepatic adverse reactions including jaundice, worsening ascites, and primary biliary cholangitis flare with dosages of OCALIVA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCALIVA in two 3-month, placebo-controlled clinical trials in patients with primarily early stage PBC.

Routinely monitor patients for progression of PBC, including hepatic adverse reactions, with laboratory and clinical assessments to determine whether drug discontinuation is needed. Closely monitor patients with compensated cirrhosis, concomitant hepatic disease (e.g., autoimmune hepatitis, alcoholic liver disease), and/or with severe intercurrent illness for new evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), or increases above the upper limit of normal in total bilirubin, direct bilirubin, or prothrombin time to determine whether drug discontinuation is needed. Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy), have compensated cirrhosis and develop evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia), experience clinically significant hepatic adverse reactions, or develop complete biliary obstruction. If severe intercurrent illness occurs, interrupt treatment with OCALIVA and monitor the patient's liver function. After resolution of the intercurrent illness, consider the potential risks and benefits of restarting OCALIVA treatment.

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 clinical 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 binding 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 (≥5%) are: 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 co-administering OCALIVA and warfarin.

- CYP1A2 Substrates with Narrow Therapeutic Index
  Obeticholic acid 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 co-administered 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 click here for Full Prescribing Information, including Boxed WARNING.
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.

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Contact Information:

Alfasigma S.p.A.

Corporate Communication
Simona Gelpi simona.gelpi@alfasigma.com
Gea Gardini gea.gardini@alfasigma.com
www.alfasigma.it

iCorporate
Luca Bolzoni luca.bolzoni@icorporate.it +39.347.6498627
Alberto Colombini alberto.colombini@icorporate.it + 39.335.1222631

Tancredi Intelligent Communication
Emma Valgimigli emma@tancredigroup.com
Emma Hodges hemma@tancredigroup.com
alfasigma@tancredigroup.com
+44 203 434 2330