PRESS RELEASE

Ipsen to present new Bylvay® (odevixibat) data at annual ESPGHAN congress, showcasing commitment to furthering treatment for rare cholestatic liver diseases

- Six abstracts to be presented demonstrating efficacy and tolerability of investigational Bylvay in select cholestatic liver diseases
- New data emphasizes the consistent benefit of Bylvay as an investigational drug in Alagille syndrome and an approved medicine in PFIC, with evidence of rapid, sustained, and significant improvements in pruritus and sleep, and reductions in serum bile acids (sBAs)
- Further data shows evidence of disease modification with longer-term native liver survival in PFIC patients

PARIS, FRANCE, 17 May 2023 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that new data from its growing rare disease portfolio will be presented at the 55th Annual Meeting of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), taking place in Vienna, Austria 17-20 May 2023. The six data presentations, made up of four oral, one poster, and one e-poster, consistently demonstrate the efficacy and tolerability of investigational Bylvay® (odevixibat) for the potential treatment of cholestatic liver disease patients with Alagille syndrome (ALGS) and the treatment of patients with progressive familial intrahepatic cholestasis (PFIC).

“This new data continues to build evidence in support of the potential impact Bylvay can have on those living with cholestatic liver diseases, such as ALGS and PFIC, where we have investigational findings of significant improvements in pruritus and sleep, and reductions in sBAs. In PFIC, longer native liver survival suggests there may be a disease-modifying benefit to this treatment,” said Dr. Howard Mayer, Executive Vice President and Head of Research and Development, Ipsen.

Highlights from key investigational data on Bylvay to be presented during the 55th Annual Meeting of ESPGHAN include:

- Additional data from the ASSERT Phase III and ASSERT-EXT studies showing Bylvay demonstrated rapid, sustained, and highly significant improvements in pruritus, reductions in sBAs, and improvements in sleep in patients with Alagille syndrome.
- Findings exploring Bylvay usage in association with PFIC patients keeping their native livers for up to three years – additional data from the PEDFIC 1 and PEDFIC 2 studies.
- Discoveries from a study with real-world data exploring diarrhea and quality of life issues in PFIC1 patients post liver transplant and the impact of Bylvay usage.

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Presentations

Oral (Abstract #328): Efficacy and Safety of Odevixibat in Patients with Alagille Syndrome: Top-line Results from Assert, A Phase III, Double-blind, Randomized, Placebo-controlled Study
Presenter: Dr. Nadia Ovchinsky, Professor of Pediatrics, Hassenfeld Children's Hospital at NYU Langone, NYU Grossman School of Medicine
Session Title: Plenary Session: Highest Scoring Abstracts
Date & Time: 05/18 | 11:45-13:15 | Hall A

Oral (Abstract #361): Efficacy and Safety of Odevixibat in Patients with Alagille Syndrome: Interim Results from The Open-label, Phase III Assert-EXT Study
Presenter: Dr. Nadia Ovchinsky, Professor of Pediatrics, Hassenfeld Children's Hospital at NYU Langone, NYU Grossman School of Medicine
Session Title: Parallel Session Hepatology – Abstract Session 02
Date & Time: 5/19 | 12-13 | Hall G

Oral (Abstract #369): Native Liver Survival in Odevixibat Serum Bile Acid Responders: Data from the PEDFIC Studies in Patients with Progressive Familial Intrahepatic Cholestasis
Presenter: Prof. Richard J. Thompson, Molecular Hepatology, Institute of Liver Studies, King's College London
Session Title: Plenary Session: Highest Scoring Abstracts
Date & Time: 5/19 | 8:30-10 | Hall A

Oral (Abstract #179): Odevixibat Treatment Induces Biliary Bile Acid Secretion in Responsive Patients with Bile Export Pump Deficiency (PFIC2)
Presenter: Dr. Mark Nomden, Department of Pediatric Surgery, Department of Pediatrics, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands
Session Title: Parallel Session: Hepatology – Abstract Session 02
Date & Time: 5/19 | 12-13 | Hall G

Poster (Abstract #579): Odevixibat Treatment in a Patient with Undefined Cholestasis and No Unified Genetic Diagnosis: A Case Report
Presenter: Dr. Tassos Grammatikopoulos, Institute of Liver Studies, King's College London
Session Title: Paper Poster Viewing
Date & Time: Available for viewing during Exhibition opening hours onsite

E-Poster (Abstract #805): Odevixibat Therapy After Liver Transplantation in Patients with FIC1-Deficient Progressive Familial Intrahepatic Cholestasis and Severe Diarrhea: A Retrospective Case Series
Presenter: Dr. Georg-Friedrich Vogel, Department of Paediatrics I and Institute of Cell Biology, Medical University of Innsbruck
Session Title: E-Poster Presentations: HEP - Transplantation
Date & Time: 5/20 | 11:50-12:40 | E-Poster Station 1

About the Phase III PEDFIC & ASSERT Studies
The PEDFIC trials represent the largest studies ever completed in children with PFIC, or progressive familial intrahepatic cholestasis, a rare genetic disorder that causes progressive, life-threatening liver disease. PEDFIC 1 was a randomized, double-blind, placebo-controlled Phase III trial that evaluated the efficacy and tolerability of Bylvay in reducing pruritus and serum bile acids (sBAs) in children with PFIC, and PEDFIC 2 is a long-term, open-label Phase III extension study. Patients with PFIC have impaired bile flow, or cholestasis, and the resulting bile build-up in liver cells causes liver disease and symptoms, such as intense itching, poor sleep, delayed growth, and diminished quality of life. The harmful impacts of the disease

extend to parents and caregivers, as the 2022 multinational PICTURE study revealed that PFIC negatively affects caregivers' quality of life, relationships, and career prospects.

ASSERT is a gold standard, prospective intervention trial with 32 sites across North America, Europe, Middle East, and Asia Pacific. The double-blind, randomized, placebo-controlled trial was designed to evaluate the safety and efficacy of 120 µg /kg/day Bylvay for 24 weeks in relieving pruritus in patients with ALGS. Key secondary endpoints measure serum bile acid levels and safety and tolerability. The trial enrolled patients aged 0 to 17 years of age with a genetically confirmed diagnosis of ALGS. In the primary analysis, the study met the primary endpoint showing statistically significant reduction in pruritus as measured by the PRUCISION Observer-Reported Outcome scratching score (0-4 point scale), from baseline at month 6 (weeks 21 to 24), compared to the placebo arm (p=0.002). Over 90% of patients were pruritus responders during the study, as defined as at least a 1-point drop at any time point. The study also met the key secondary endpoint showing a statistically significant reduction in serum bile acid concentration from baseline to the average of weeks 20 and 24 (compared to the placebo arm p=0.001). Statistically significant improvements in multiple sleep parameters were observed as early as week 1-4 compared to patients on placebo with continued improvement through week 24. In the study, there were no patient discontinuations. Bylvay was well tolerated, with an overall adverse event incidence similar to placebo and a low incidence of drug-related diarrhea (11.4% vs. 5.9% placebo).

About Bylvay (odevixibat)
A potent, once-daily, non-systemic ileal bile acid transport inhibitor (IBATi), Bylvay has minimal systemic exposure and acts locally in the small intestine. It is approved in the U.S. for the treatment of pruritus in patients three months of age and older in all types of PFIC, where it has orphan exclusivity. Bylvay was first launched as a treatment option for patients with PFIC in the U.S. in 2021, where it is supported by a program designed to assist with access to treatment and patient support. Bylvay is also approved in the E.U. for the treatment of PFIC in patients aged six months or older. It has launched in over nine countries and has secured public reimbursement across several major markets including Germany, Italy, the U.K., France and Belgium.

View full E.U. prescribing information here: **Bylvay, INN-odevixibat (europa.eu)**
View full U.S. prescribing information here: **label (fda.gov)**

About Ipsen
Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With total sales of €3.0bn in FY 2022, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, the Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has around 5,000 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

On March 3rd, 2023, Ipsen completed the acquisition of Albireo Pharma Inc, a leading innovator in bile-acid modulators to treat rare liver conditions, and the marketing authorization holder of Bylvay.

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Ipsen's forward-looking statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and

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