

patients

The acquisition of Albireo

9 January 2023



Focus. Together.
For patients & society

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# **Speakers**

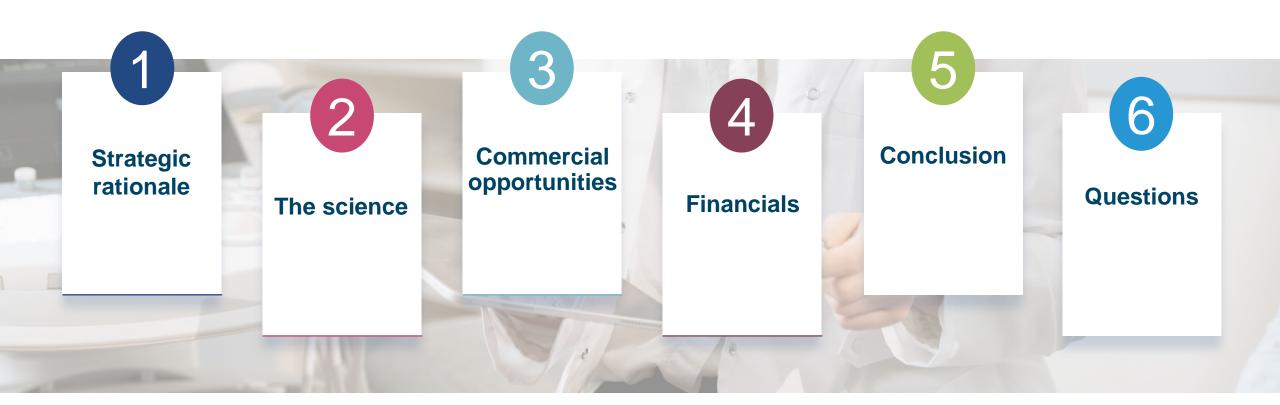








# Agenda







# The focus on three therapy areas

**Our vision** 

To be a leading global, mid-sized biopharmaceutical company with a focus on transformative medicines in Oncology, Rare Disease & Neuroscience







### Albireo: expanding Ipsen's scope in Rare Disease

Perfectly aligned to the external-innovation strategy

#### Global rights<sup>1</sup>

 Bylvay: a potentially best-in-class rare liver-disease medicine approved in the U.S. & E.U.



#### Strategic fit

Expanding the pipeline
 & portfolio in rare liver diseases

#### **◀** Multiple opportunities

- Bylvay: progressive familial intrahepatic cholestasis, Alagille syndrome, biliary atresia
- Early-stage pipeline: adult cholestatic liver diseases

#### **← Financial impact**

- Sizeable peak sales ~\$800m
- Accretive to core operating income from 2025





### Pediatric cholestatic liver diseases

#### Bile acids

Chemicals made by the liver from cholesterol

Transported from the liver to the intestines

Help to absorb fats, fat soluble vitamins & nutrients for growth and development

95% recycled back to the liver & reused

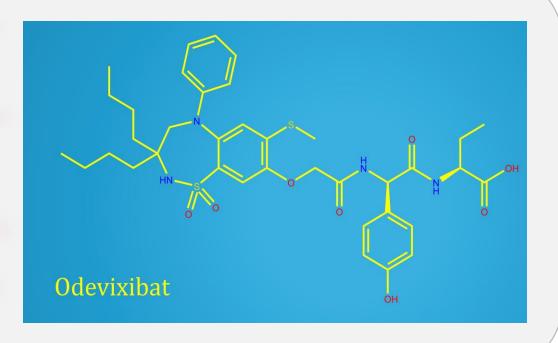
#### Failure of draining bile from liver to intestine

Caused by defects in the intrahepatic production of bile, transmembrane transport of bile, or mechanical obstruction to bile flow





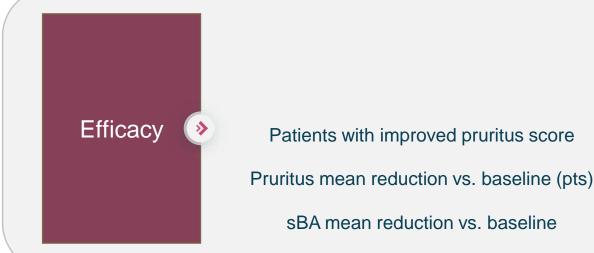
- Bylvay is a potent, oral non-systemic iBAT inhibitor that acts locally in the gut
- By blocking the actions of iBAT, Bylvay reduces the reabsorption of bile acids from the terminal ileum and their return to the liver
- Reducing the build-up of bile acids (cholestasis) will prevent progressive liver damage leading to cirrhosis, end-stage liver disease and need for liver transplant





### PEDFIC 1 & 2 Phase III trials

### Bylvay demonstrated efficacy across multiple PFIC types



Patients with improved pruritus score

sBA mean reduction vs. baseline

24 weeks			
PFIC1	PFIC2		
N=12	N=30		
95%	80%		
-1.13	-1.13		
-31.7 µmol/L	-120.8 µmol/L		

54 weeks				
PFIC3	PFIC6			
N=5	N=1			
80%	100%			
-1.6	-1.8			
-91	-78			
μmol/L	µmol/L			

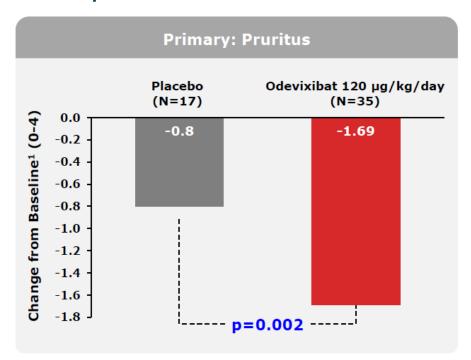


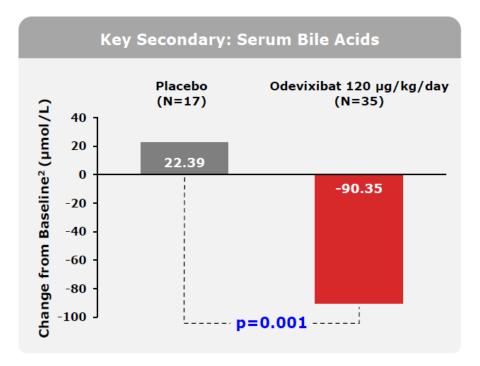
- Bylvay was generally well tolerated
- Most TEAEs were mild to moderate in severity; no serious TEAEs, discontinuation or death



# **ASSERT: Alagille syndrome**

#### Double-blind placebo-controlled Phase III trial





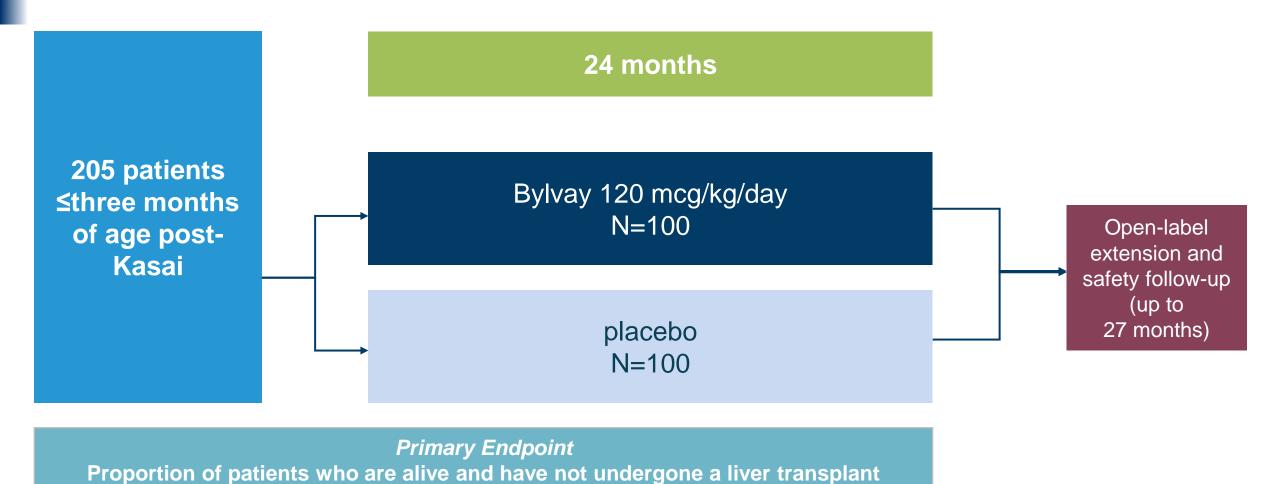
24-week treatment with Bylvay led to highly statistically significant improvement in pruritus severity and reduction in serum bile acid levels compared to placebo

Bylvay: well tolerated over 24 weeks, no discontinuations



# **BOLD:** biliary atresia

Double-blind placebo-controlled Phase III trial







# Bylvay roadmap & commercial assumptions

	Developm	Development status iBAT-eligible population		e population		
Indication	Phase III Approved	U.S.				
indication		Incidence (live births/year)	Prevalence (at time of launch)			
PFIC	Approved		~30	~500	Eligible PFIC patients include incident & prevalent patients < 17-yrs that have pruritus and have not had liver transplant	
ALGS	Submitted		~90	~1,300	Eligible ALGS patients include incident & prevalent patients < 17-yrs that have cholestasis, pruritus and have not had liver transplant	
ВА	Ongoing		~130	~600	Eligible BA patients will mainly be incident patients post- Kasai; lower iBAT eligibility in the prevalent BA patients due to age, Kasai outcomes & transplant rates	

PFIC: progressive familial intrahepatic cholestasis; ALGS: Alagille syndrome; BA: biliary atresia; iBAT: ileal bile-acid transporter.

Eligible patients: a literature review analyzing over 60 sources has been performed for the epidemiology estimation. Only non-liver-transplanted patients are shown in the prevalence population, which has been estimated based on native liver survival curves in each indication (sources: literature review and extensive market research). IBAT-eligibility cuts are included for each indication at steady state; include age, rate of pruritus in PFIC, rate of cholestasis and pruritus in ALGS, Kasai rate and Kasai success in biliary atresia (differs between newly-diagnosed incident and older prevalent population) (sources: literature review and extensive market research).

Patient numbers are shown at expected launch year for each indication.



# **Commercial opportunities: Bylvay**



- Limited number of competitors:
   Bylvay leading in PFIC and biliary atresia with most advanced program for biliary atresia
- Reimbursement secured across the E.U. & favorable coverage in the U.S. in PFIC
- Data from ASSERT in ALGS support regulatory submissions



- Global rights<sup>2</sup>: leveraging Ipsen's infrastructure to accelerate sales of an approved medicine
- Convenient dosing: once per day capsules
- Good patent life<sup>1</sup> in the U.S. and E.U.

#### Peak-sales potential: around \$800m<sup>3</sup>





### **Financials**

- Ipsen to initiate a tender offer to acquire all outstanding shares¹ of Albireo
- Offer price at \$42.00 per share in cash at closing, equating to \$952m

  Additional contingent-value payment of \$10.00 per share, based on a potential U.S. regulatory approval of Bylvay in biliary atresia, equating to \$244m
- Transaction expected to close by the end of Q1 2023, subject to the satisfaction of all closing conditions, including regulatory

Accretive to core operating income from 2025





### Conclusion

Further execution of the external-innovation strategy

- Expanding the scope in Rare Disease
- Albireo: a leading innovator in bile-acid modulators for rare liver diseases
- An on-market and potentially best-in-class medicine
- Significant commercial opportunities
- An excellent strategic fit





# APPENDIX



# **Bylvay development in three Rare Disease indications**

		PFIC	Alagille syndrome	Biliary atresia
Presentation	>	Age ~1-2 years, cholestasis, pruritus, jaundice	Age ~4-12 months, multiple symptoms	Age ~2 weeks - 3 months, failure to strive, acholic stools, jaundice
Cause or genetic disorder	<b>&gt;</b>	Multiple genes, bile-acid build-up in the liver	Autosomal dominant genes, paucity of bile ducts, bile-acid build-up in the liver	Absence of bile ducts, no bile-acid flow, fatal without Kasai surgery
Disease progression	<b>&gt;</b>	Serum bile-acid elevation inflammation, fibrosis, cirrhosis, death	Serum bile-acid elevation, multiple organ impact	Serum bile-acid elevation post-Kasai correlates with lower native liver survival
Treatment & survival	*	Almost no patients survive beyond age 20 without surgical diversion or liver transplant	Many patients may need surgical diversion or liver transplant. Disease can stabilize	Kasai life-saving surgery ~50% of patients have liver transplant in first two years





### **Investor Relations**







