

**Oddo BHF Forum** 2023

Efficiencies to enable targeted investment &

> Focus. Together. For patients & society

*<b>FIPSEN* 

Innovation for patient care

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- This presentation includes only summary information and does not purport to be comprehensive. Forward-looking statements, targets and estimates contained herein are for illustrative purposes only and are based on management's 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 in the summary information. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably given that a new medicine can appear to be promising at a preparatory stage of development or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons. Ipsen must deal with or may have to deal with competition from generic medicines that may result in market-share losses, which could affect its level of growth in sales or profitability. The Company expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this presentation to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law.
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- Ipsen operates in certain geographical regions whose governmental finances, local currencies or inflation rates could erode the local competitiveness of Ipsen's medicines relative to competitors operating in local currency, and/or could be detrimental to Ipsen's margins in those regions where Ipsen's sales are billed in local currencies.
- In a number of countries, Ipsen markets its medicines via distributors or agents; some of these partners' financial strengths could be impacted by changing economic or market conditions, potentially subjecting Ipsen to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by changing economic or market conditions, and where Ipsen sells its medicines directly to hospitals, Ipsen could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.
- Ipsen also faces various risks and uncertainties inherent to its activities identified under the caption 'Risk Factors' in the Company's Universal Registration Document.
- 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.







# The Ipsen investment case





<sup>1.</sup> As at the end of H1 2022 and reflected the subsequent closing of the Consumer HealthCare and Epizyme transactions. Based on net debt below 2.0x 12-months' rolling EBITDA.

# A future focused on Specialty Care

Consumer HealthCare divested last year







# September year to date 2022: sales increased by 9.5%

### Growth platforms up by 20.8%





RCC: renal cell carcinoma. Growth rates are at constant exchange rates.

# A strong platform for sustainable growth





# **Consistent execution of the external-innovation strategy**

16 assets in the last 18 months





IO: immuno-oncology; SNAs: spherical nucleic acids; BCH: Boston Children's Hospital; UOS: University of Stockholm; BoNT/X: a novel botulinum toxin serotype.

# Expanding the portfolio and pipeline

Acquisition of Epizyme





#### **Tazverik**

- U.S. on-market compound with good patent life leveraging lpsen's existing in-market presence
- Compelling clinical data at ASCO with potential for new indications
- \$150-250m sales based on current indication and \$800m of peak sales upon anticipated regulatory approval in 2L+ FL

#### **Other clinical & pre-clinical assets**

- First-in-class oral SETD2 inhibitor and portfolio of preclinical programs focused on epigenetic targets
- Complementing preclinical pipeline

Accelerating growth: focus on fast integration preparation



### **Building a high-value, sustainable pipeline**



Information shown as at the end of September 2022. IPN60210: formerly EZM0414; R/R: relapsed/refractory; DLBCL: diffuse large B-cell lymphoma; fidrisertib: formerly IPN60130; FL: follicular lymphoma; mCRPC: metastatic castration-resistant prostate cancer; FOP: fibrodysplasia ossificans progressiva; PD-LID: Parkinson's disease - levodopa-induced dyskinesia; 2L: second line; NSCLC: non-small cell lung cancer; 1L: first line; PDAC: pancreatic ductal adenocarcinoma; R<sup>2</sup>: lenalidomide + rituximab; PBC: primary biliary cholangitis.



# **Pipeline: H1 major milestones**

#### Palovarotene: FOP

Regulatory decisions<sup>1</sup> - U.S., E.U.

Mesdopetam: PD-LID

Phase IIb data readout

Elafibranor: 2L PBC

Phase III data readout





<sup>1.</sup> Assumed timeline. **FOP**: fibrodysplasia ossificans progressiva; **PD-LID**: Parkinson's disease - levodopa-induced dyskinesia; **2L**: second line. **PBC**: primary biliary cholangitis.

# Conclusion

### Successfully executing on our strategy







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# Oncology

### Key ongoing clinical-trial highlights

Trial	Population	Patients	Design	Primary endpoint(s)	Status
Cabometyx CONTACT-01 Phase III NCT04471428	2L NSCLC	366	Docetaxel or Cabometyx + atezolizumab	OS	Primary endpoint not met
Cabometyx CONTACT-02 Phase III NCT04446117	2L mCRPC	580	Second novel hormonal therapy (abiraterone and prednisone or enzalutamide) or Cabometyx + atezolizumab	OS, PFS	Recruiting
Onivyde NAPOLI-3 Phase III NCT04083235	1L PDAC	770	Nab-paclitaxel + gemcitabine or Onivyde + 5-FU/LV + oxaliplatin	OS	Primary endpoint met



2L: second line; NSCLC: non-small cell lung cancer; OS: overall survival; 1L: first line; PDAC: pancreatic ductal adenocarcinoma; mCRPC: metastatic castration-resistant prostate cancer; PFS: progression-free survival.

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## Oncology

### Key ongoing clinical-trial highlights

Trial	Population	Patients	Design	Primary endpoint(s)	Status
Tazverik SYMPHONY-1 Phase III NCT04224493	R/R FL: following at least one prior systemic chemotherapy, immunotherapy, or chemoimmunotherapy	540	Placebo + R <sup>2</sup> or Tazverik + R <sup>2</sup>	PFS	Recruiting
Tazverik ARIA Phase Ib/II NCT05205252	R/R hematologic malignancies	156	Tazverik in various combinations: multi-cohort	Phase Ib: dosing, safety Phase II: ORR	Recruiting
IPN60210 Phase I/Ib NCT05121103	R/R multiple myeloma and R/R DLBCL	96	IPN60210	Treatment-emergent adverse events, dosing and ORR	Recruiting
Tazverik CELLO-1 Phase Ib/II NCT04179864	mCRPC: patients who have not received chemotherapy	104	Enzalutamide + Tazverik or abiraterone/prednisone + Tazverik	Phase Ib: dosing, safety Phase II: rPFS Tazverik + enzalutamide	Recruiting
<b>R/R</b> : relapsed/refractory; <b>FL</b> : follicular lymphoma; <b>R</b> <sup>2</sup> : lenalidomide + rituximab; <b>PFS</b> : progression-free survival;					



R/R: relapsed/refractory; FL: follicular lymphoma; R<sup>2</sup>: lenalidomide + rituximab; PFS: progression-free surviva ORR: objective response rate; IPN60210: formerly EZM0414; DLBCL: diffuse large B-cell lymphoma; mCRPC: metastatic castration-resistant prostate cancer; rPFS: radiographic progression-free survival.

### **Rare Disease**

### Key ongoing clinical-trial highlights

Trial	Population	Patients	Design	Primary endpoint(s)	Status
Palovarotene MOVE Phase III NCT03312634	FOP (chronic)	107	Palovarotene - 5mg QD and upon flare-up, 20mg QD for 28 days, followed by 10mg for 56 days	Annualized change in new HO volume	Regulatory decisions anticipated: U.S., E.U H1 2023 <sup>1</sup>
Fidrisertib FALKON Phase II NCT05039515	FOP (chronic)	~90	Placebo or two dosing regimens of fidrisertib	Annualized change in new HO volume and safety	First patient commenced dosing Q1 2022
Elafibranor ELATIVE Phase III NCT04526665	2L PBC	161	Placebo or elafibranor	Response to treatment defined as ALP < 1.67 x ULN and total bilirubin ≤ ULN and ALP decrease ≥ 15 percent	Recruitment completed Data anticipated H1 2023





fidrisertib: formerly IPN60130; ALP: alkaline phosphatase; ULN: upper limit normal.

### **Neuroscience**

### Key ongoing clinical-trial highlights

Trial	Population	Patients	Design	Primary endpoint	Status
Mesdopetam Phase IIb NCT04435431	Levodopa-induced dyskinesia in Parkinson's disease	156	Mesdopetam or placebo	Change in average daily hours of ON-time <sup>1</sup> without troublesome dyskinesia	Recruitment completed Data anticipated H1 2023
IPN59011 Ax LONG-SET Phase I/II NCT04736745	Moderate to severe upper facial lines	424	Dose escalation and dose finding versus Dysport or placebo	Safety	Recruiting
IPN10200 Ax LANTIC Phase I/II NCT04821089	Moderate to severe upper facial lines	424	Dose escalation and dose finding versus Dysport or placebo	Safety	Recruiting
IPN10200 Tx LANTIMA Phase I/II NCT04752774	Adult patients with upper limb spasticity	209	Dose escalation and dose finding versus Dysport or placebo	Safety	Recruiting



1. Good 'ON-time' is the time that people living with Parkinson's disease experience improved Parkinsonian symptoms and no dyskinesia.







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