**Bring**

The full potential of our innovative medicines to patients

**Build**

A high-value sustainable pipeline

**Deliver**

Efficiencies to enable targeted investment & growth

**Boost**

A culture of collaboration & excellence

# Q1 2023 sales update

27 April 2023

IPSEN
Innovation for patient care

***Focus. Together.***
***For patients & society***

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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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- The implementation of the strategy has to be submitted to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation.
- In those countries in which public or private-health cover is provided, Ipsen is dependent on prices set for medicines, pricing and reimbursement-regime reforms and is vulnerable to the potential withdrawal of certain medicines from the list of reimbursable medicines by governments, and the relevant regulatory authorities in its locations.
- 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.

# Speakers

**David Loew**
Chief Executive Officer

**For Q&A**
**Aymeric Le Chatelier**
Chief Financial Officer

# Highlights

*Consistent strong delivery on the strategic roadmap*

## Total sales

- Q1 sales growth of 5.7%
- Growth platforms, up by 14.7%, led by Dysport & Cabometyx
- Contribution from newly acquired medicines

## Albireo

- Albireo acquisition completed in March
- One month of Bylvay sales in Q1

## Pipeline update

- Onivyde 1L PDAC
  - Full Phase III data presented
- Forthcoming PDUFA dates:
  - 15 June: Bylvay (Alagille syndrome)
  - 16 August: palovarotene (FOP)

## 2023 guidance confirmed

- Total-sales growth greater than 4.0%[1]
- Core operating margin around 30%[2]

All growth rates are at constant exchange rates.

1. Excludes adverse impact of around 2% from currencies based on the average level of exchange rates in Q1 2023.
2. Excludes any potential impact of incremental investments from external-innovation transactions.

**Growth platforms**: Dysport, Decapeptyl, Cabometyx and Onivyde; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma; **PDUFA**: Prescription Drug User Fee Act; **FOP**: fibrodysplasia ossificans progressiva.

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# Sales highlights

*Growth platforms outweighing the gradual decline of Somatuline*

| | Q1 2023 | | |
|---|---|---|---|
| | €m | change | % of total sales |
| Dysport | 155 | 25.2% | 21% |
| Cabometyx | 130 | 31.0% | 18% |
| Decapeptyl | 130 | 0.8% | 17% |
| Onivyde | 37 | -12.3% | 5% |
| **Growth platforms** | **452** | **14.7%** | **61%** |
| Tazverik | 9 | n/a | 1% |
| Bylvay | 5 | n/a | 1% |
| **Newly acquired medicines** | **14** | **n/a** | **2%** |
| **Somatuline** | **263** | **-9.8%** | **35%** |
| Others | 13 | -20.8% | 2% |
| **Total Sales** | **742** | **5.7%** | **100%** |

All growth rates are at constant exchange rates.

# Strong performance from growth platforms of +14.7%

**Dysport®** Clostridium botulinum Type A Toxin

**+25.2%**

Further strong performance in aesthetics in Ipsen & partner markets

Continued therapeutics growth across the regions

**CABOMETYX®** (cabozantinib) tablets

**+31.0%**

Further launches of the combo in first-line renal cell carcinoma

Momentum in second-line renal cell carcinoma monotherapy

**Decapeptyl®** triptorelin

**+0.8%**

Continued market-share uptakes in a number of geographies

Reduced sales in China reflected COVID-related stocking in Q1 2022

**onivyde®** (irinotecan liposome injection)

**-12.3%**

Performance reflected shipment phasing to ex-U.S. partner

Solid underlying growth in the U.S.

All growth rates are at constant exchange rates.

# Somatuline sales continuing to decline gradually

*Q1 2023: -9.8%*

## NORTH AMERICA

*58% of Somatuline sales*

**-2.7%**

Favorable wholesaler-inventory comparison to Q1 2022

Solid volume-demand growth

Ongoing adverse pricing

## EUROPE

*30% of Somatuline sales*

**-25.7%**

Generic competition across more geographies (France, Spain & Italy)

Impacts through a combination of volume & pricing

## REST OF WORLD

*12% of Somatuline sales*

**+7.3%**

Solid underlying growth

Several geographies performing well, including Latin America

All growth rates are at constant exchange rates.
In this presentation, Europe is defined as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

# Recently acquired medicines

Bylvay™ (odevixibat)

**€5m**

Momentum in
North America and Europe

An increasing
number of treated PFIC patients

Anticipated regulatory decisions this year in Alagille syndrome

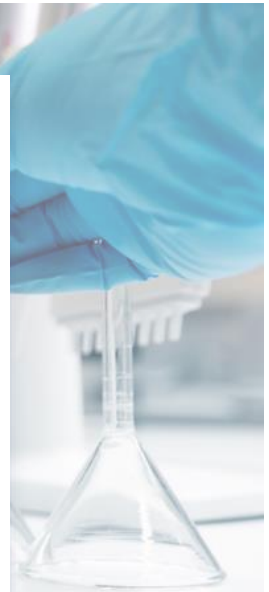
TAZVERIK® (tazemetostat) tablets 200 mg

**€9m**

Growth of 21% in commercial sales[1]

Focus on all-comers, new-patient starts & duration of therapy

NCCN guidelines recently updated



All growth rates are at constant exchange rates. [1.] Reference to Epizyme's published Q1 2022 performance.
**PFIC**: progressive familial intrahepatic cholestasis; **NCCN**: National Comprehensive Cancer Network.

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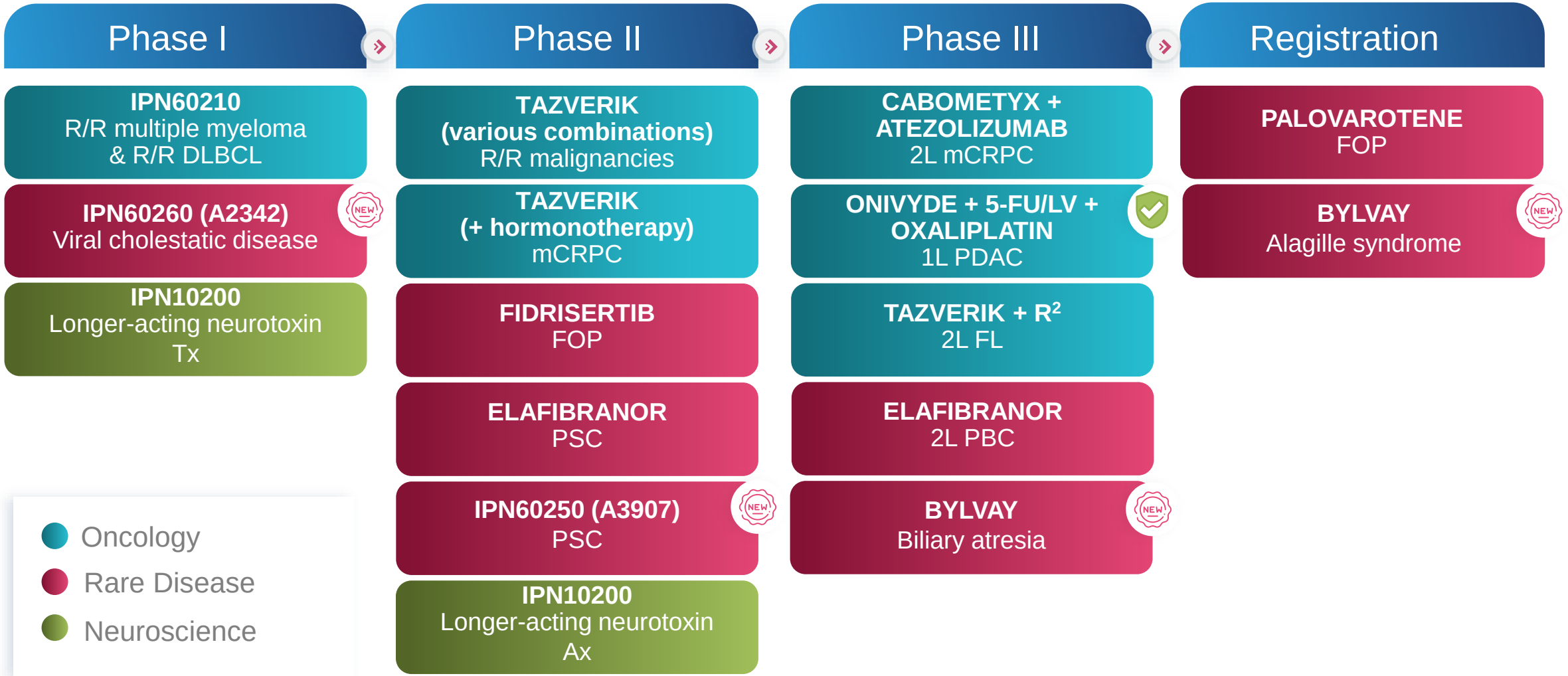
# Building a high-value, sustainable pipeline




Information shown as at the end of March 2023. **R/R**: relapsed/refractory; **DLBCL**: diffuse large B-cell lymphoma; **Tx**: therapeutics; **mCRPC**: metastatic castration-resistant prostate cancer; **FOP**: fibrodysplasia ossificans progressiva; **PSC**: primary sclerosing cholangitis; **Ax**: aesthetics; **2L**: second line; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma; **R²**: lenalidomide + rituximab; **FL**: follicular lymphoma; **PBC**: primary biliary cholangitis.

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# Pipeline: near-term major milestones

## Bylvay: Alagille syndrome

PDUFA date: 15 June 2023 (U.S.)
Regulatory decision: H2 2023 (E.U.)

## Onivyde: 1L PDAC

Regulatory submission (U.S.): H1 2023

## Elafibranor: 2L PBC

Phase III data readout: end of H1 2023

## Palovarotene: FOP

PDUFA date: 16 August 2023 (U.S.)
Re-examination of CHMP opinion requested (E.U.)[1]

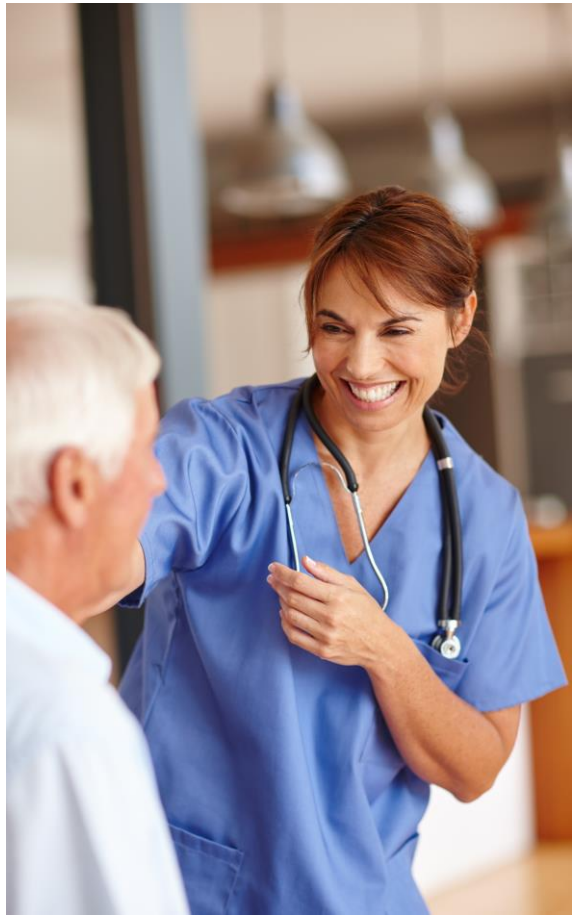
## Cabometyx + atezolizumab: 2L mCRPC

Phase III data readout (PFS): H2 2023

[1.] Negative opinion published in January 2023. **PDUFA**: Prescription Drug User Fee Act; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma; **2L**: second line; **PBC**: primary biliary cholangitis; **FOP**: fibrodysplasia ossificans progressiva; **CHMP**: the Committee for Medicinal Products for Human Use, the European Medicines Agency's committee responsible for human medicines; **mCRPC**: metastatic castration-resistant prostate cancer; **PFS**: progression-free survival.

# Conclusion

*Consistent strong delivery on the strategic roadmap*



**A strong Q1 sales performance**

*Double-digit increase in the growth platforms*

*Financial guidance for 2023 confirmed*

**Expanding the scope in Rare Disease**

*The integration of Albireo*

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

*Several near-term milestones*

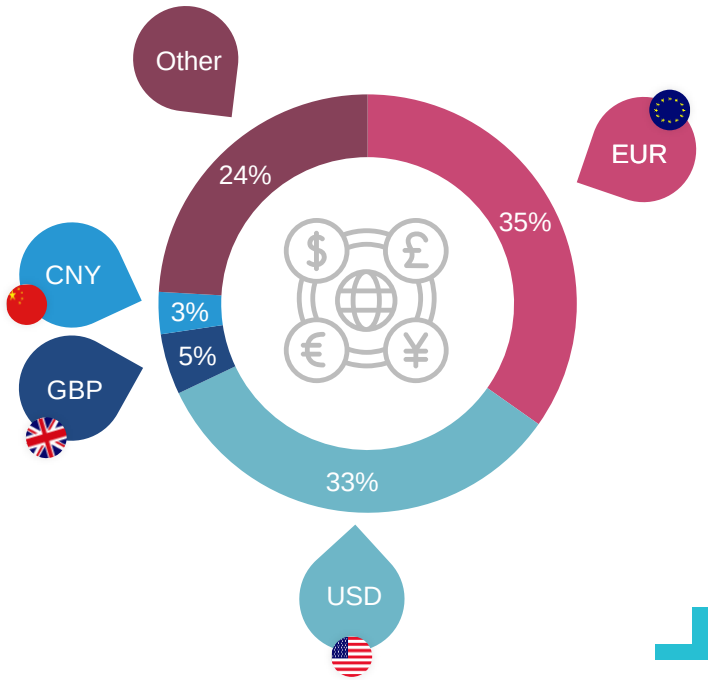
*External-innovation focus continues*

# QUESTIONS

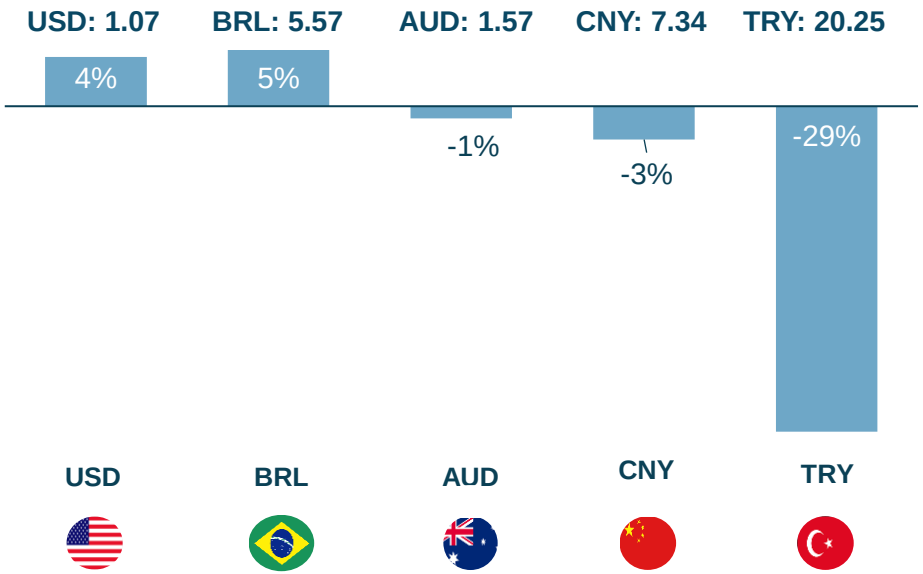
# APPENDIX

# Q1 2023 total sales: favorable 2.1% impact of fx rates

## Q1 2023 sales by currency




## Average rate changes
(Q1 2023 vs. Q1 2022)



# Oncology

*Key ongoing clinical-trial highlights*

| TRIAL | POPULATION | PATIENTS | DESIGN | PRIMARY ENDPOINT(S) | STATUS |
|---|---|---|---|---|---|
| **Cabometyx CONTACT-02** Phase III NCT04446117 | 2L mCRPC | 580 | Second novel hormonal therapy (abiraterone & prednisone or enzalutamide) or Cabometyx + atezolizumab | OS, PFS | Recruiting[1] PFS data anticipated H2 2023 |
| **Onivyde NAPOLI-3** Phase III NCT04083235 | 1L PDAC | 770 | Nab-paclitaxel + gemcitabine or Onivyde + 5-FU/LV + oxaliplatin | OS | Primary endpoint met |
| **Tazverik SYMPHONY-1** Phase III NCT04224493 | R/R FL: following at least one prior systemic chemotherapy, immunotherapy, or chemo-immunotherapy | 540 | Placebo + $R^2$ or Tazverik + $R^2$ | PFS | Recruiting |

1. Recruitment is anticipated to complete in H2 2023. **2L**: second line; **mCRPC**: metastatic castration-resistant prostate cancer; **OS**: overall survival; **PFS**: progression-free survival; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma; **R/R**: relapsed/refractory; **FL**: follicular lymphoma**;** $R^2$: lenalidomide + rituximab.

# Oncology

*Key ongoing clinical-trial highlights*

| TRIAL | POPULATION | PATIENTS | DESIGN | PRIMARY ENDPOINT(S) | STATUS |
|---|---|---|---|---|---|
| **Tazverik ARIA**<br>Phase Ib/II<br>NCT05205252 | R/R hematologic malignancies | 156 | Tazverik in various combinations: multi-cohort | Phase Ib: dosing, safety<br>Phase II: ORR | Recruiting |
| **IPN60210**<br>Phase I/Ib<br>NCT05121103 | R/R multiple myeloma & R/R DLBCL | 96 | IPN60210 | Treatment-emergent adverse events, dosing & ORR | Recruiting |
| **Tazverik CELLO-1**<br>Phase Ib/II<br>NCT04179864 | mCRPC: patients who have not received chemotherapy | 104 | Enzalutamide + Tazverik or abiraterone/prednisone + Tazverik | Phase Ib: dosing, safety<br><br>Phase II: rPFS<br>Tazverik + enzalutamide | Recruiting |

**R/R**: relapsed/refractory; **ORR**: objective response rate; **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 | STATUS |
|---|---|---|---|---|---|
| **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 | Data anticipated H1 2023 |
| **Bylvay ASSERT** Phase III NCT04674761 | Alagille syndrome | 63 | Placebo or Bylvay | Change from baseline in scratching score | U.S. PDUFA date 15 June 2023<br><br>E.U. regulatory decision anticipated in H2 2023 |
| **Bylvay BOLD** Phase III | Biliary atresia | 205 | Placebo or Bylvay | Proportion of patients who are alive and have not undergone a liver transplant after 104 weeks of study treatment | Recruiting |

**2L**: second line; **PBC**: primary biliary cholangitis; **ALP**: alkaline phosphatase; **ULN**: upper limit normal; **PDUFA**: Prescription Drug User Fee Act.

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# 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 | U.S.: PDUFA date 16 August 2023<br><br>E.U. CHMP: negative opinion January 2023 - re-examination requested |
| **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 |

**FOP**: fibrodysplasia ossificans progressiva; **QD**: once a day; **HO**: heterotopic ossification; **PDUFA**: Prescription Drug User Fee Act; **CHMP**: the Committee for Medicinal Products for Human Use, the European Medicines Agency's committee responsible for human medicines.

# Rare Disease

*Key ongoing clinical-trial highlights*

| TRIAL | POPULATION | PATIENTS | DESIGN | PRIMARY ENDPOINT(S) | STATUS |
|---|---|---|---|---|---|
| **IPN60250 (A3907)**<br>Phase II<br>NCT05642468 | Primary sclerosing cholangitis | 12 | 10mg IPN60250 tablet QD for 12 weeks<br><br>30mg (3x10 mg) IPN60250 tablets QD for 12 weeks | Treatment-related adverse events | Recruiting |
| **Elafibranor ELMWOOD**<br>Phase II<br>NCT05627362 | Primary sclerosing cholangitis | 60 | Placebo or elafibranor | Safety, significant changes in physical examination findings, laboratory parameters, vital signs, electrocardiogram readings | Recruiting |
| **IPN60260 (A2342)**<br>Phase I<br>ISRCTN13265717 | Viral cholestatic disease | 108 | Interventional | To be confirmed | Recruiting |

**QD**: once a day.

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# Neuroscience

*Key ongoing clinical-trial highlights*

| TRIAL | POPULATION | PATIENTS | DESIGN | PRIMARY ENDPOINT | STATUS |
|---|---|---|---|---|---|
| **IPN10200 Ax LANTIC** Phase II NCT04821089 | Moderate to severe upper facial lines | 424 | Dose escalation & dose finding versus Dysport or placebo | Safety | First patient commenced dosing Q1 2023 |
| **IPN10200 Tx LANTIMA** Phase I/II NCT04752774 | Adult patients with upper limb spasticity | 209 | Dose escalation & 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.

# THANK YOU

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