The acquisition of Albireo

9 January 2023

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

Focus. Together. For patients & society
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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. In light of recent economic conditions, there could be increased pressure on the pharmaceutical industry to lower medicine prices.

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 at the time.
Speakers

David Loew
Chief Executive Officer

Howard Mayer
Head of Research & Development

Aymeric Le Chatelier
Chief Financial Officer
Agenda

1. Strategic rationale
2. The science
3. Commercial opportunities
4. Financials
5. Conclusion
6. Questions
STRATEGIC RATIONALE
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

- **ONCOLOGY**
  - Strengthening the position

- **RARE DISEASE**
  - Expanding the scope

- **NEUROSCIENCE**
  - Excelling & accelerating
Albireo: expanding Ipsen’s scope in Rare Disease

Perfectly aligned to the external-innovation strategy

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

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

Strategic fit:
- Expanding the pipeline & portfolio in rare liver diseases

Financial impact:
- Sizeable peak sales ~$800m
- Accretive to core operating income from 2025

1. Except Japan.
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*

**Efficacy**
- Patients with improved pruritus score
  - PFIC1: N=12 - 95%
  - PFIC2: N=30 - 80%
- Pruritus mean reduction vs. baseline (pts)
  - PFIC1: -1.13
  - PFIC2: -1.13
- sBA mean reduction vs. baseline
  - PFIC1: -31.7 µmol/L
  - PFIC2: -120.8 µmol/L

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

**PFIC**: progressive familial intrahepatic cholestasis; **sBA**: serum bile acids; **TEAEs**: treatment-emergent adverse events.
Source: Albireo Corporate Overview, November 2022. Reduction from baseline pruritus score (0 to 4 point scale).
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

205 patients ≤three months of age post-Kasai

Bylvay 120 mcg/kg/day
N=100

placebo
N=100

24 months

Open-label extension and safety follow-up (up to 27 months)

Primary Endpoint
Proportion of patients who are alive and have not undergone a liver transplant
## Bylvay roadmap & commercial assumptions

<table>
<thead>
<tr>
<th>Indication</th>
<th>Development status</th>
<th>iBAT-eligible population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>U.S.</td>
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<tr>
<td></td>
<td></td>
<td>Incidence (live births/year)</td>
</tr>
<tr>
<td>PFIC</td>
<td>Approved</td>
<td>~30</td>
</tr>
<tr>
<td>ALGS</td>
<td>Submitted</td>
<td>~90</td>
</tr>
<tr>
<td>BA</td>
<td>Ongoing</td>
<td>~130</td>
</tr>
</tbody>
</table>

Eligible PFIC patients include incident & prevalent patients < 17-yrs that have pruritus and have not had liver transplant.

Eligible ALGS patients include incident & prevalent patients < 17-yrs that have cholestasis, pruritus and have not had liver transplant.

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\(^2\): leveraging Ipsen’s infrastructure to accelerate sales of an approved medicine
- Convenient dosing: once per day capsules
- Good patent life\(^1\) in the U.S. and E.U.

Peak-sales potential: around $800m\(^3\)

1. November 2031 for the U.S. and E.U., with pending patent-term-extension and supplementary-protection-certificate applications.
2. Except Japan.
3. Assuming success in all three indications, including approximately half from biliary atresia.

PFIC: progressive familial intrahepatic cholestasis; ALGS: Alagille syndrome.
Ipsen to initiate a tender offer to acquire all outstanding shares\(^1\) 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
## Bylvay development in three Rare Disease indications

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