



# H1 2020 Results

July 30, 2020

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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.

The Group operates in certain geographical regions whose governmental finances, local currencies or inflation rates could be affected by the current crisis, which could in turn erode the local competitiveness of the Group's products relative to competitors operating in local currency, and/or could be detrimental to the Group's margins in those regions where the Group's drugs are billed in local currencies.

In a number of countries, the Group markets its drugs via distributors or agents: some of these partners' financial strength could be impacted by the crisis, potentially subjecting the Group to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by the crisis and where the Group sells its drugs directly to hospitals, the Group could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.

Finally, in those countries in which public or private health cover is provided, the impact of the financial crisis could cause medical insurance agencies to place added pressure on drug prices, increase financial contributions by patients or adopt a more selective approach to reimbursement criteria.

All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.



Agenda

| 01 H1 2020 Business Overview     | David Loew<br>Chief Executive Officer           |
|----------------------------------|---|
| 02 H1 2020 Financial Performance | Aymeric Le Chatelier<br>Chief Financial Officer |
| 03 Conclusion                    | David Loew<br>Chief Executive Officer           |
| 04 Q&A                           | David Loew<br>Aymeric Le Chatelier              |





# 01 H1 2020 Business Overview



## Delivering solid performance in H1 2020 despite impact of COVID-19

#### **Top line**

**Group growth** of +3.1%<sup>1</sup>, reaching €1,268.3m, driven by Specialty Care growth of +5.9%<sup>1</sup>

**Specialty Care** represented 92% of sales; Consumer Healthcare represented 8%

Good geographic diversification of sales

#### **Bottom line**

**Core Operating Income** growth of +5.9%, reaching €410.2m, and **margin** of 32.3%

Protecting profitability through expense management

**Leveraging** global commercial Oncology infrastructure



Advancements in late-stage pipeline, resulting in upside potential for the Cabometyx and Onivyde franchises

Option agreement with **IRICoR** and the University of Montreal for a discoverystage oncology program



# Ipsen's relative resilience during the COVID-19 pandemic

#### People

- High level of engagement from employees
- Priorities remain the safety of our employees, business continuity and patient access to important medicines

#### **Commercial portfolio**

- Resilient Oncology portfolio
- Commercial organization supported healthcare providers virtually

#### Manufacturing

- Adequate level of inventory across all products and geographies
- No manufacturing/ supply chain issues

#### R&D

- Limited disruption to investigational drug supply for patients
- General slowdown in patient recruitment and new site activation in ongoing clinical trials











# Oncology driving Specialty Care and Group sales growth





+9.5%<sup>1</sup> growth, representing 76% of Group sales and including de-stocking impact in Q2 2020 in EU countries

 Somatuline sales +16%<sup>1</sup> including +20% in North America despite COVID-19 impact, and limited impact of octreotide generic in EU

- Cabometyx sales +23%<sup>1</sup> reflecting continued steady launch across indications and most geographies
- Onivyde sales -18%<sup>1</sup> reflecting lower sales to ex-U.S. partner and steady growth in the U.S.
- Decapeptyl sales -2% <sup>1</sup>
   driven by negative COVID-19 impact in China



7

### Neuroscience negatively impacted by COVID-19



Janice Living with cervical dystonia Tennessee, USA



#### **Dysport sales -7.4%**<sup>1</sup>, representing 13% of Group sales

- Negative impact of COVID-19 across most geographies in both the therapeutics and aesthetics markets as treatment centers were closed
- Carefully monitoring the COVID-19 recovery
- Excluding COVID-19, attractive underlying market dynamics for the neurotoxin market
- Limited impact from increased competitive environment in the U.S. aesthetics market





8

## Rare Diseases: Palovarotene program progressing

Marin Living with fibrodysplasia ossificans progressiva Hamilton, Canada

#### Rare Diseases sales -12.5%<sup>1</sup>, representing 2% of Group sales

#### Palovarotene

- Ongoing dialogue with the FDA on the appropriate patient population eligible for treatment and a potential regulatory path forward for palovarotene in FOP
- Patients gradually re-initiating palovarotene therapy in Phase 3 MOVE trial
- MO indication discontinued due to lack of efficacy signals from Phase 2 MO-PED trial
- BLU-782 Phase 2 program on track to initiate in 2020

Strong commitment to the FOP patient community





### Consumer Healthcare negatively impacted by COVID-19



Smecta Tanakan Forlax Fortrans/ Eziclen Other CHC/ Drug related

#### **Consumer Healthcare sales -21.1%**<sup>1</sup>, representing 8% of Group sales

Smecta sales -34%<sup>1</sup>

Reflecting negative impact of COVID-19 in China and other territories, China hospital central procurement policy and weakness in France Gradual recovery expected beginning in H2 2020

- Tanakan sales +12%<sup>1</sup>
   Driven by positive market dynamics in Russia
- Fortrans/Eziclen sales -29%<sup>1</sup>
   Mainly due to impact of COVID-19 in China and Russia



### **Progressing the Pipeline**

#### Cabometyx

- Decision to opt-in for two ongoing Phase 3 trials:
  - CONTACT-01: Cabometyx in combination with atezolizumab in previously treated metastatic NSCLC
  - CONTACT-02: Cabometyx in combination with atezolizumab in CRPC
- CheckMate -9ER<sup>1</sup>
  - Met all three efficacy endpoints in 1L RCC
  - Detailed results accepted for presentation at ESMO Virtual Congress in September
- COSMIC -312<sup>2</sup>: Top-line results in 1L HCC by end of 2020

#### Onivyde

- FDA fast-track designation for 1L PDAC
- Presentation of Onivyde 1L PDAC one-year follow-up data from Phase 1/2 trial at ESMO GI

#### **Dysport**

- Approval for glabellar lines in China
- FDA approval to treat upper and lower limb spasticity in pediatric patients aged two years and older



(1) Cabometyx in combination with nivolumab for the treatment of 1L RCC;
 (2) Cabometyx in combination with atezolizumab for the treatment of 1L HCC;
 RCC: Renal Cell Carcinoma; CRPC: Castration-Resistant Prostate Cancer; NSCLC: Non Small-Cell Lung Cancer; PDAC: Pancreatic Ductal Adenocarcinoma



# 02 H1 2020 Financial Performance



# No impact of foreign exchange on sales in H1 2020

#### 60% of sales in non-EUR currencies USD now 34% of sales

H1 2020 sales by currency<sup>1</sup>



#### **Currency evolution in H1 2020**

Average rate change (2020 vs. 2019)



No impact on Sales with higher USD offset by lower emerging market currencies Positive impact on margin due to cost base in local currencies and hedging strategy



## Investments impacted by COVID-19 and focused on pipeline

| In€m   | H1 2020                 | H1 2019                 | % Change |
|--|-------------------------|-------------------------|----------|
| Net sales                                    | 1,268.3                 | 1,229.6                 | +3.1%    |
| Other Revenues                               | 38.6                    | 63.3                    | -38.9%   |
| <b>COGS</b><br>as % of net sales             | (241.8)<br><i>19.1%</i> | (236.9)<br><i>19.3%</i> | +2.1%    |
| Selling expenses<br>as % of net sales        | (375.4)<br><i>29.6%</i> | (399.7)<br><i>32.5%</i> | -6.1%    |
| <b>R&amp;D Expenses</b><br>as % of net sales | (190.6)<br><i>15.0%</i> | (176.3)<br><i>14.3%</i> | +8.1%    |
| <b>G&amp;A Expenses</b><br>as % of net sales | (94.0)<br><i>7.4%</i>   | (90.4)<br>7.4%          | +3.9%    |
| Other Core operating income and expenses     | 5.1                     | (2.0)                   |          |
| Core Operating Income                        | 410.2                   | 387.5                   | +5.9%    |
| Core Operating Margin                        | 32.3%                   | 31.5%                   | +0.8 pts |

**COGS:** Favorable impact of Specialty Care growth on the product mix partly offset by the increase of royalties paid to partners

**Selling expenses:** Reflects activities postponed or cancelled mainly due to COVID-19

**R&D investments:** Continued investments to support advancement of internal pipeline programs in oncology, neurotoxins and rare disease for palovarotene

**G&A expenses:** Increase resulted primarily from the reinforcement of the Specialty Care organization



14

# Further Core Operating Margin expansion in H1 2020



Further Core Operating Income margin expansion **exceeding 32%** of net sales

Group margin expansion **driven by Specialty Care growth** despite dilutive impact of palovarotene development costs

**Consumer Healthcare** lower profitability as compared to the Group margin with limited investments based on top-line decrease

Positive impact of currencies on profitability



## Core Operating Income to Consolidated Net Profit



| ln€m  | H1 2020 | H1 2019 | Change  |
|---|---------|---------|---------|
| Core Operating Income                             | 410.2   | 387.5   | +5.9%   |
| Core operating margin                             | 32.3%   | 31.5%   | +0.8pts |
| Amortization of intangible assets                 | (43.9)  | (41.0)  | -2.9    |
| Restructuring/ Other operating income and expense | (34.7)  | (28.6)  | -6.0    |
| Impairment gain / (loss)                          | (81.7)  | -       | -81.7   |
| Operating Income / (loss)                         | 249.8   | 317.8   | -68.0   |
| Net financing costs                               | (13.6)  | (11.7)  | -1.9    |
| Other financial income / expense                  | 33.9    | (23.2)  | +57.1   |
| Income taxes and other                            | (47.4)  | (62.4)  | +15.0   |
| Consolidated net profit / (loss)                  | 222.7   | 220.6   | +2.2    |
|   |         |         |         |

| Core consolidated net profit | 297.0 | 283.0 | +5.0% |
|------------------------------|-------|-------|-------|
| Core EPS fully diluted       | 3.55  | 3.38  | +5.0% |

#### **Operating Income**

Impairment loss of €82 million before tax mainly related to the recent setbacks in the palovarotene development program

Restructuring and Other Operating costs mainly from the Group's transformation programs

#### **Consolidated net profit**

Other financial income/ expense including the Clementia CVR write-up

Income taxes including the positive impact of the non taxation of Clementia CVR write-up

#### **Core EPS**

Higher net finance costs post-Clementia

Lower effective tax rate at 22.5% due to positive geographical mix CVR: Contingent Value Rights

16

## Strong Cash Flow generation and sound financial structure

### 1166.86 1104.86 559.57 980.86

#### Strong H1 2020 Free Cash Flow at €233m (+130% versus H1 2019)

- Solid EBITDA of €460m (+6,8%)
- Good management of working capital
- Lower level of capital expenditure due to project delay from COVID-19

#### Net Debt at €923m at the end of H1 2020 (an improvement of €192m versus 31 December 2019)

- After dividend payment of €84m
- Assuming no Clementia MO CVR payable

#### Net debt to LTM EBITDA at 1.0x<sup>1</sup> in H1 2020

# Solid financial position to fuel external innovation €1bn business development firepower based on 2.0x Net Debt to EBITDA by end of 2020



### Reinstating guidance for 2020

Sales growth >+2.0% at constant currency

# Core Operating margin > 30.0% of net sales

- Expected impact of -0.5% from currencies based on the current level of exchange rates
- Excluding any potential impact of incremental investments in pipeline expansion initiatives

Assumes only a gradual recovery from the pandemic due to high level of uncertainty regarding COVID-19
Assumes no impact of new somatostatin analog (SSA) generic entry





# 05 Conclusion



## Ipsen H1 2020 highlights



Resilient performance through COVID-19 pandemic



Reinstated 2020 financial guidance



#### R&D pipeline advancing



### 2020 Objectives





#### Growth

- Maximize growth and value worldwide for differentiated best-in-class Specialty Care products
- Prepare for COVID-19 business recovery, protecting profitability, Cash Flow generation
- Leverage current organization and optimize cost base for growth



#### Pipeline

- Increase value of internal pipeline by transforming R&D organization and prioritizing key internal R&D programs
- Foster disciplined business development strategy to bring new assets or products and build innovative and sustainable pipeline



#### Culture

- People: Continue transformation through leadership and people
- Patients: Bring innovative therapies to patients with unmet medical needs
- Environment: Minimize impact by ensuring activities are safe and sustainable

Strategic review underway Capital Markets Day – 1 December











# Thank You



## H1 2020 sales growth driven by Specialty Care

Janice Living with cervical dystonia Tennessee, USA

Net sales of key products in H1 2020 in million euros – % excluding foreign exchange impact

#### **Specialty Care**





Consumer Healthcare €101.2m -**21.1%**<sup>1</sup>



## Advancing solid pipeline across 3 strategic TAs with several significant Phase 3 / registrational trials



| Preclinical                                       | Phase I  | Phase II   | Phase III  | Registration                        |
|---|--|--|--|-------------------------------------|
| IPN59011<br>Longer-acting neurotoxin<br>mrBoNT/A  | <sup>177</sup> Lu-IPN-01072<br>(Satoreotide Tetraxetan)<br>GEP-NET | <sup>68</sup> Ga-IPN-01070<br>(Satoreotide Trizoxetan)<br>GEP-NET, breast cancer imaging | IPN60120<br>(Palovarotene)<br>FOP*                     | Dysport solution<br>Glabellar lines |
| IPN10200<br>Longer-acting neurotoxin<br>mrBoNT/A' | <sup>177</sup> Lu-IPN-01087<br>NTSR1 solid tumors                  | Dysport<br>Vulvodynia  | Cabometyx<br>combination with nivolumab<br>1L RCC      |                                     |
|   | IPN60130<br>(ALK2 inhibitor)<br>FOP                                |  | Cabometyx<br>combination with atezolizumab<br>1L HCC   |                                     |
|   | Cabometyx<br>combination with atezolizumab<br>Solid tumors         |  | Cabometyx<br>combination with atezolizumab<br>2L NSCLC |                                     |
|   |  |  | Cabometyx<br>combination with atezolizumab<br>2L CRPC  |                                     |
|   |  |  | Onivyde<br>1L PDAC                                     |                                     |
| New chemical entity (NCE) Neuroscience            |  |  | Onivyde<br>2L SCLC                                     |                                     |

Oncology Rare Diseases/ Other



\*Partial clinical hold for all patients <14 years of age as of December 6, 2019 CRPC: Castration-Resistant Prostate Cancer; FOP: Fibrodysplasia Ossificans Progressiva; GEP-NET: Gastroenteropancreatic Neuroendocrine Tumors; HCC: Hepatocellular Carcinoma; NSCLC: Non-Small Cell Lung Cancer; PDAC: Pancreatic ductal adenocarcinoma; rBoNT/A: recombinant Botulinum Toxin Type A; RCC: Renal Cell Carcinoma; SCLC: Small Cell Lung Cancer; 1L: First line; 2L: Second line</li>

# Oncology ongoing clinical trial highlights

| Trial   | Population   | Patients | Design   | Endpoints  | Status                                     | Addressable<br>population in Ipsen<br>territories |
|---|--------------|----------|--|--|--|---|
| Cabometyx<br>Phase 3 CheckMate 9ER<br>NCT03141177 | 1L RCC       | 638      | <ul><li>Arm 1: cabozantinib + nivolumab</li><li>Arm 2: sunitinib</li></ul>   | <ul> <li>Primary: PFS</li> <li>Secondary: OS, ORR,<br/>safety</li> </ul>               | Positive top-line results in<br>April 2020 | ~30K patients                                     |
| Cabometyx<br>Phase 3 COSMIC 312<br>NCT03755791    | 1L HCC       | 740      | <ul> <li>cabozantinib 40 mg oral, qd + atezolizumab<br/>1200 mg infusion, q3w</li> <li>sorafenib 400 mg bid</li> </ul>   | <ul> <li>Primary: PFS, OS</li> </ul>   | Recruiting                                 | ~26K patients (ex-China)                          |
| Cabometyx<br>Phase 3 CONTACT-01                   | 2L NSCLC     | 350      | <ul> <li>cabozantinib in combination with<br/>atezolizumab</li> <li>Docetaxel</li> </ul>   | <ul> <li>Primary: OS</li> <li>Secondary: PFS, ORR,<br/>duration of response</li> </ul> | Recruiting                                 |   |
| Cabometyx<br>Phase 3 CONTACT-02                   | 2L CRPC      | 580      | <ul> <li>cabozantinib in combination with<br/>atezolizumab</li> <li>second novel hormonal therapy (either<br/>abiraterone and prednisone or enzalutamide)</li> </ul> | <ul> <li>Primary: OS, PFS</li> </ul>   | Recruiting                                 |   |
| Cabometyx<br>Phase 1b<br>NCT03170960              | Solid tumors | 1732     | <ul> <li>cabozantinib + atezolizumab</li> </ul>  | <ul><li>Primary: MTD, ORR</li><li>Secondary: safety</li></ul>                          | Recruiting                                 |   |
| Cabometyx<br>Phase 1b<br>NCT03299946              | 1L HCC       | 15       | <ul> <li>cabozantinib 40mg daily for 8 weeks +<br/>nivolumab 240mg intravenously every 2<br/>weeks</li> </ul>  | <ul> <li>Primary: safety</li> </ul>  | Recruiting                                 | ~26K patients (ex-China)                          |



# Oncology ongoing clinical trial highlights

| Trial  | Population  | Patients | Design  | Endpoints   | Status/ Other  |
|--|---|----------|---|---|--|
| Onivyde<br>Phase 3 NAPOLI 3<br>NCT04083235                                     | 1L PDAC   | 750      | <ul> <li>Arm 1: Onivyde (nanoliposomal irinotecan) + 5-FU/LV + oxaliplatin</li> <li>Arm 2: Nab-paclitaxel + Gemcitabine</li> </ul>      | <ul><li>Primary: OS</li><li>Secondary: PFS, ORR</li></ul>   | Recruiting/~28K addressable patients in Ipsen territories                    |
| Onivyde<br>Phase 3 RESILIENT<br>NCT03088813                                    | 2L SCLC   | 486      | <ul><li>Onivyde (nanoliposomal irinotecan)</li><li>Topotecan</li></ul>  | <ul><li>Primary: OS</li><li>Secondary: PFS, ORR, safety</li></ul>   | Recruiting/~14K drug-treated<br>addressable patients in Ipsen<br>territories |
| Onivyde<br>Phase 1<br>NCT01770353  | Breast cancer<br>(ER/PR positive,<br>TNBC,<br>active brain<br>metastasis) | 45       | <ul> <li>Onivyde (nanoliposomal irinotecan) IV on Days 1 and<br/>15 every 4 weeks + ferumoxytol 5 mg/kg IV once on<br/>Day 1</li> </ul> | <ul> <li>Primary: tumor levels of irinotecan and SN-38</li> <li>Secondary: safety, tumor response rate</li> </ul>         | Ongoing  |
| Satoreotide trizoxetan<br><sup>68</sup> Ga-IPN-01070<br>Phase 2<br>NCT03220217 | GEP-NET   | 25       | <ul> <li>Satoreotide trizoxetan</li> </ul>  | <ul> <li>Primary: Difference in<br/>relative lesion counts</li> <li>Secondary: Difference in<br/>image quality</li> </ul> | Recruiting   |
| IPN01087<br>Phase 1<br>NCT03525392   | NTSR1 solid<br>tumors   | 320      | IPN01087  | <ul> <li>Incidence DLTand organ<br/>exposure to radiation</li> </ul>  | Recruiting   |



# Neuroscience ongoing clinical trial highlights

| Trial                             | Population | Patients | Design   | Endpoints   | Status     | Addressable<br>population in Ipsen<br>territories  |
|-----------------------------------|------------|----------|--|---|------------|--|
| Dysport<br>Phase 2<br>NCT03598777 | Vulvodynia | 93       | <ul><li>Dysport (AbobotulinumtoxinA)</li><li>Placebo</li></ul> | <ul> <li>Primary: Safety, change<br/>from baseline in vaginal<br/>pain on Numeric Rating<br/>Scale</li> </ul> | Recruiting | <ul> <li>6.5%<sup>3</sup> of female<br/>population</li> <li>69%<sup>4</sup> consult specialist</li> <li>40% vulvodynia<br/>diagnosis</li> <li>60%<sup>5</sup> provoked<br/>vulvodynia</li> </ul> |



# Rare Diseases ongoing clinical trial highlights

| Trial                                       | Population  | Patients | Design   | Endpoints  | Status   | Addressable<br>population in Ipsen<br>territories |
|---|---|----------|--|--|--|---|
| Palovarotene<br>Phase 3 MOVE<br>NCT03312634 | FOP (chronic)<br>* Dosing<br>restarted in<br>patients >14<br>years of age | 90       | <ul> <li>Palovarotene - 5 mg once daily and upon<br/>flare-up, 20 mg once daily for 28 days<br/>followed by 10 mg for 56 days</li> </ul> | <ul> <li>Primary: Change in HO volume</li> </ul> | Dosing paused after<br>reaching pre-specified<br>second interim analysis<br>futility criteria / partial<br>clinical hold on patients<br><14 years of age | ~9K WW  |

