# Ipsen Half Year 2016 Financial Results



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#### **Safe Harbor**

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.



## Half year 2016 overview

Marc de Garidel Chairman



#### **Agenda**

Marc de Garidel H1 2016 overview Chairman **Aymeric Le Chatelier** H1 2016 financial performance **EVP CFO Claude Bertrand R&D** update EVP R&D, CSO **David Meek** Conclusion CEO



### H1 2016 highlights: Accelerated transformation

Solid operating performance driven by Specialty Care sales growth and in particular Somatuline® in the US

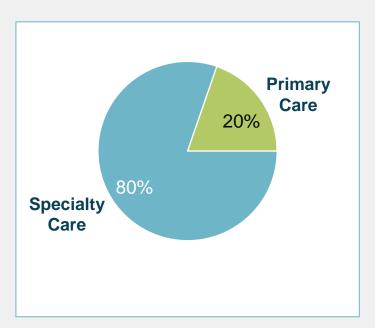
In-licensing of Cabometyx<sup>™</sup> to strengthen oncology portfolio, recent positive CHMP opinion & launch preparation in Europe

New corporate governance model: David Meek joins as CEO; Marc de Garidel assumes the role of non-executive chairman of the Board of Directors

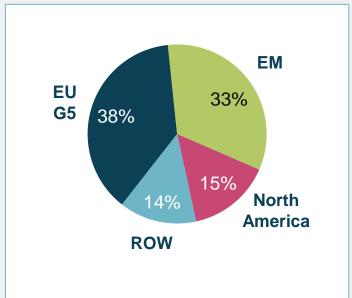


## Ipsen: Global specialty pharma company; US now top affiliate

H1 2016 sales by segment



H1 2016 sales by geography



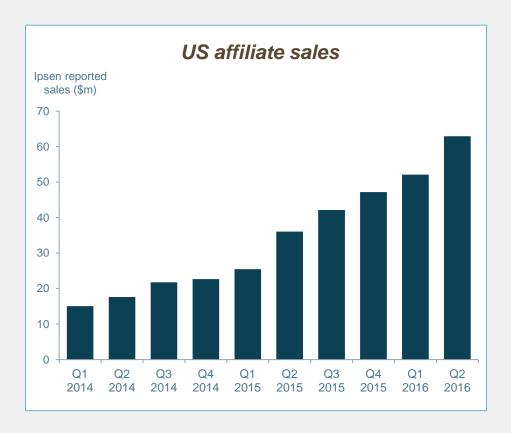
Top 5 affiliates



Specialty care increasing as a percentage of overall sales

Broad global footprint

## US: Continued momentum and high potential for growth



- US represents 15% of global sales
- Additional growth drivers for continued momentum
- Strong leverageable infrastructure in place



## H1 2016 financial highlights: Solid sales & margin improvement

Net sales €763.8 million sales growth +9.7%\*

Specialty Care sales growth +14.3%\*

Primary Care sales growth - 5.9%\*

Core Operating margin 24.7% +1.2 pt improvement



#### **Executing on base business growth strategy**

#### **Specialty Care**

## Leadership in NET

- Develop Somatuline® in new indications and delivery devices
- Expand portfolio with telotristat etiprate and 177Lu-OPS201/ <sup>68</sup>Ga-OPS202

## Maximize Dysport® potential

- Launch Dysport® in new indications (PLL, ALL) and formulation
- Successful Galderma partnership in aesthetics, especially in the US

## In-licensing of Cabometyx™

- Accelerate Specialty Care growth; reinforce niche oncology strategy
- Ensure successful launch in 2L RCC; expand in other indications

#### **Primary Care**

#### **GI** focus

- Expand portfolio of products: recent launches in France, Probi in-licencing agreement
- Transition to OTC model and continued focus in China



## Cabometyx™ EU launch: Positive momentum on a significant market opportunity

Significant RCC 2L market opportunity Treatment paradigm shift from PFS benefit only to PFS+OS

Hiring of quality staff in key functions

Ensure appropriate medical support

Prepare market access submission

Accelerated review in Europe

Positive CHMP opinion: July 21, 2016

EMA decision: Sept. 2016



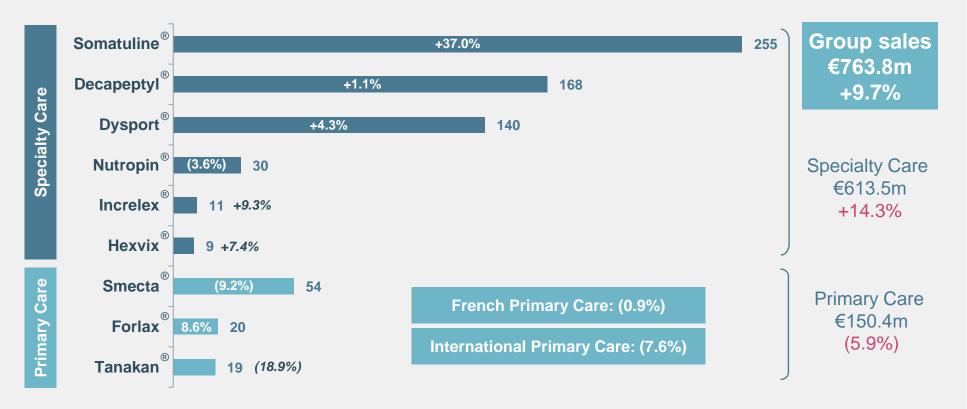
## H1 2016 financial performance

**Aymeric Le Chatelier** EVP CFO



### H1 2016 sales growth driven by specialty care business

Drug sales – H1 2016 in million euros – % excluding foreign exchange impact



Somatuline® NET driving Specialty Care growth

Primary Care affected by international markets headwinds, notably in China / Russia



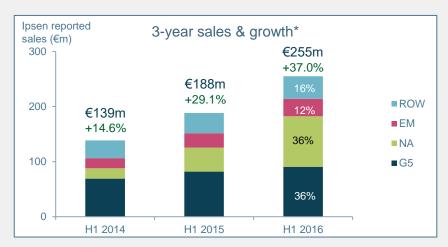
## Somatuline®: strong performance globally driving oncology franchise growth

#### H1 highlights

 US: Increasing penetration of centers, new patients and patients transitioning from prior therapy in an expanding market



 Strong performance in most European countries, notably Germany, Poland, France and the UK





Source: IMS MIDAS, May 2016



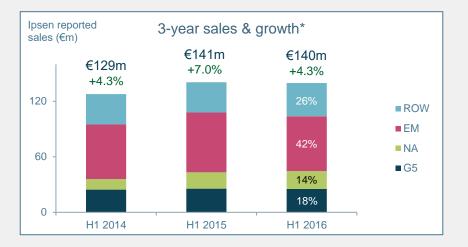
<sup>\*</sup> Q2 2016 market share reflects data through May 2016

## Dysport® driven by solid market growth

#### H1 highlights

- Launch of AUL spasticity (US)
- Launch readiness for PLL spasticity (US)
- Continued strength of aesthetics performance in Russia and in Galderma territories
- Adverse inventory effects in the Middle East and Brazil
- Progressive ramp up of spasticity sales in the US



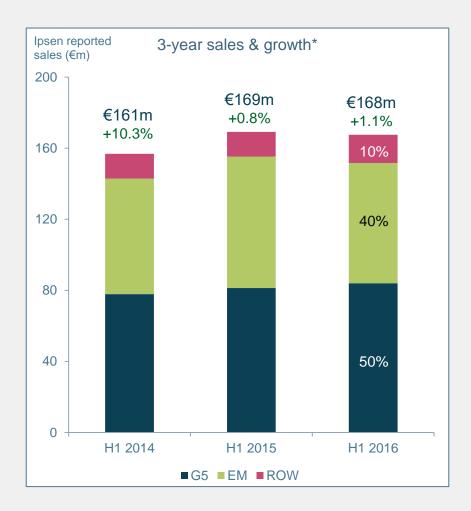




## Decapeptyl®: strong performance in Europe offset by inventory trends in the Middle East

#### H1 highlights

- Increased commercial focus in China with dedicated sales force per indication
- Progress on potential combination in breast cancer
- Good volume growth and market penetration in Europe especially in Spain, France and the UK
- Volume in China offset by continued pricing pressure

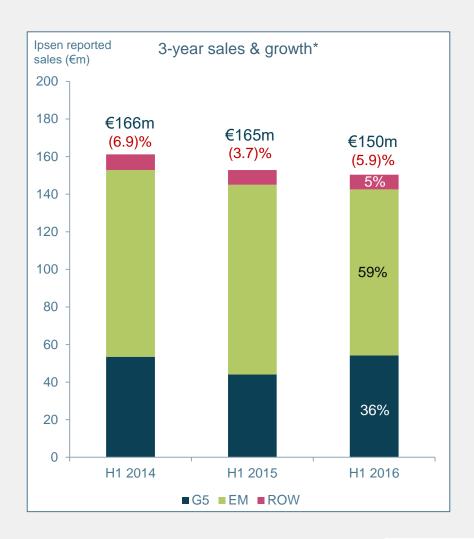




## Primary care impacted by Smecta® and Tanakan® slowdown

#### H1 highlights

- Accelerated transition in China of the Primary care model to OTx
- Portfolio expansion with distribution agreement for probiotic LP299V<sup>®</sup> signed with Probi
- Smecta<sup>®</sup> impacted by 2015 destocking in China and Vietnam
- Tanakan<sup>®</sup> market slowdown in Russia and France
- Expected rebound in H2 2016 from OTC ramp up in China





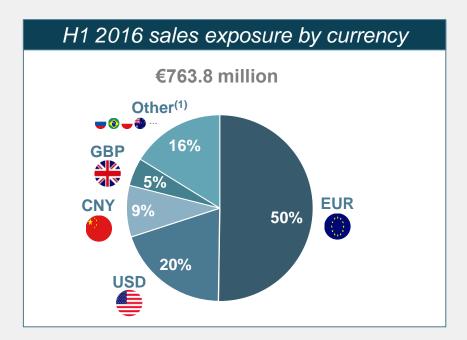
## **P&L - From sales to Core Operating Income**

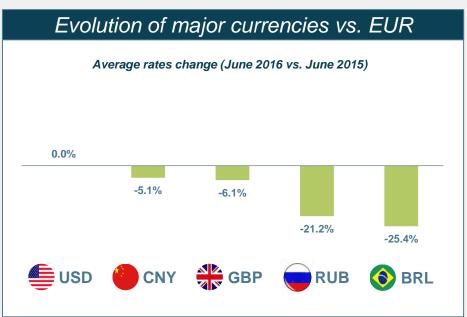
In million euros	H1 2016	H1 2015	Change	% Change	Change at constant FX
Net sales	763.8	713.9	+49.9	+7.0%	+9.7%
Other revenues	42.8	38.0	+4.8	+12.4%	
Revenue	806.6	751.9	+54.7	+7.3%	
Cost of goods sold	(172.2)	(168.3)	-3.9	+2.3%	
Selling expenses	(283.2)	(259.9)	-23.3	+8.9%	
R&D expenses	(95.0)	(91.8)	-3.2	+3.4%	
G&A expenses	(59.0)	(61.3)	+2.3	-3.7%	
Other core	(8.4)	(2.9)	-5.5	NA	
Core Operating Income	188.8	167.6	+21.2	+12.6%	
Core Operating margin	24.7%	23.5%	+1.2pt		

Operating leverage driving margin expansion



### **Exposure to foreign currencies**



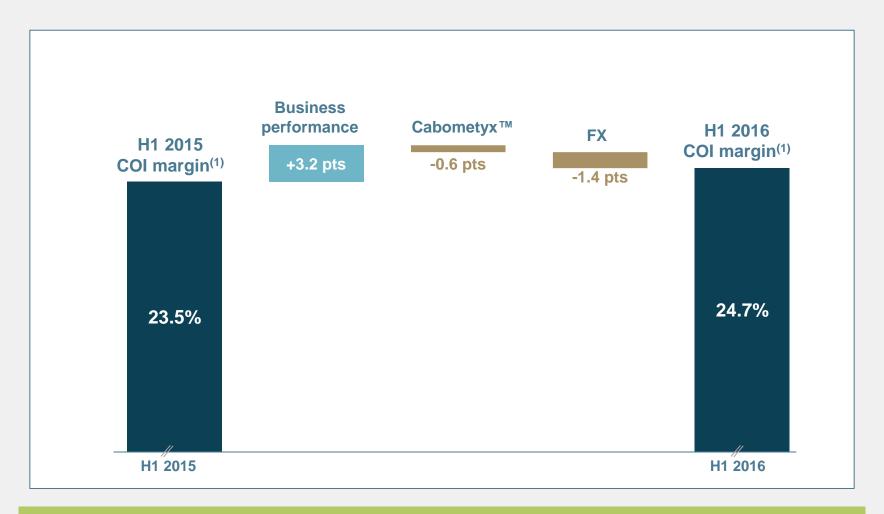


#### Foreign currency policy

- H1 2016 sales impacted by currency depreciation in emerging countries (BRL, CNY, RUB)
- Global FX exposure mitigated by cost base in local currency and hedging of key currencies



## **Core Operating margin evolution**



H1 2016 margin expansion driven by Specialty care growth and cost-monitoring efforts

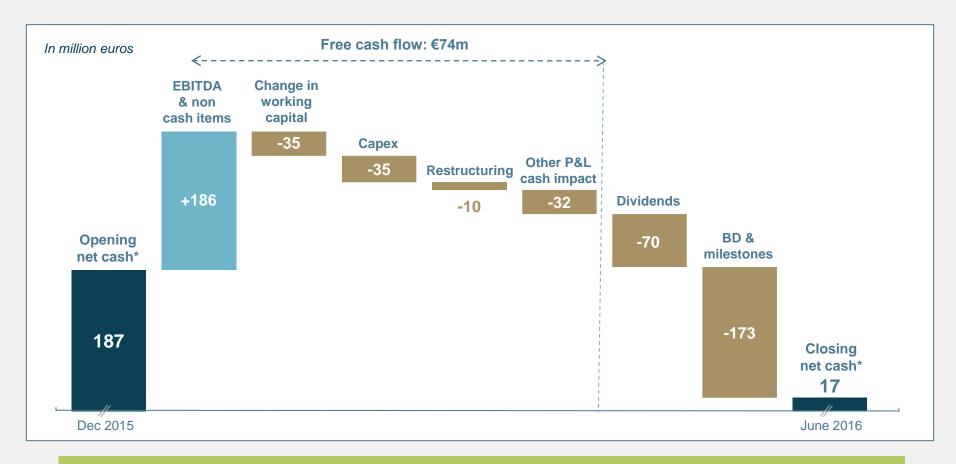
## **P&L - From Core Operating Income to EPS**

In million euros	H1 2016	H1 2015	Change	% Change
Net sales	763.8	713.9	+49.9	+7.0%
Core Operating Income	188.8	167.6	+21.2	+12.6%
Core Operating margin	24.7%	23.5%	+1.2 pt	
Other non core	(5.5)	(6.6)	+1.1	
Restructuring costs	(0.4)	(0.7)	+0.3	
Impairment gain / (losses)	(8.4)	(57.0)	+48.6	
Operating Income	174.6	103.4	+71.2	+68.8%
Financial result	(2.9)	3.2	-6.1	
Income taxes	(39.4)	(17.9)	-21.5	
Share of profit from entities accounted for using equity method	1.3	1.5	-0.2	
Discontinued operations	(0.3)	0.3	-0.6	
Consolidated net profit	133.3	90.5	+42.8	+47.4%
Consolidated net profit margin	17.5%	12.7%	+4.8 pts	
EPS – fully diluted (€)	1.61	1.09	+0.52	
Core EPS – fully diluted (€)	1.74	1.50	+0.24	16.0%

Impact of tasquinimod impairment in H1 2015 Core EPS +16%



### Strong cash flow generation



Cash flow of €74 million driven by strong COI

Closing net cash position of €17 million at the end of H1 2016



### 2016 financial objectives

**Specialty Care sales** 

Raised

Previous New
Growth >+10.0% Growth >+12.0%

At constant currency

Primary Care sales

**Reaffirmed** 

Slight growth, year-on-year

At constant currency

Core Operating margin

Reaffirmed Around 21%

Assumina:

- higher investments required to prepare the commercial launch of Cabometyx™
- further investments in the US to support the accelerated growth of Somatuline® and additional launches of Dysport®



### **Key financial takeaways**

Group sales up 9.7% at constant currency

Strong Core Operating Income margin of 24.7%<sup>(1)</sup>

Consolidated net profit of €133.3m, up 47.4% year-on-year Fully diluted core EPS of €1.74, up 16.0% year-on-year

Successful issuance of inaugural €300 million 7-year Notes

## **R&D** update

Claude Bertrand EVP R&D, CSO



### H1 2016: Pipeline milestones

#### Oncology

#### Cabometyx™

- In-licensing rights (ex-US, Canada, Japan)
- Positive OS results in 2L RCC (METEOR)
- Positive top-line results in 1L RCC (CABOSUN)
- Positive CHMP opinion for 2L RCC

#### Telotristat etiprate

- Priority review granted by FDA
- Regulatory submission in EU

#### Decapeptvl®

Breast submission in EU

#### Neurosciences

#### Dysport®

- Regulatory submission for ALL (EU)
- Regulatory submission for PLL (EU)
- Regulatory approval CD & AUL (Canada)
- Ph3 start in neurogenic detrusor overactivity

#### Strengthening pipeline capabilities through strategic collaborations



Research partnership in oncology



Ex-US, ex-Canada, ex-Japan licensing deal for Cabometvx™



WW licensing

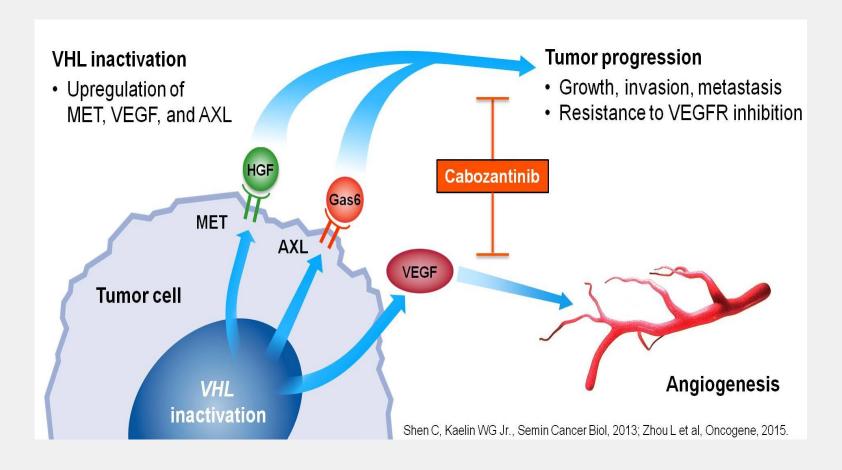
agreement for novel radiopharmaceutical in oncology



Strategic partnership for preclinical pharmacology (oncology)



## Cabometyx<sup>™</sup> targets oncogenic drivers of RCC through multi-kinase inhibitory effect





### Cabometyx™: Aim to become standard of care in 2L RCC

First therapy in 2L RCC to show clinically meaningful improvement in 3 key metrics<sup>(1)</sup>:

**PFS: 7.4 months (+3.6 months\*)** 

OS: 21.4 months (+4.9 months\*)

**ORR: 24%** 

Subgroup analysis indicates benefit regardless of:

Risk group

Type or duration of prior therapy

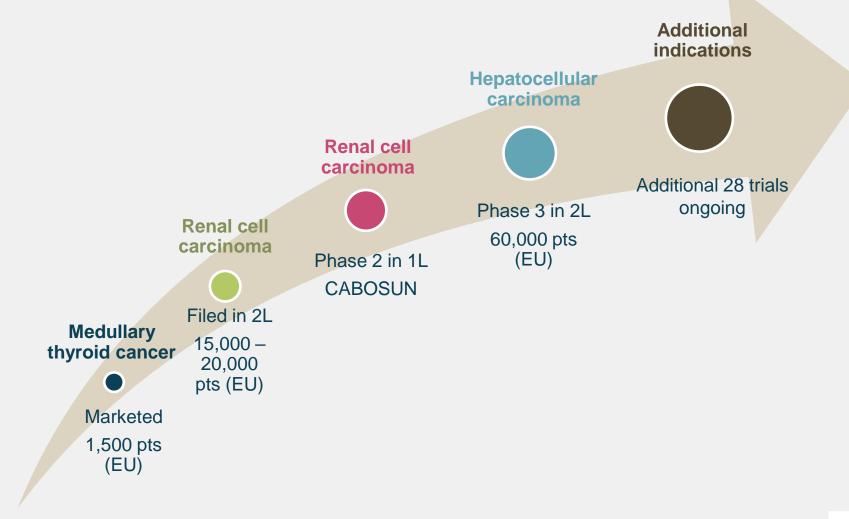
Location and extent of tumor metastases

Rate; OS: Overall Survival; PFS: Progression Free Survival; RCC: Renal Cell Carcinoma

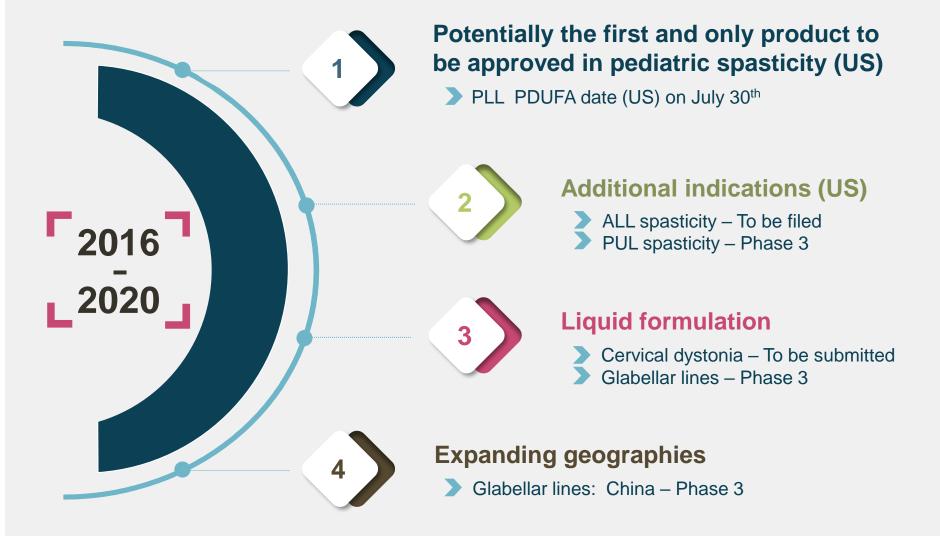
**Updated NCCN and EAU Kidney Cancer Guidelines** include Cabometyx™ for 2L RCC



## Cabometyx™: 2L RCC key indication with potential for future indications



## Dysport®: development opportunities to expand reach





## **Upcoming key news flow**

H2 2016 2017

#### **Oncology**

Cabometyx™	Regulatory decision 2L RCC (EU)	CELESTIAL Phase 3 results HCC
	CABOSUN Phase 2 results 1L RCC	
Somatuline®	Filing for symptom control GET NET (US)	
Telotristat etiprate	NET carcinoid syndrome submission (EU)	Regulatory decision (EU) NET carcinoid syndrome
<sup>68</sup> Ga-OPS202		Phase 3 start NET diagnostic

#### **Neurosciences**

Dysport <sup>®</sup>	ALL submission (US)	ALL regulatory decision (US)
		Solution Submission (EU) Cervical Dystonia
		Solution Submission (EU) Glabellar Lines



## Conclusion

**David Meek** CEO



### New corporate governance model

#### David Meek joins as CEO



- Joined Ipsen on July 18, 2016, based at headquarters in Boulogne-Billancourt
- Over 25 years of experience in the pharmaceutical & biotech industry, most recently leading the oncology division of Baxalta
- International and BD experience through various executive positions at major pharmaceutical and biotechnology companies

### 2016 roadmap

Position Somatuline® as a leader in NET and secure Dysport® spasticity launch

Implement new Primary Care OTx model, notably in China

Prepare for the imminent launch of Cabometyx™ for the treatment of RCC in Europe

Continue business development to replenish pipeline and complement marketed product portfolio

Ipsen to deliver strong growth and value creation to shareholders



## Thank you

