

TWSE 1789

# ScinoPharm Management Presentation

First Quarter 2015 On-Line Investor Meeting

May 8, 2015



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# Table of Content

- Overview of ScinoPharm
- Financial & Operating Results in Q1, 2015
- Market Trend Update

# Overview of ScinoPharm

- An API + ANDA Company

Active Pharmaceutical Ingredients  
Abbreviated New Drug Application

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# Business Overview

- Established in 1997 in Taiwan and listed on TWSE in 2011, current market cap around US\$1.2 billion
- Specializes in high potency (steroid/cytotoxic) APIs and expands to injectable formulations
- Facility & organization built in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai
- 70 generic APIs developed with 27 APIs launched; 50 US DMFs filed (703 DMFs WW), 24 US DMFs in oncological APIs. 80+ NCE CRAM projects, with 5 launched and 9 in phase III for NDA filing in 2-3 years
- Full compliance to world class quality and regulatory practices; Successfully passed US FDA, EMA, Australian TGA, Japanese PMDA inspections

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# Long Term Strategies

Transforming to a full-scope pharma company per our core competency of R&D and cGMP manufacturing in high-technical barrier APIs

- Vertical Integration to Generic Formulations:  
Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain
- Innovative Delivery Formulations:  
Targeted delivery & extended release of proven APIs via 505(b)2 fast track
- Brand New Chemical Entities (New Drugs):  
Collaborating with academic research institutes, focusing on un-met oncological medical needs of high prevalence in Asia

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# Keys to Generic Formulation Business

- Expanding formulation portfolio
- Building on-site oncological injectable facility and establishing a complete supply chain of oral products
- Promoting our formulations via strategic alliance, especially in China and US
- Acquiring critical resources via M&A

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# Passed the 5th US FDA GMP Inspection

- **Zero 483 observation on 18 products sold to the US**
- **US FDA newly adopted “Quality Metrics Initiative”, for each production site to provide "quality level" data; FDA can check how well the quality system maintained and how successfully the system affects the quality of the medicinal products**
- **Focus on the Rates of Lot Acceptance, Right First Time, Product Quality Complaint, Management Engagement, etc.**
- **More emphasis on initial selection criteria and evaluation of suppliers and ways to deal with quality and compliance issues in a timely manner**

\* An FDA Form 483 is issued to the management of a production site at the conclusion of an inspection when an investigator has observed any conditions that in his/their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts.

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# Top Warning Letter Citations

- Inadequate design & construction features
- Inadequate control of microbiological contamination
- Data integrity
- Inadequate raw material testing
- Inadequate special training requirement
- Inadequate stability testing

**ScinoPharm successfully passed FDA audits on these key quality matters**

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# More Tightened cGMP Requirement

Company	Warning Letter Issue Date
Hospira S.p.A.	03/31/2015
Hospira Australia	09/26/2014
GSK Biologicals	06/12/2014
Sun Pharmaceutical	05/07/2014
Johnson & Johnson International	06/06/2013
Teva Neuroscience	04/08/2013
Hospira Healthcare India	05/28/2013
Boehringer Ingelheim Pharma	05/06/2013
Genentech	10/03/2012
Eli Lilly	08/10/2012
Pfizer	06/19/2012
Watson	06/07/2012

Source : US FDA Website

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# GMP Compliance as Competitive Advantage

- To handle the stringent cGMP requirements, many pharmas face severe challenges, leading to either outsource production or shut down product lines
- Due to CAPEX concern, many old pharmas hesitate to upgrade facility and staff training, which creates huge demands for high quality contract research & manufacturing services
- With FDA inspected facilities in all scales and effective quality management systems, ScinoPharm offers world class quality services to brand name and generic customers in a flexible, reliable, and competitive approach

# Financial & Operating Results

# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	1Q 2015 (Reviewed)	1Q 2014 (Reviewed)	YoY
Net Sales	979	1,097	-11%
Gross Profit	344	433	-21%
<i>Gross margin</i>	<i>35%</i>	<i>39%</i>	
Operating Expenses	(203)	(250)	-19%
Operating Income	141	183	-23%
<i>Operating margin</i>	<i>14%</i>	<i>17%</i>	
Other Rev.(Exp.)	(7)	2	-450%
Net Income before Tax	134	185	-28%
Net Income after Tax	113	165	-32%
<i>Net margin after tax</i>	<i>12%</i>	<i>15%</i>	
EPS (after tax)	0.16	0.24	-33%

# Balance Sheet- Consolidated

In NT\$ million	2015/3/31 (Reviewed)		2014/3/31 (Reviewed)	
Cash and Cash Equivalents	2,008	17%	2,793	23%
Accounts Receivable	653	6%	630	5%
Inventories	2,402	21%	2,637	22%
Long-Term Investments	244	2%	260	2%
Property, plant & equipment	5,109	44%	4,434	37%
Other assets	1,155	10%	1,275	11%
<b>Total Assets</b>	<b>11,571</b>	<b>100%</b>	<b>12,029</b>	<b>100%</b>
Current Liabilities	2,004	17%	2,156	18%
L-T Liabilities and Others	91	1%	66	-
<b>Stockholders' Equities</b>	<b>9,476</b>	<b>82%</b>	<b>9,807</b>	<b>82%</b>

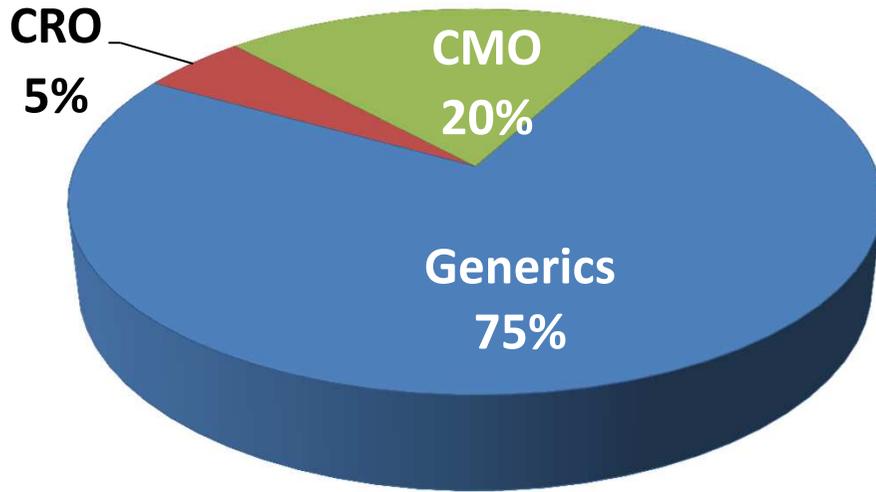
# Cash Flows- Consolidated

In NT\$ million	1Q 2015 (Reviewed)	1Q 2014 (Reviewed)
Cash and cash equivalents at beginning of period	1,928	2,289
Cash flows from operating activities	241	492
CAPEX	(269)	(372)
Short-term borrowings	86	380
Others	22	4
Cash and cash equivalents at end of period	2,008	2,793

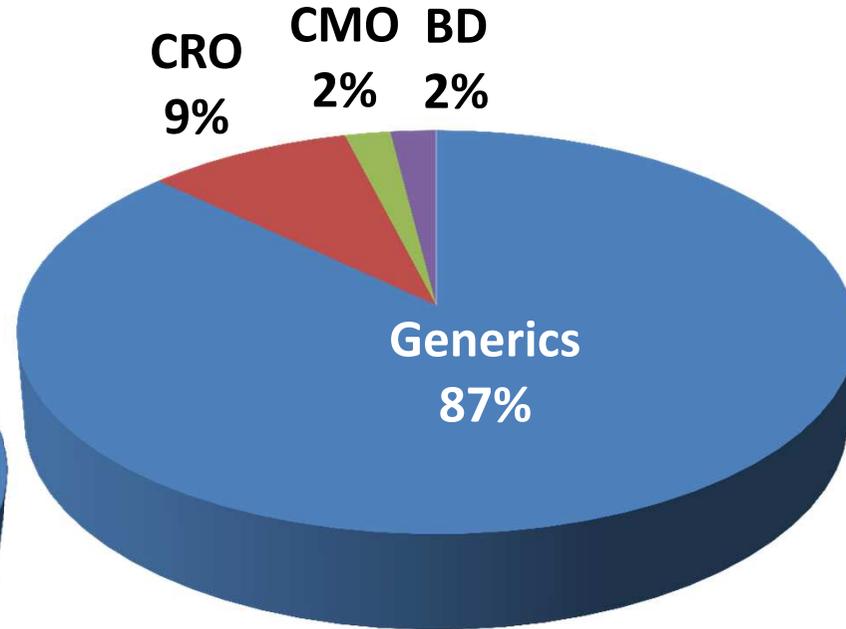
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# Sales by Business

## 2014 Q1



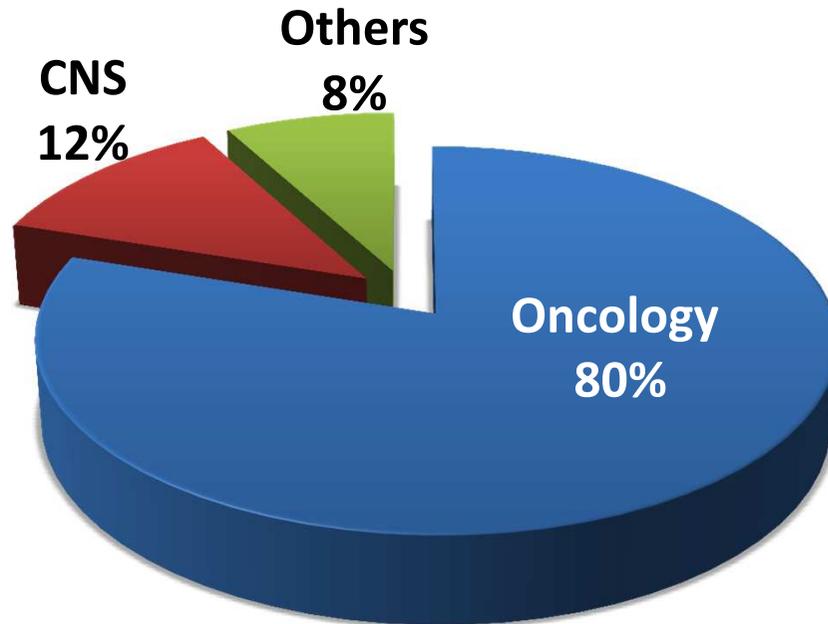
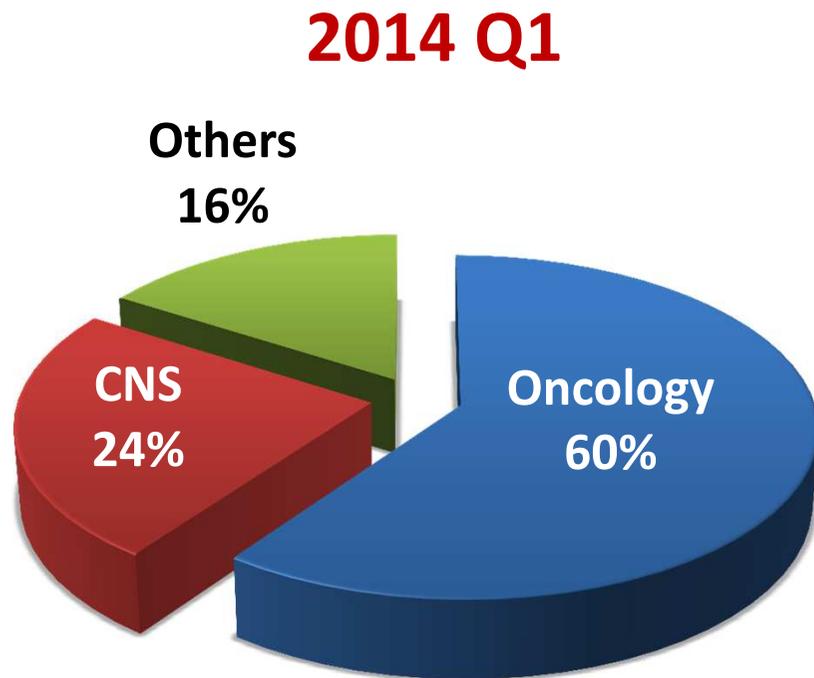
## 2015 Q1



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# Sales by Indications

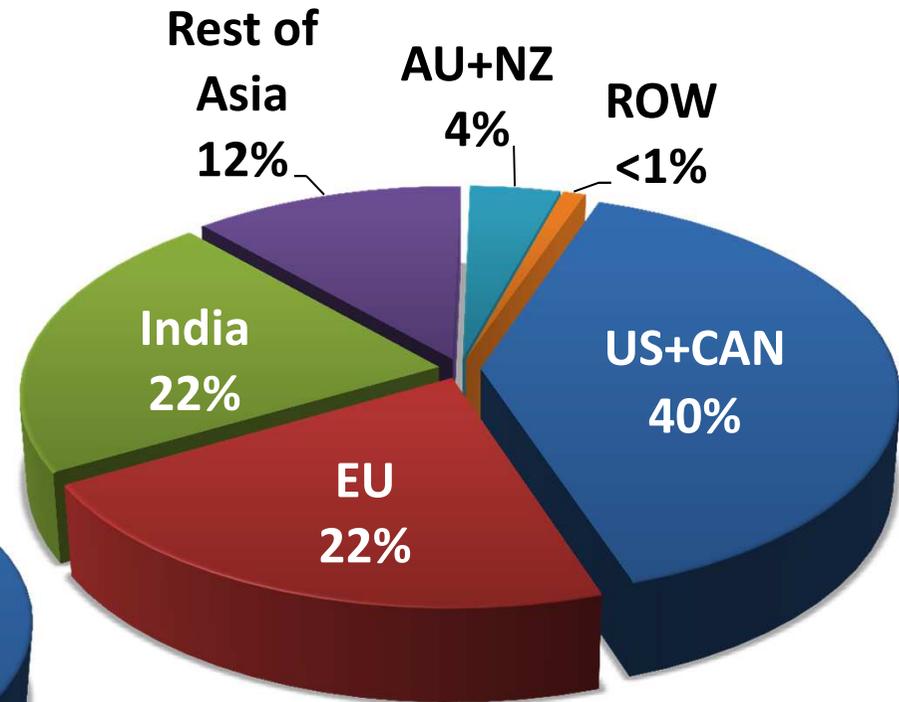
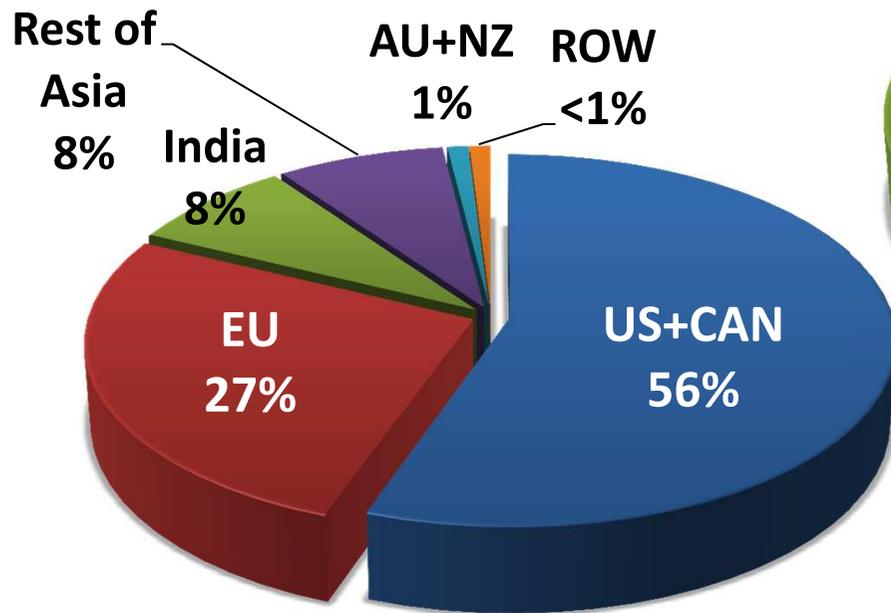
2015 Q1



# Sales by Region

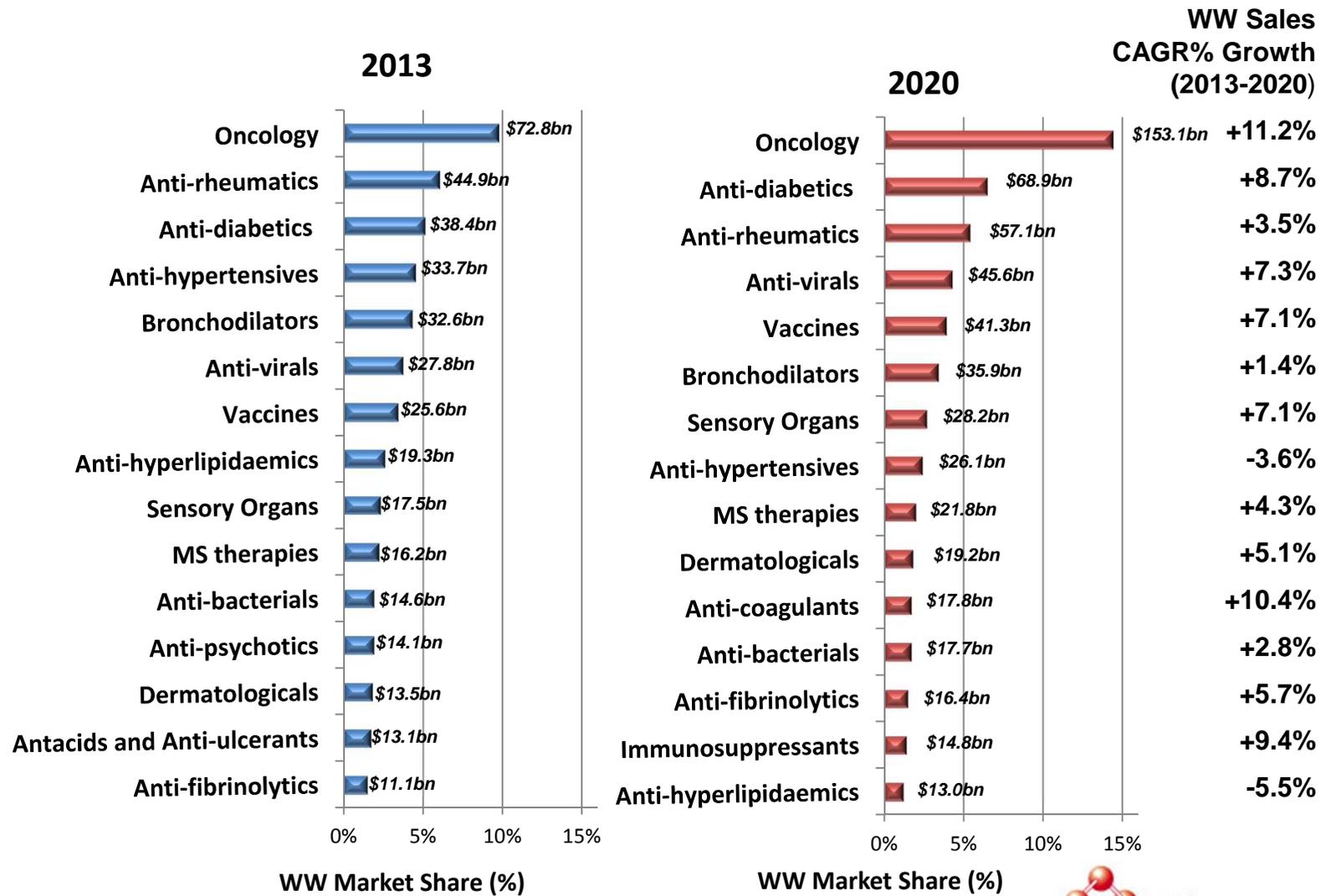
2015 Q1

2014 Q1



# Market Trend Update

# Oncology as Global Top 1 Therapy



Source: Evaluate Pharma



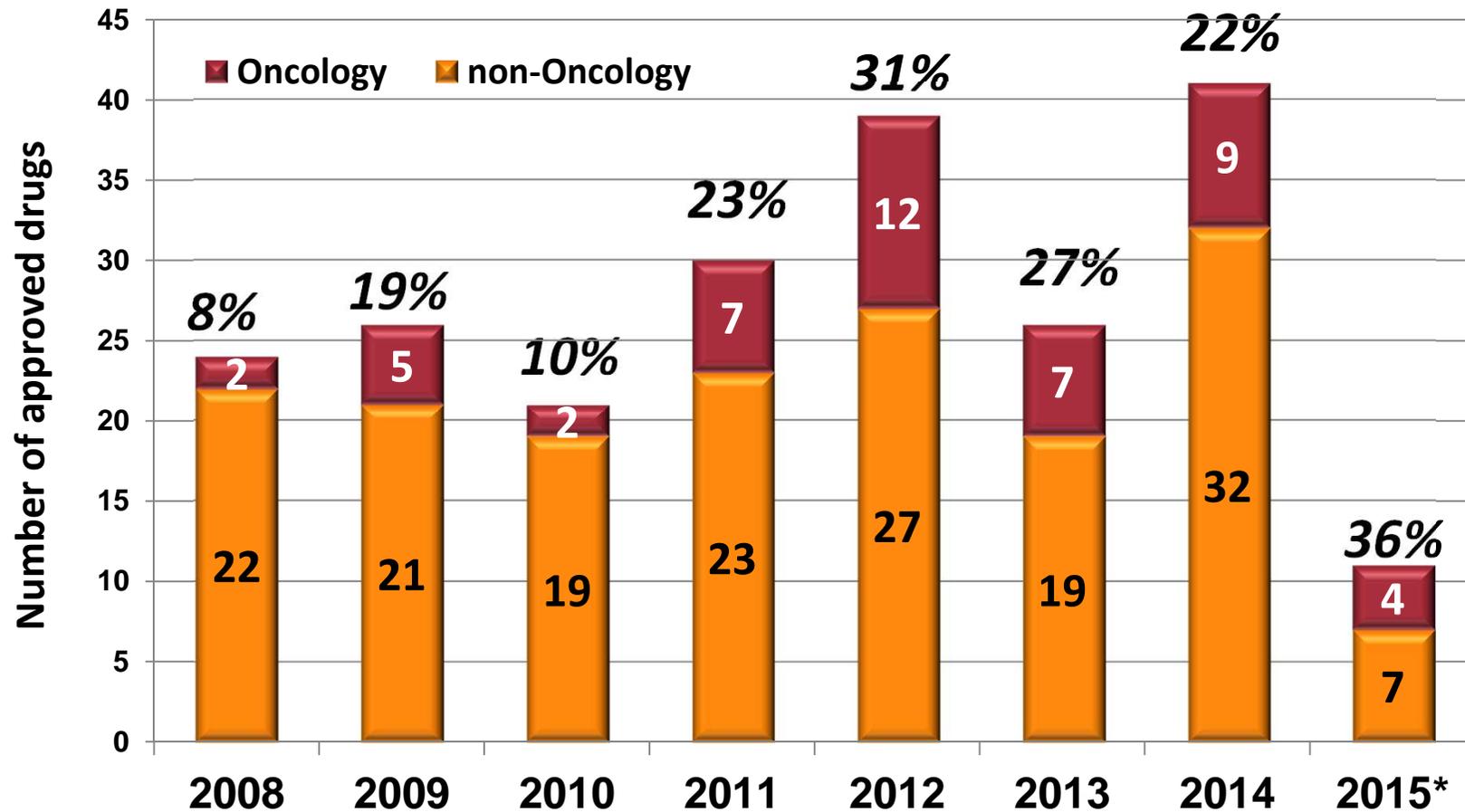
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# Global Oncology Value Soaring

- **Oncology has become the top 1 therapy area since 2013**
- **Global cancer drug spending reached \$100 Billion in 2014 per *IMS Health***
- **Oncology will keep growing to \$153.1 Billion in 2020 per *Evaluate Pharma***
- **CAGR in global cancer drug spending jumped to 6.5% during the past 5 years and projected to be 8% in 2018, per *IMS Health***
- **ScinoPharm's oncology emphasis echoes the global therapy trend**

# Oncology as US FDA Approval Focus

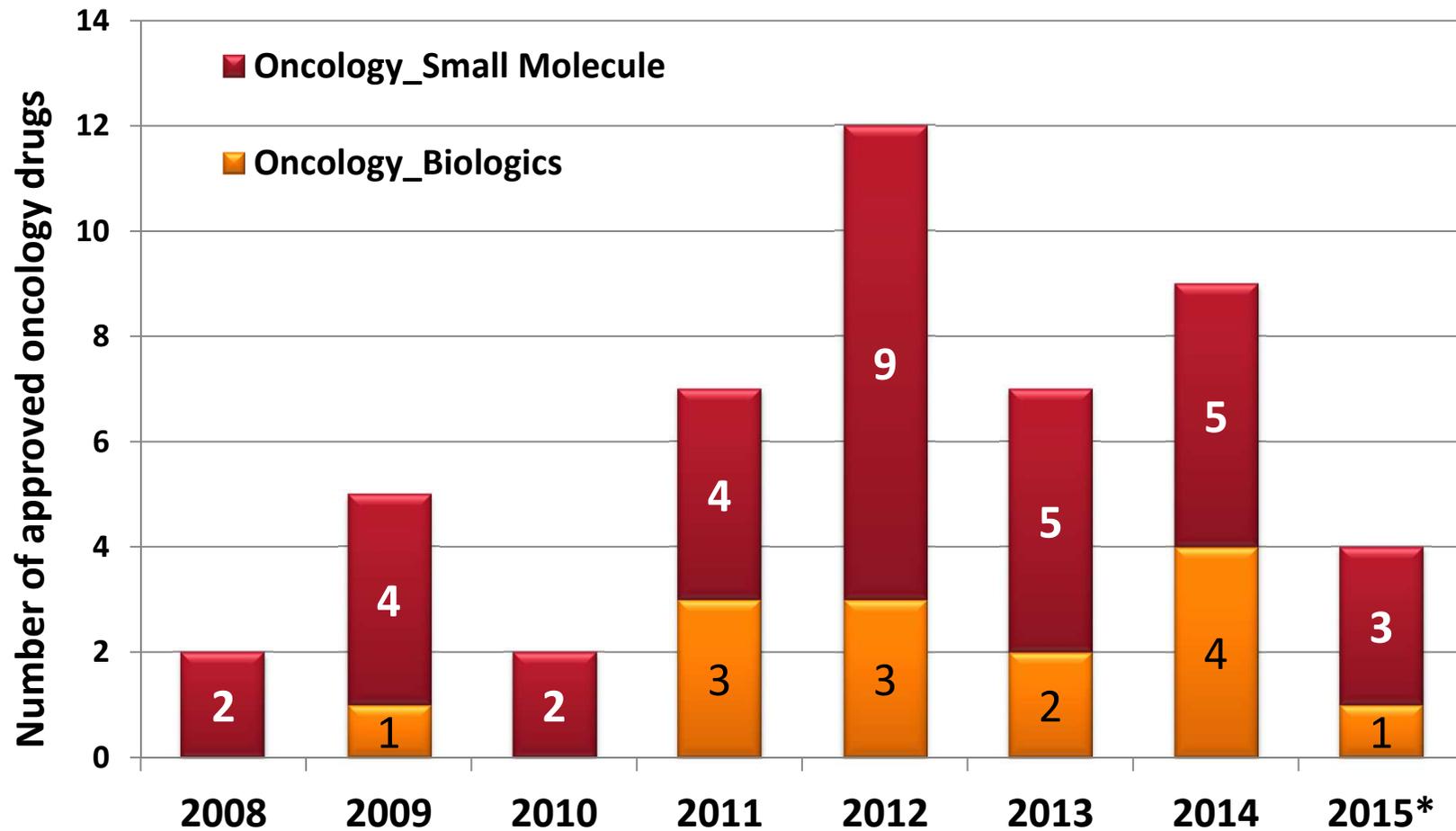
- Approved in oncology more than in other therapies



Note: \*: as of 2015/4/20 \*\* The number of oncology products is not including radioactive drugs Source: US FDA Website

# Small Molecules Still Oncology Mainstream

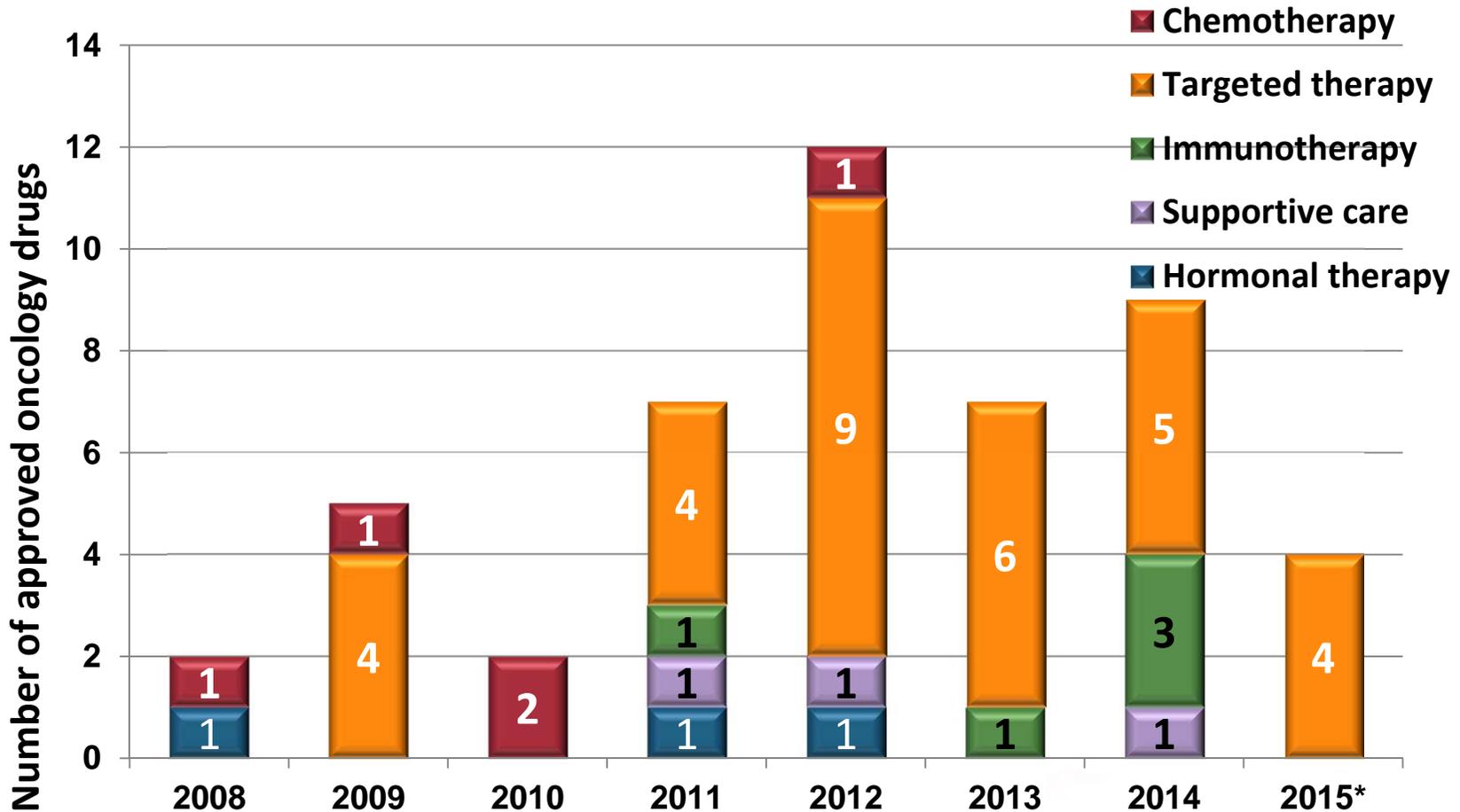
## ■ Oncology biologics increasing



Note: \* as of 2015/4/20 Source: US FDA Website

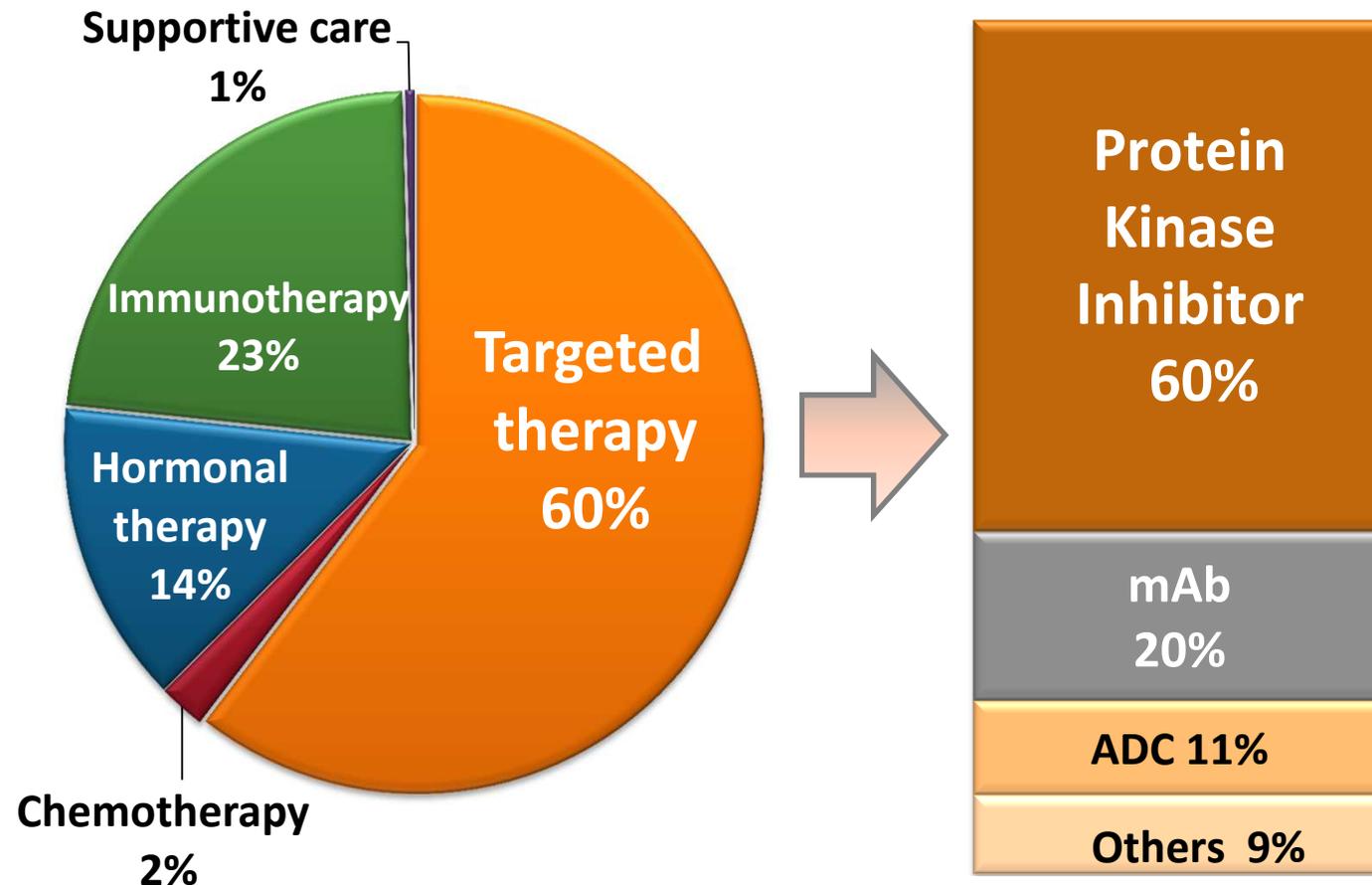
# Targeted & Immuno-therapies Flying

## ■ Chemo- and hormonal therapies declined



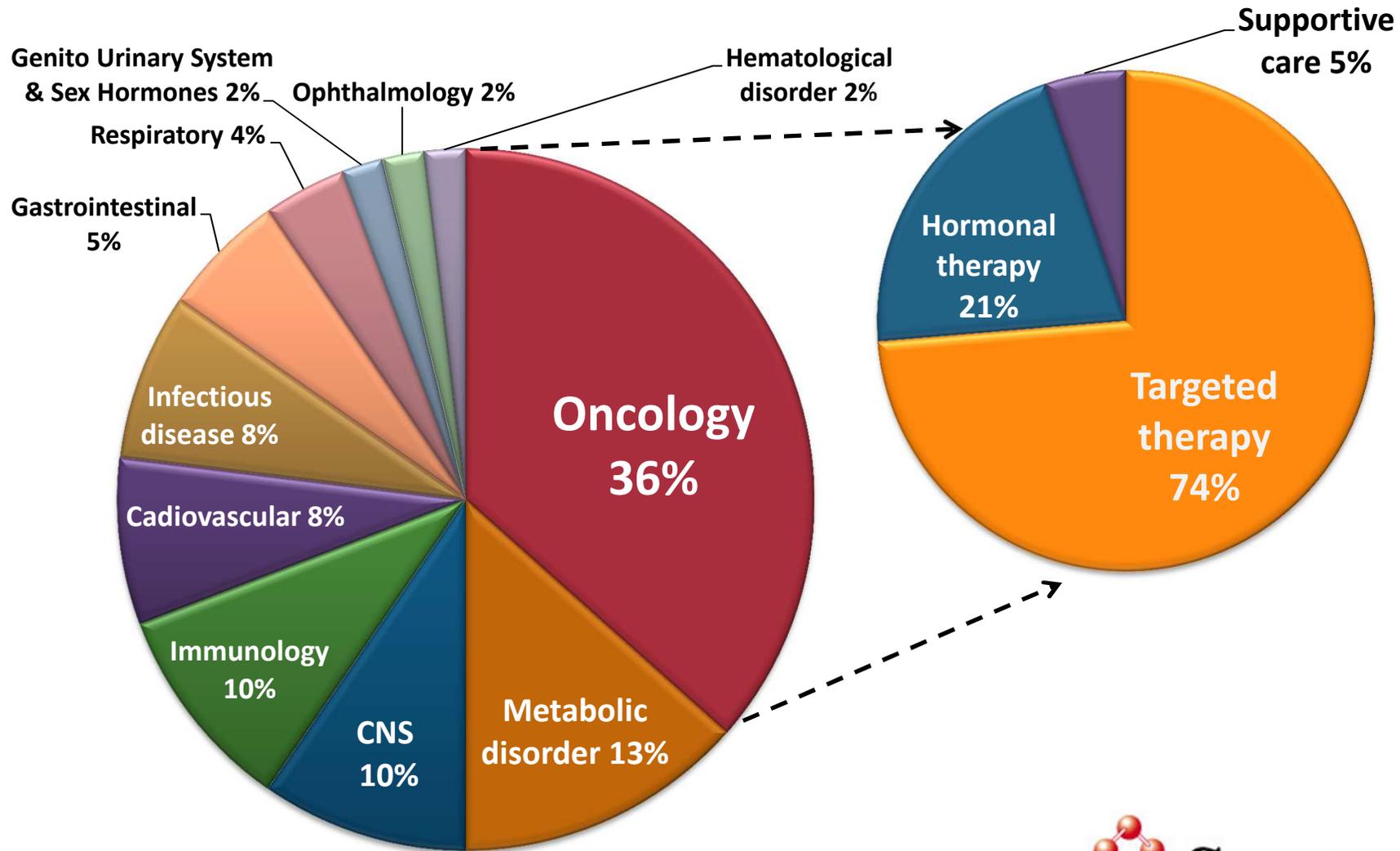
Note: \* as of 2015/4/20 Source: US FDA Website

# Targeted Therapy Dominates Oncology



Source: 2020 Sales Forecast, Global Data

# ScinoPharm Pipeline Echoes Therapy Trend



# 2015 Product Launch Plan

API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Azacitidine	US	MDS Oncology	Celgene	US\$323MM*	US\$815MM*
Benazepril	CN	Hypertension, CV	Novartis	US\$65MM**	US\$480MM*
Desmopressin	US	Polyuria	Ferring	US\$131MM*	US\$395MM*
✔ Letrozole	JP	Breast Cancer	Novartis	US\$51MM**	US\$581MM*
Tamsulosin	US	Benign prostatic hyperplasia (BPH)	Boehringer Ingelheim	US\$335MM*	US\$1,829MM*

Source: \* IMS Data (2013Q3-2014Q2) \*\* In-house research

✔ Launched



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**Q***uestions*

**&**

**A***nswers*



## Brand Quality with Asian Advantages

[www.scinopharm.com](http://www.scinopharm.com)