# First Quarter 2019 Financial Results

**Exelixis, Inc.**
**Nasdaq: EXEL**

**Wednesday, May 1, 2019**

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# Safe Harbor Statement

This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' belief that cabozantinb's best-in-class TKI profile can continue to drive strong growth in the face of emerging competition from ICI-based therapies; Exelixis' continued financial performance, including the growth of revenues from product sales, collaboration milestones and royalties, and rigorous management of expenses to generate free cash to reinvest in the business; Exelixis' commitment to staying focused and delivering on goals for both patients and stockholders; Exelixis' financial guidance for 2019 costs of goods sold, R&D and SG&A expenses (including non-cash expenses related to stock-based compensation), and effective tax rate, as well as Exelixis' expectations regarding deductions from gross sales for CABOMETYX and COMETRIQ and increased variability in wholesale buying patterns; RCC market trends and sequencing dynamics and the commercial potential for CABOMETYX in the RCC market; HCC market trends and the commercial potential for CABOMETYX in the HCC market; expectations for results of CheckMate 9ER in early 2020; Exelixis' plans for additional late-stage ICI combination trials, including potential bladder cancer and non-small cell lung cancer trials, as well as in potential tumor types from COSMIC-021 study; Exelixis' receipt of a $10.0 million milestone payment from Takeda in connection with Takeda's Japanese regulatory application seeking approval for cabozantinib as a treatment for advanced RCC; Exelixis' data-dependent clinical plans to include both single-agent and combination testing for XL092; presentations at the 2019 ASCO Annual Meeting featuring cabozantinib and cobimetinib as subjects and Exelixis' opportunity to connect with key opinion leaders and partners; the potential for Roche to submit additional regulatory filings for cobimetinib later in 2019, if data from the IMspire 150 TRILOGY and IMspire170 trials are supportive; Exelixis' belief that it is vectoring towards a billion dollar per year global run rate; and Exelixis' opportunity for long-term future potential growth through continued investment in R&D to expand Exelixis' product portfolio, including future additional cabozantinib label-enabling trials and the addition of new product candidates through both internal discovery and business development efforts. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and are based upon Exelixis' current plans, assumptions, beliefs, expectations, estimates and projections. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include, without limitation: the degree of market acceptance of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO in the territories where they are approved, and Exelixis' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX, COMETRIQ, COTELLIC and MINNEBRO in comparison to competing products; the level of costs associated with Exelixis' commercialization, research and development, in-licensing or acquisition of product candidates, and other activities; the potential failure of cabozantinib, cobimetinib, esaxerenone and other Exelixis product candidates, both alone and in combination with other therapies, to demonstrate safety and/or efficacy in clinical testing; uncertainties inherent in the drug discovery and product development process; Exelixis' dependence on its relationships with its collaboration partners, including their pursuit of regulatory approvals for partnered compounds in new indications, their adherence to their obligations under relevant collaboration agreements and the level of their investment in the resources necessary to complete clinical trials or successfully commercialize partnered compounds in the territories where they are approved; risks and uncertainties related to regulatory review and approval processes, including that regulatory authorities may not approve Exelixis' products as treatments for the indications in which approval has been sought; Exelixis' continuing compliance with applicable legal and regulatory requirements; unexpected concerns that may arise as a result of the occurrence of adverse safety events or additional data analyses of clinical trials evaluating cabozantinib, cobimetinib or esaxerenone; Exelixis' dependence on third-party vendors for the manufacture and supply of its products; Exelixis' ability to protect its intellectual property rights; market competition, including the potential for competitors to obtain approval for generic versions of Exelixis' marketed products; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 2019, and in Exelixis' future filings with the SEC. All forward-looking statements in this presentation are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein.

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# Today's Agenda

| | |
|---|---|
| **Introduction** | **Susan Hubbard**<br>EVP, Public Affairs and Investor Relations |
| **Overview** | **Michael M. Morrissey, Ph.D.**<br>President and CEO |
| **Financial Results & Guidance** | **Chris Senner**<br>EVP and CFO |
| **Commercial Update** | **PJ Haley**<br>SVP, Commercial |
| **Development Update** | **Gisela Schwab, M.D.**<br>President, Product Development and Medical Affairs and CMO |
| **Q&A** | All, joined by:<br>**Peter Lamb, Ph.D.**<br>EVP, Scientific Strategy and CSO |

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# Overview

## Michael M. Morrissey, Ph.D.

President and CEO

# First Quarter 2019 Highlights

## Growth in Revenues, Earnings and Cash

Cabozantinib net franchise revs of ~$180M; Non-GAAP net income of $85.5M or $0.27/share diluted; Cash* $1.02B

## Continued CABOMETYX® Performance

Maintained leadership as best-in-class TKI for advanced RCC; Notable traction in 2L and 3L HCC

## Clinical Progress

Four pivotal trials of cabozantinib in single agent and combination regimens, incl. COSMIC-313 announced today

## Ongoing Discovery and BD Efforts

Phase 1 trial of XL092 underway; additional discovery and BD activities to bring new assets into the pipeline

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***On a mission to help patients with cancer recover stronger and live longer***

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**Includes cash and cash equivalents, short- and long-term investments, and long-term restricted cash and investments.*

*TKI = tyrosine kinase inhibitor; RCC = renal cell carcinoma; 2L = second-line; 3L = third-line HCC = hepatocellular carcinoma*
*BD = business development*

# Strong Performance in an Evolving Landscape


- Seek to grow revenues from product sales, collaboration milestones and royalties, while rigorously managing our expenses
- Generate free cash to reinvest in our business to build long-term, sustainable growth
- Committed to staying focused and delivering on our goals for patients and stockholders

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# Financial Update

Chris Senner

EVP and CFO

# GAAP Financial Highlights: Q1'19

*(in millions, except per share amounts)*

| | Q1'18 | Q4'18 | Q1'19 | YoY Delta | QoQ Delta |
|---|---|---|---|---|---|
| **Total revenues** | **$213.7 M** | **$228.6 M** | **$215.5 M** | **+1%** | **-6%** |
| **Cost of goods sold** | $5.6 M | $7.4 M | $7.5 M | +33% | +2% |
| **R&D expenses *** | $37.8 M | $57.3 M | $63.3 M | +68% | +11% |
| **SG&A expenses *** | $54.0 M | $52.4 M | $60.1 M | +11% | +15% |
| **Total operating expenses** | **$97.4 M** | **$117.0 M** | **$130.9 M** | **+34%** | **+12%** |
| **Other income (expense), net** | $2.1 M | $4.8 M | $6.1 M | +196% | +28% |
| **Provision for income taxes** | $(2.5) M | $243.7 M | $(14.9) M | +493% | -106% |
| **Net income** | $115.9 M | $360.1 M | $75.8 M | -35% | -79% |
| **Net income per share, diluted** | **$0.37** | **$1.15** | **$0.24** | **-35%** | **-79%** |
| **Ending cash and investments **** | **$525.6 M** | **$851.6 M** | **$1,019.4 M** | **+94%** | **+20%** |

*Amounts may not sum due to rounding.*
** R&D = Research and development; SG&A = Selling, general and administrative*
*** Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments.*

# Non-GAAP Financial Highlights: Q1'19

*(in millions, except per share amounts)*

| | Q1'18 | Q4'18 | Q1'19 | YoY Delta | QoQ Delta |
|---|---|---|---|---|---|
| **Total revenues** | **$213.7 M** | **$228.6 M** | **$215.5 M** | **+1%** | **-6%** |
| **Cost of goods sold** | $5.6 M | $7.4 M | $7.5 M | +33% | +2% |
| **R&D expenses** [(a)] | $34.8 M | $53.3 M | $59.0 M | +70% | +11% |
| **SG&A expenses** [(a)] | $47.7 M | $44.1 M | $51.9 M | +9% | +18% |
| **Total operating expenses** [(a)] | **$88.1 M** | **$104.7 M** | **$118.4 M** | **+34%** | **+13%** |
| **Other income (expense), net** | $2.1 M | $4.8 M | $6.1 M | +196% | +28% |
| **Provision for income taxes** [(a)] | $(2.7) M | $(0.6) M | $(17.7) M | +552% | N.M.* |
| **Net income** [(a)] | $125.0 M | $128.1 M | $85.5 M | -32% | -33% |
| **Net income per share, diluted** [(a)] | **$0.40** | **$0.41** | **$0.27** | **-32%** | **-34%** |
| **Ending cash and investments **** | **$525.6 M** | **$851.6 M** | **$1,019.4 M** | **+94%** | **+20%** |

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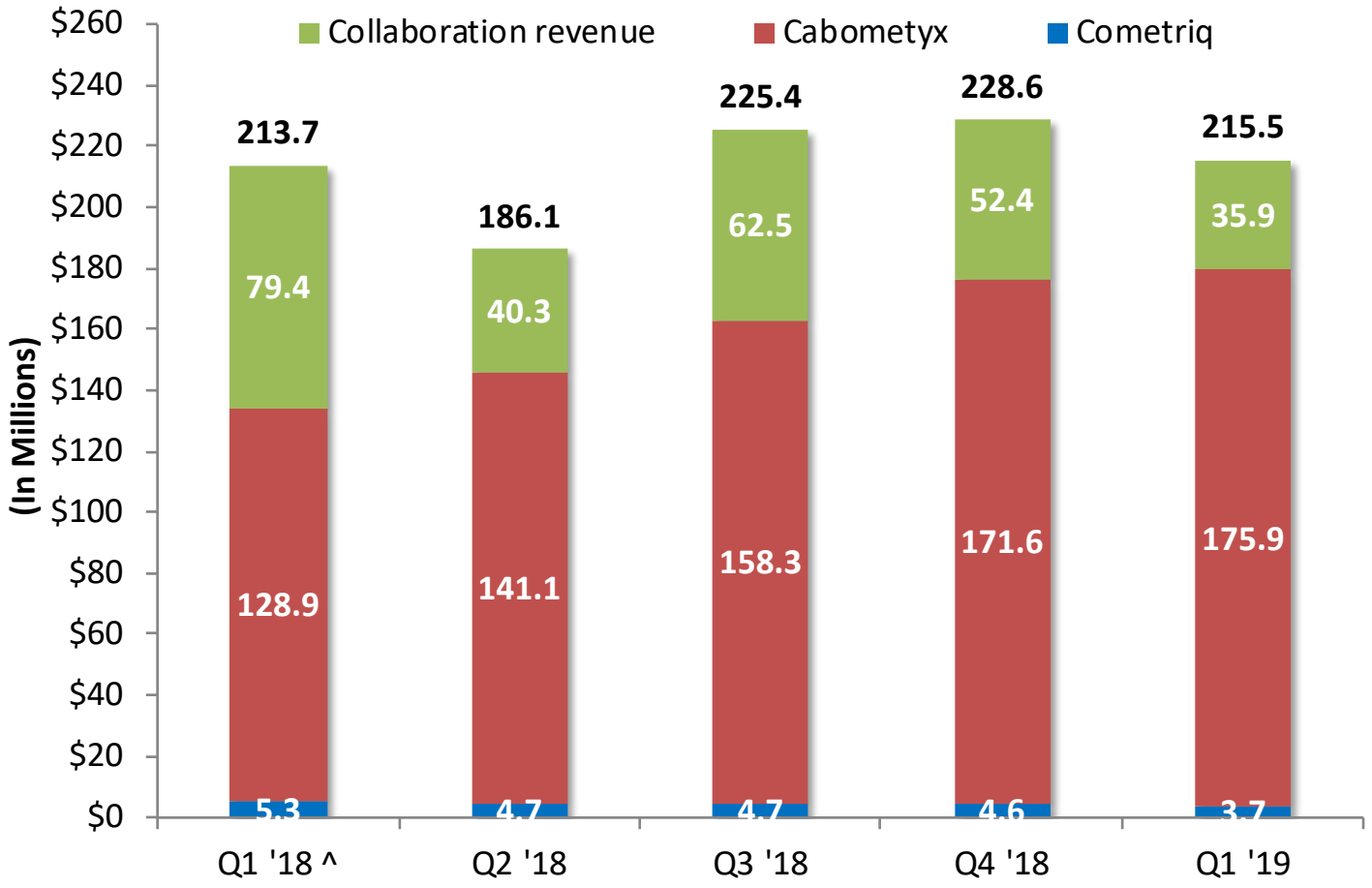
(a) *A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.*
*Amounts may not sum due to rounding.*
** N.M. = Not meaningful*
*** Cash and investments include cash and cash equivalents, short- and long-term investments and short- and long-term restricted cash and investments.*

# Q1’19 Total Revenue

*(See press release at www.exelixis.com for full details)*



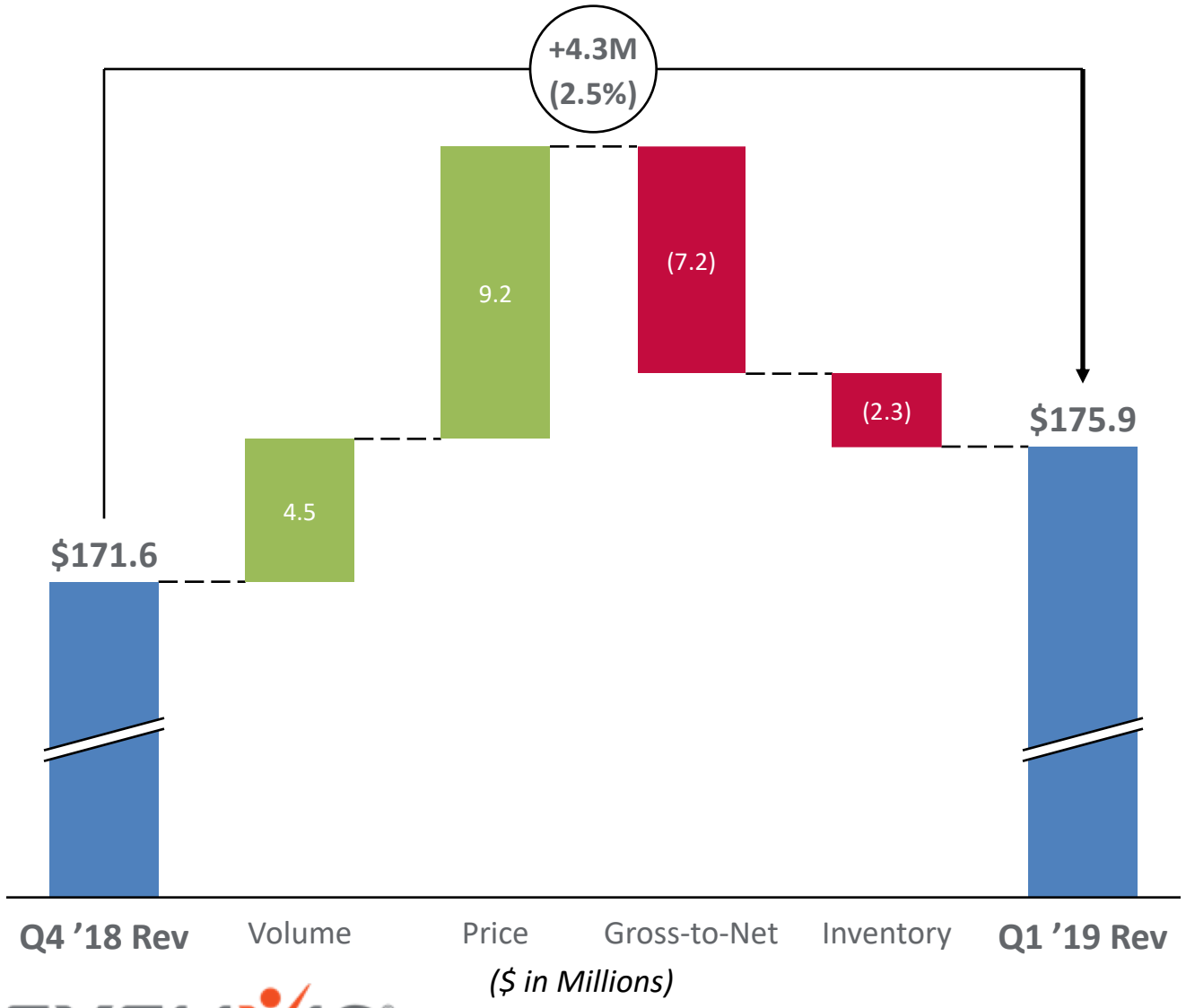

## Q1’19 Notes

- Total revenues of $215.5M
- $179.6M in Net product revenues, including $175.9M in CABOMETYX and $3.7M in COMETRIQ net product revenues
- Collaboration revenue for Q1’19 include:
  - $14.0M in Royalties from Ipsen
  - $9.4M in a Milestone from Takeda
  - $2.5M in COTELLIC Profit Share & Royalties
  - $10.0M in license, R&D reimbursement, and product supply

*Amounts may not sum due to rounding.*

*^ Q1 2018 financial results as reported on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 2018, were adjusted to conform to current period presentation resulting in an increase to both Collaboration revenue and Selling, general and administrative expense by $1.4M related to the COTELLIC U.S. Profit Share agreement with Roche. There was no impact to Net Income or Net income per share, basic and diluted.*

# CABOMETYX U.S. Net Revenue Q1’19 vs. Q4’18




*($ in Millions)*

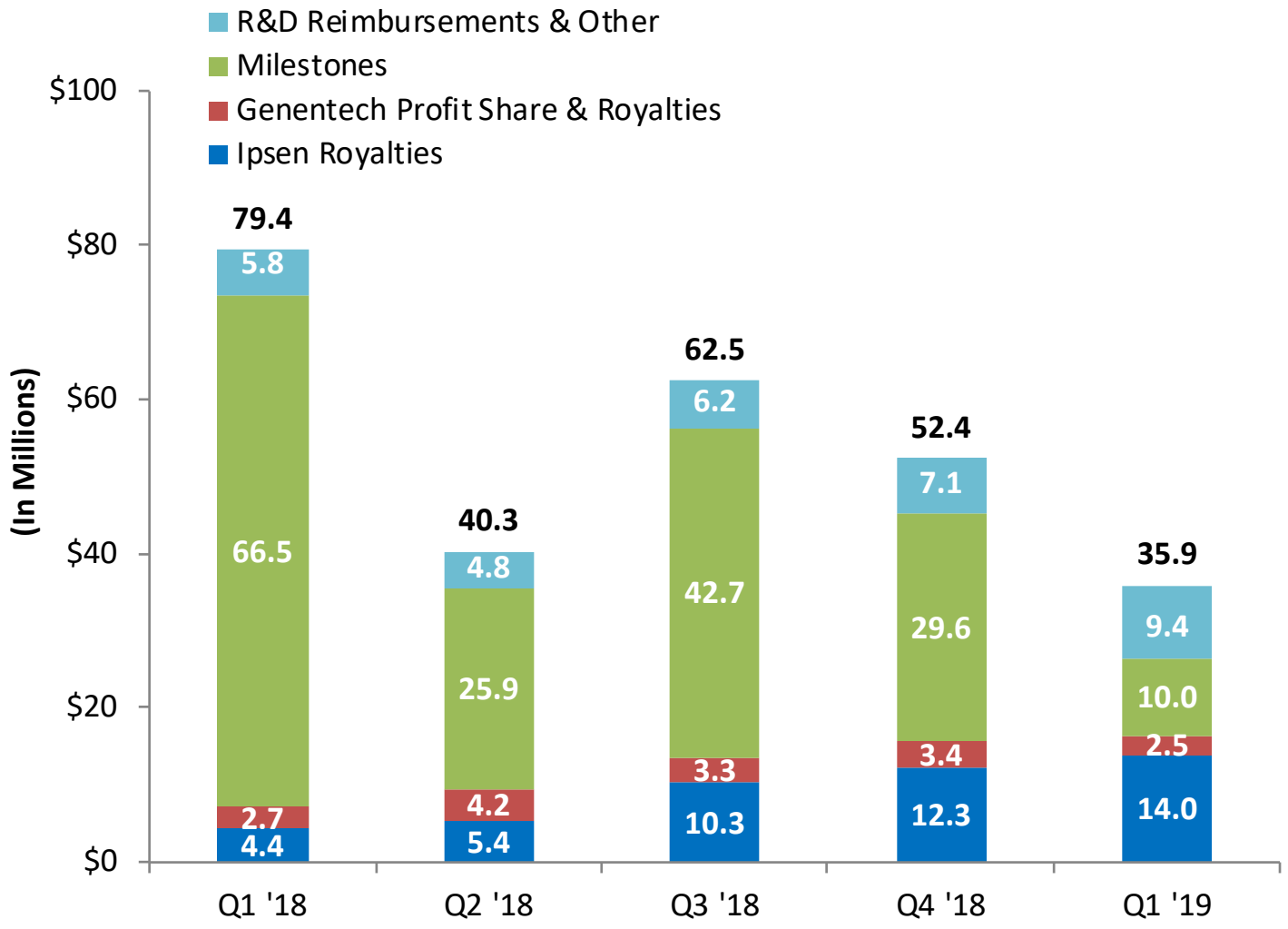
*Amounts may not sum due to rounding.*

## Notes

- Q1’19 growth of $4.3M over Q4’18
- ~$4.5M increase in CABOMETYX volume
  - Unit volume up ~3% for Q1’19 over Q4’18
- ~$9.2M increase due to price increase
  - 5% increase taken January '19
- ~$7.2M decrease from higher Gross-to-Net discounts and allowances:
  - Q1’19 Gross-to-Net of 19.8%, up from 17.4% in Q4’18
  - Driven by higher Public Health Service utilization and discount, and Medicare Part D coverage gap
- ~$2.3M decrease in wholesaler inventory
  - Inventory weeks on hand of ~2.6 for Q1’19, down from ~2.9 in Q4’18

# Collaboration Revenue Detail

*(See press release at www.exelixis.com for full details)*



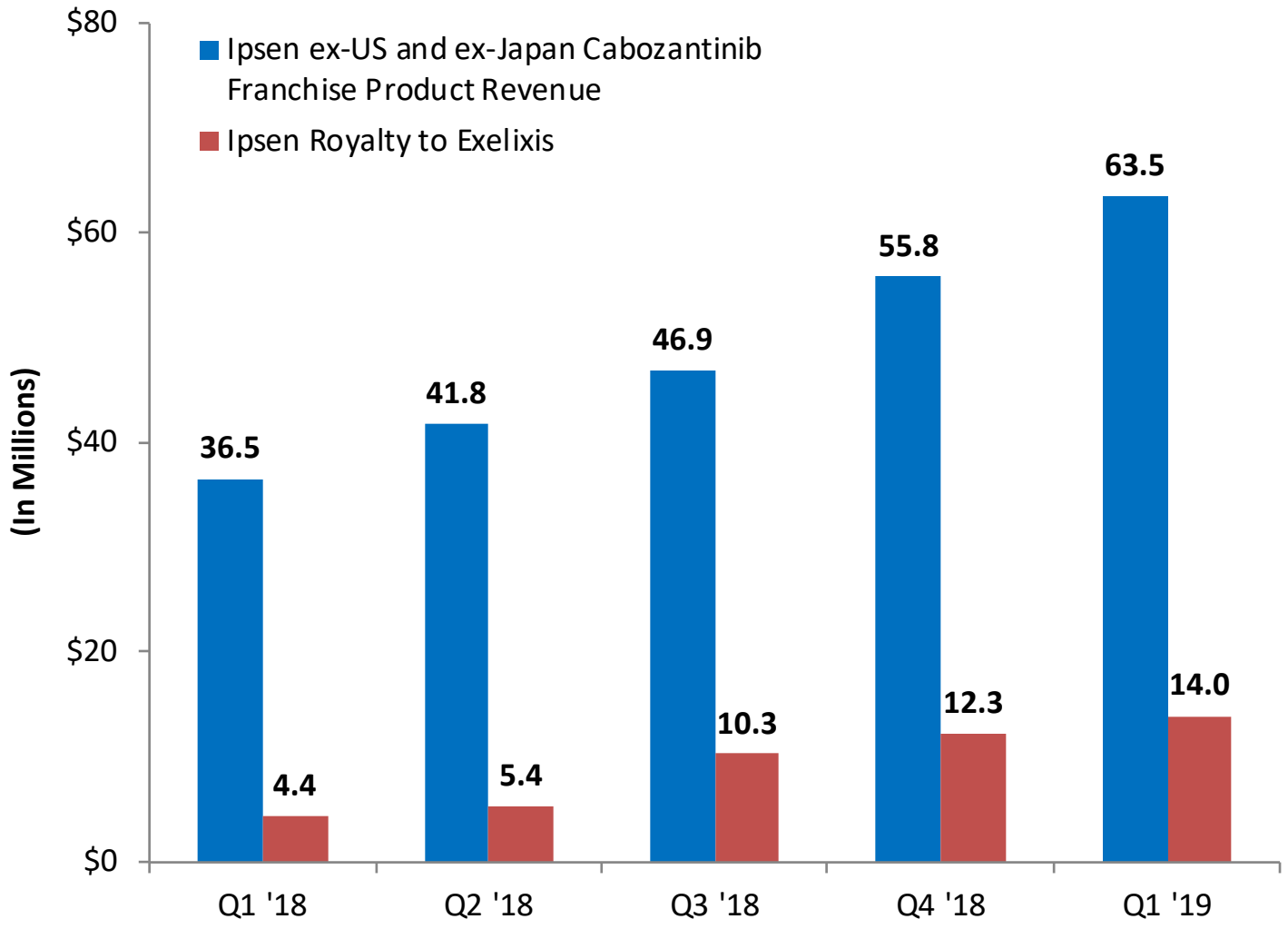

## Q1'18 – Q1'19 Notes

- Ipsen Royalty rates:
  - ~12% in 1H'18
  - 22% in 2H'18
  - 22% in Q1'19
- Genentech Collaboration:
  - Q1'19 ex-US Cotellic Royalties $1.5M
  - Q1'19 Genentech US Profit Share $1.0M
- Major Milestones by Quarter
  - Q1'19: Takeda RCC Filing in Japan
  - Q4'18: Ipsen Ph 3 1L HCC Initiation, Takeda Ph 3 BMS 9ER Initiation
  - Q3'18: Ipsen HCC 2L EU Approval, Ipsen RCC 2L Canada Approval
  - Q2'18: Ipsen Sales > $100M in four consecutive quarters
  - Q1'18: Ipsen RCC 1L EU Approval, Daiichi Sankyo NDA Acceptance

*Amounts may not sum due to rounding.*
*On January 1, 2018, we adopted Accounting Standards Codification Topic 606 which impacts the timing of revenue recognition related to contracts with our collaboration partners.*

# Ipsen Royalties

*(See press release at www.exelixis.com for full details)*




## Notes

- Q1'19 Ipsen ex-US and ex-Japan Cabozantinib franchise product revenue of ~$63.5M
- Q1'19 Ipsen royalty to Exelixis of $14.0M
- Ipsen royalty rates:
  - ~12% in 1H'18
  - 22% in 2H'18
  - 22% in Q1'19

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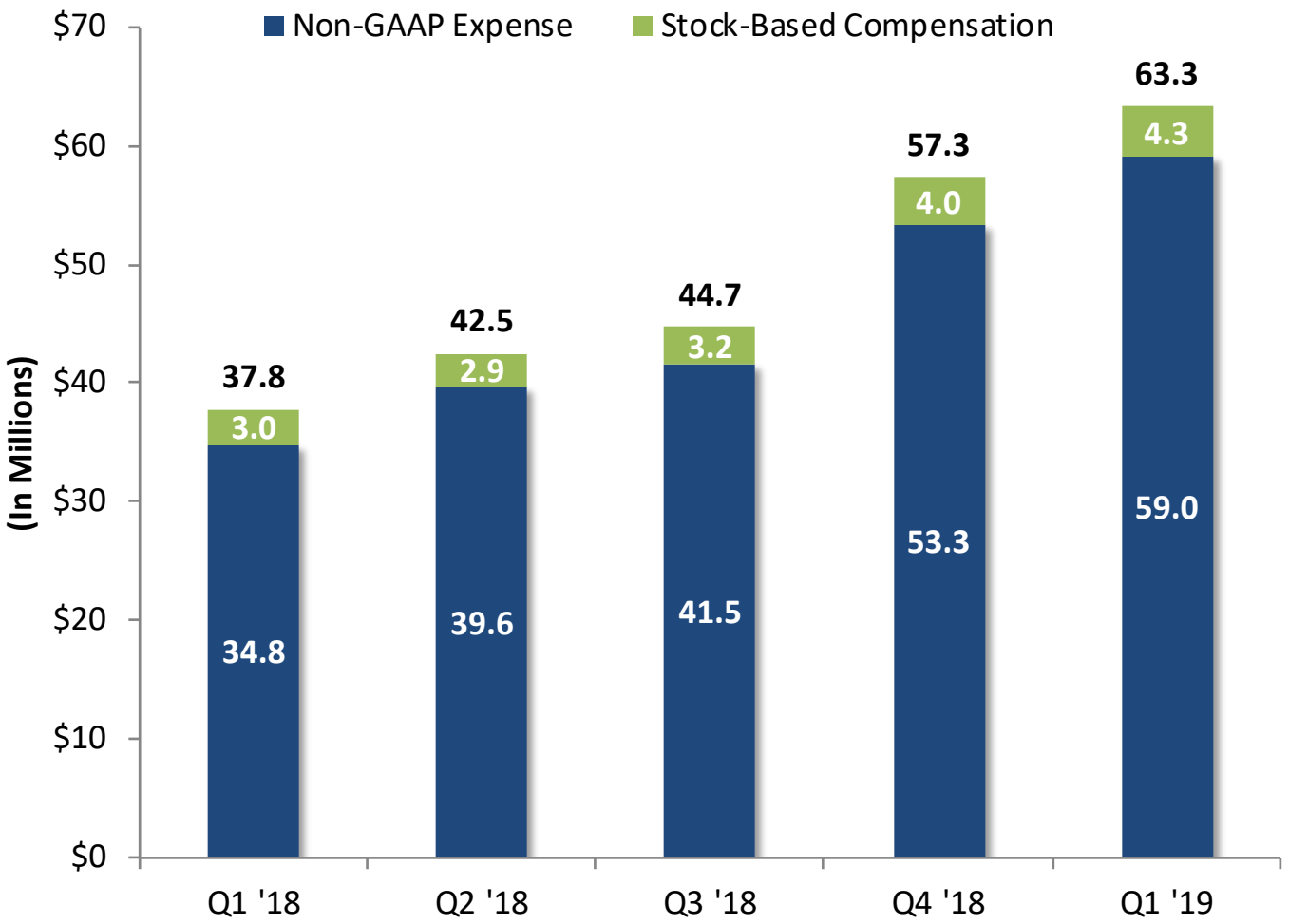
# Q1'19 R&D Expense

*(See press release at www.exelixis.com for full details)*




## Q1'19 Notes

- GAAP R&D expenses of $63.3M
- Non-GAAP R&D expenses of $59.0M (excl. stock-based compensation, before tax effect)
- Increase in R&D expenses vs. Q4'18 primarily a result of Invenra project fees and higher clinical trials spend
  - COSMIC-312
  - COSMIC-313
  - COSMIC-021
  - Checkmate 9ER

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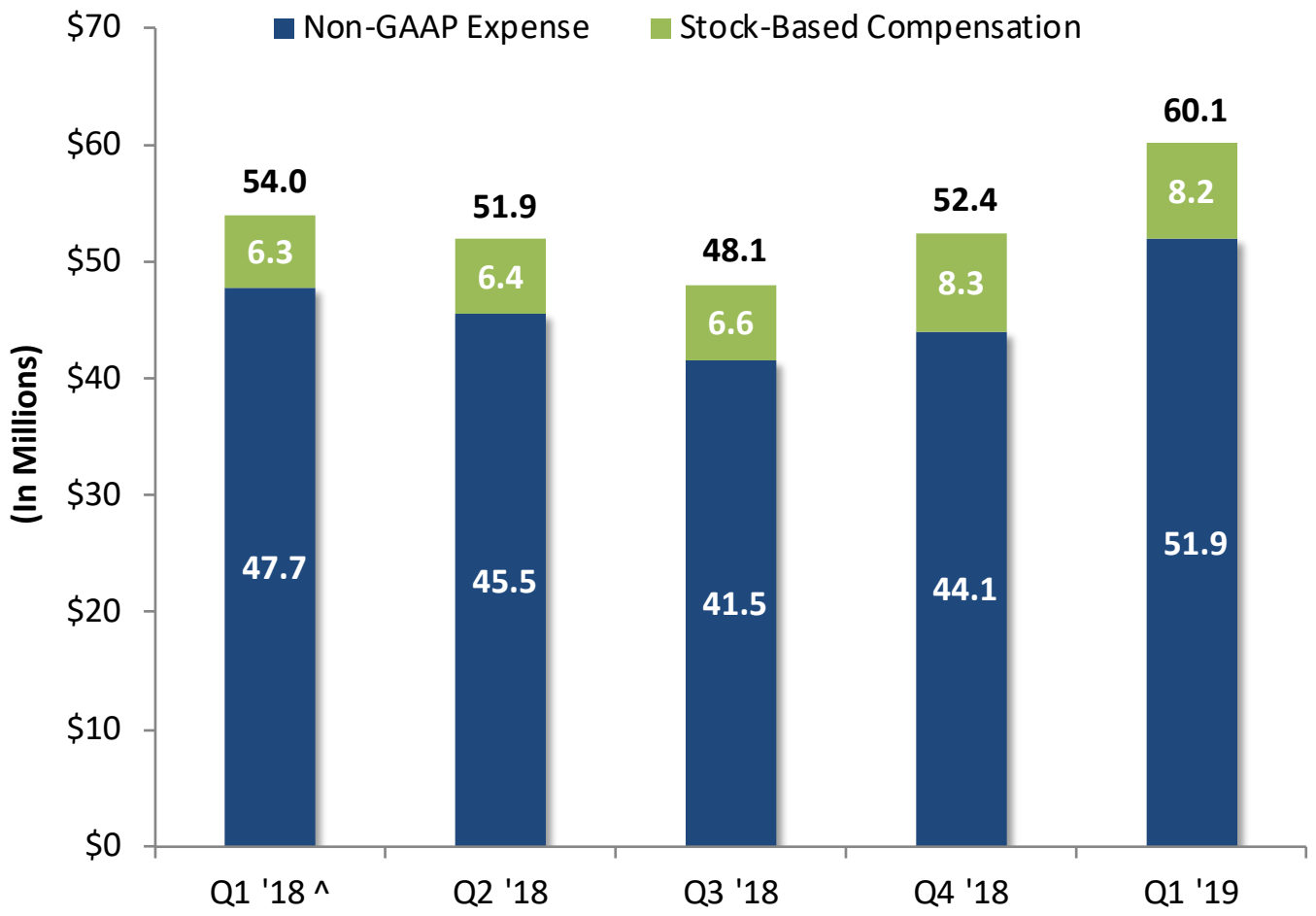
*Amounts may not sum due to rounding.*
*A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.*

# Q1'19 SG&A Expense

*(See press release at www.exelixis.com for full details)*



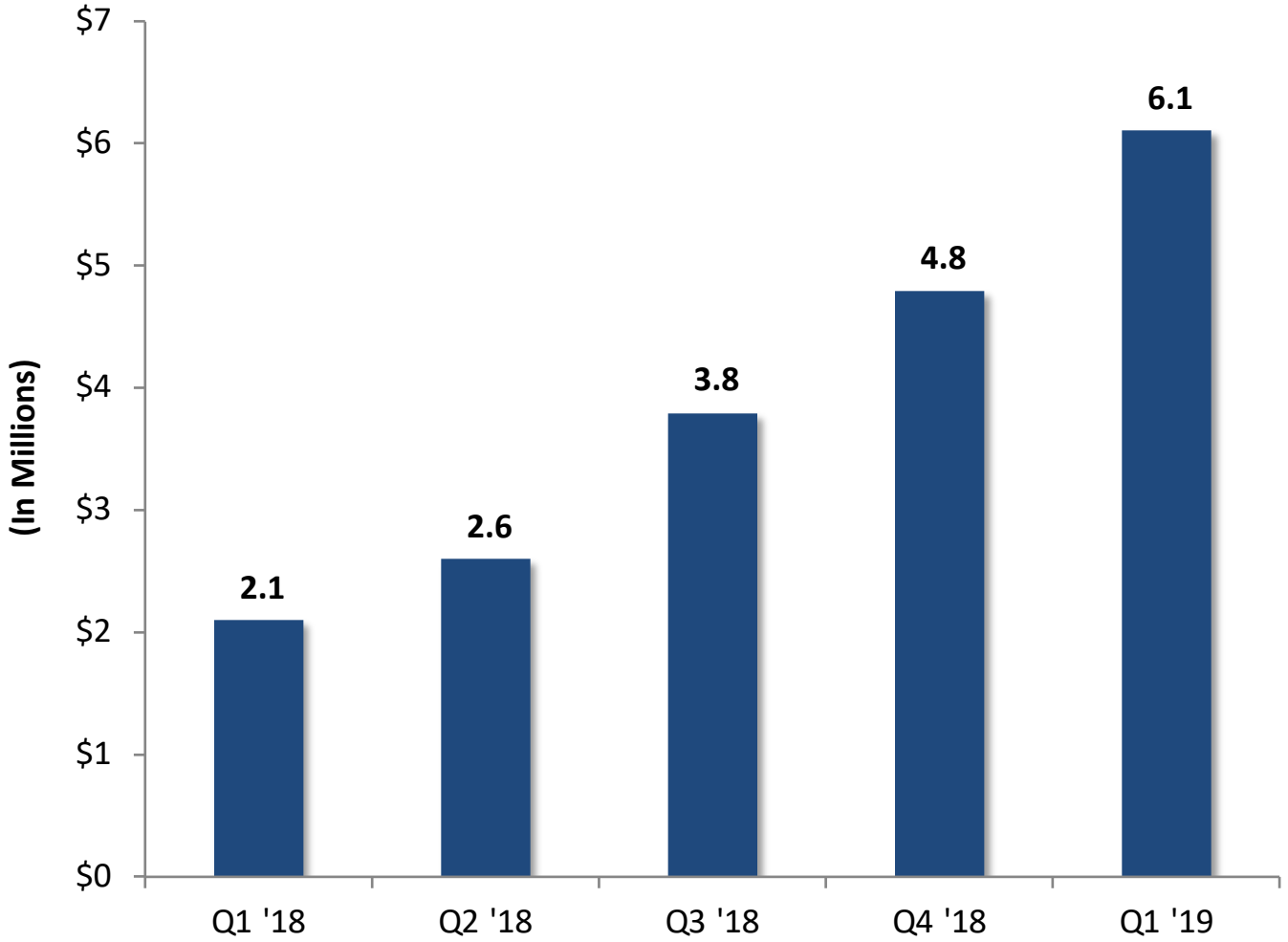

## Q1'19 Notes

- GAAP SG&A expenses of $60.1M
- Non-GAAP SG&A expenses of $51.9M (excl. stock-based compensation, before tax effect)
- Increase in SG&A expenses vs. Q4'18 is a result of higher corporate giving, branded prescription drug fees, headcount additions, and marketing

*Amounts may not sum due to rounding.*
*A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.*
*^ Q1 2018 financial results as reported on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 2, 2018, were adjusted to conform to current period presentation resulting in an increase to both Collaboration revenue and Selling, general and administrative expense by $1.4M related to the COTELLIC U.S. Profit Share agreement with Roche. There was no impact to Net Income or Net income per share, basic and diluted.*

# Q1'19 Other Income (Expense), net

*(See press release at www.exelixis.com for full details)*

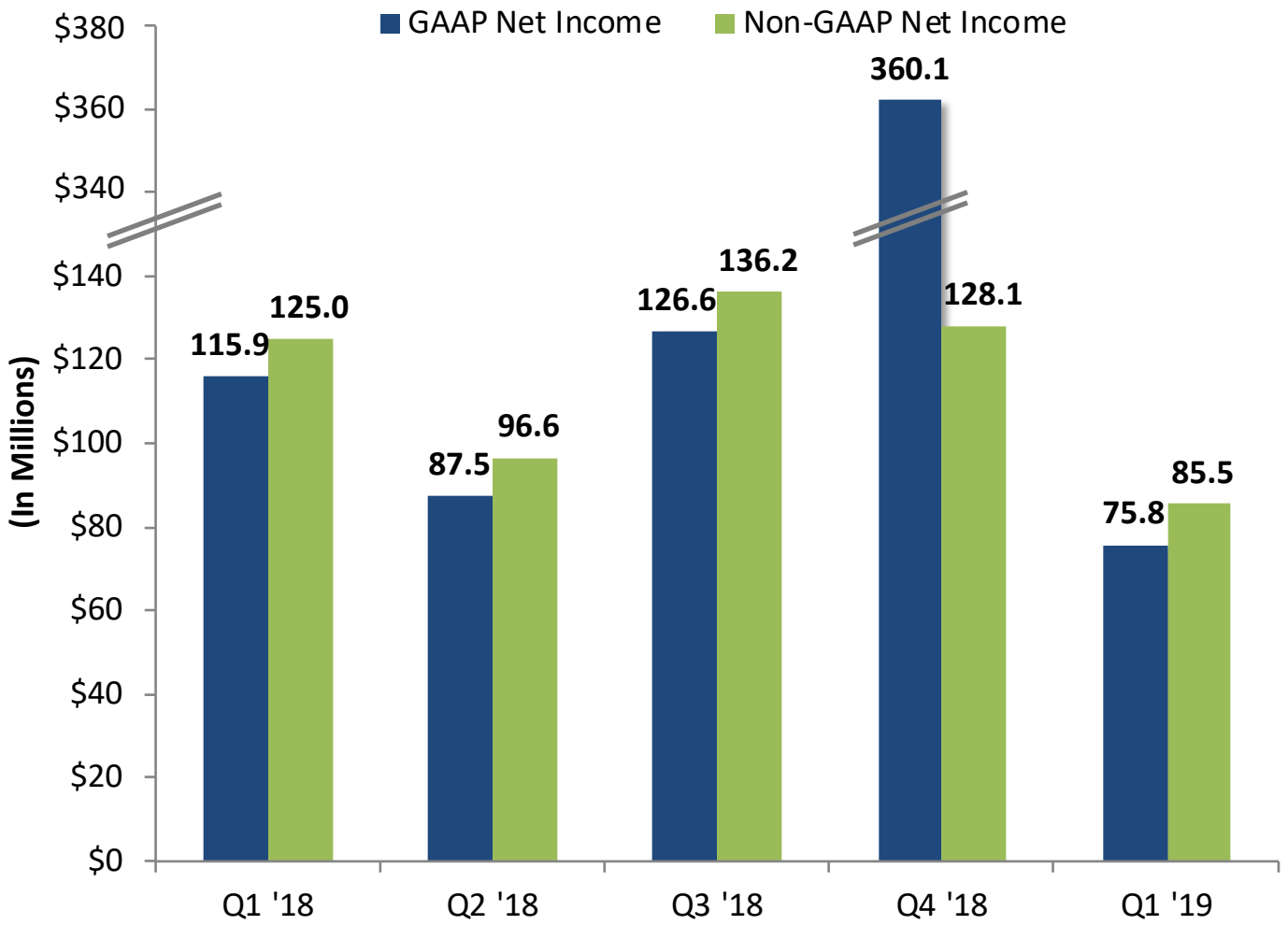



## Q1'19 Notes

- Other income (expense), net in Q1'19 reflects income of $6.1M, primarily driven by interest income from growing cash balance and higher yields
- Past five quarters primarily reflect interest income

# Q1'19 Net Income

*(See press release at www.exelixis.com for full details)*




## Q1'19 Notes

- GAAP Net income of $75.8M
- Non-GAAP Net income of $85.5M
- Non-GAAP Net income excludes stock-based compensation expense, net of tax effect
- Decrease in GAAP Net income vs. Q4'18 driven primarily by the release of the valuation allowance in Q4'18 associated with substantially all of the deferred tax assets (totaling $244.1M)
  - Q1'19 reflects the effects of recording tax expense without the offset of a valuation allowance

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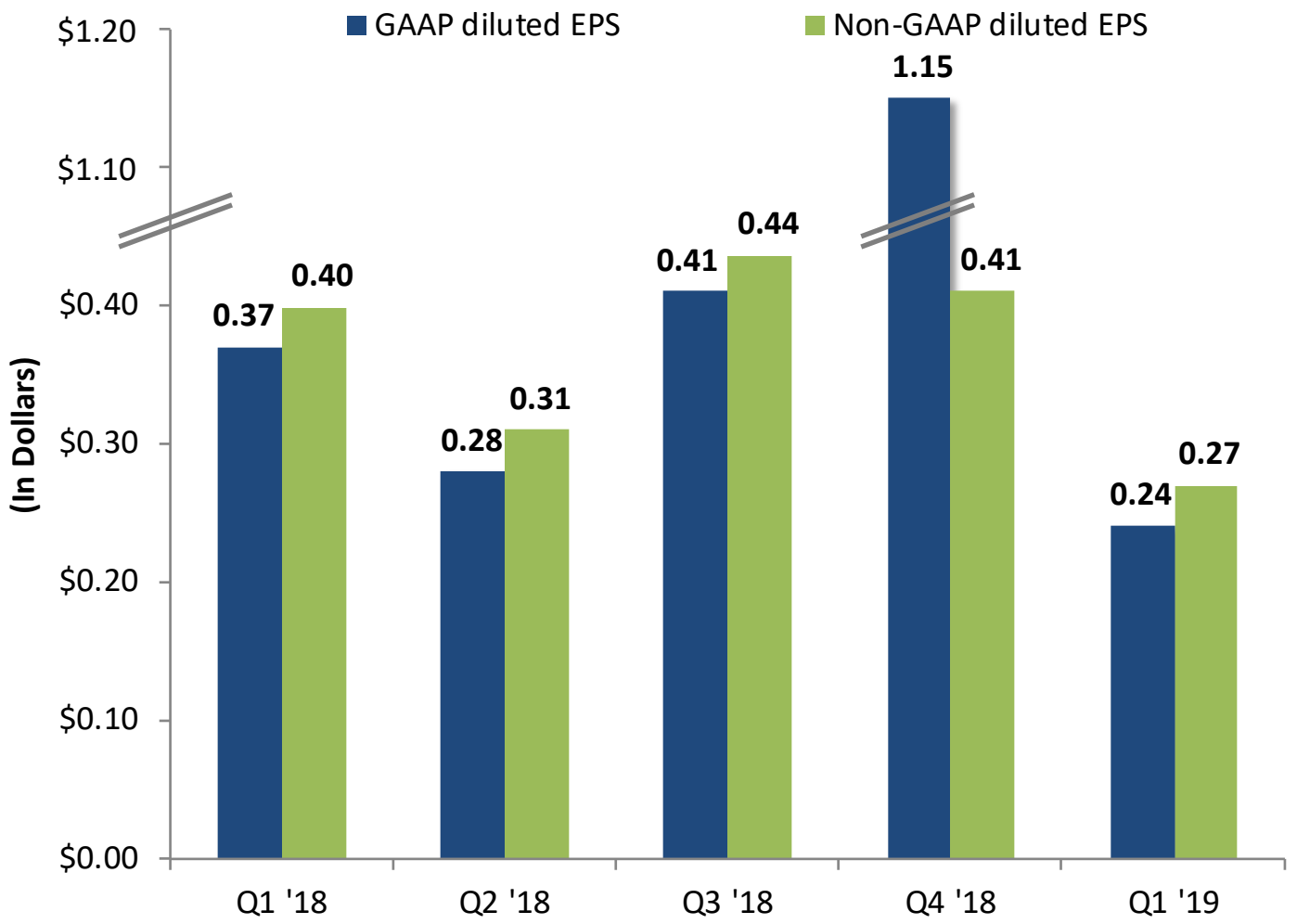
# Q1'19 Diluted Earnings Per Share

*(See press release at www.exelixis.com for full details)*




## Q1'19 Notes

- GAAP diluted EPS* of $0.24
- Non-GAAP diluted EPS of $0.27
- Non-GAAP diluted EPS excludes stock-based compensation expense, net of tax effect
- Decrease in GAAP diluted EPS vs. Q4'18 driven primarily by the release of the valuation allowance in Q4'18 associated with substantially all of the deferred tax assets
  - Q1'19 reflects the effects of recording tax expense without the offset of a valuation allowance

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**EPS = Net income per share*

# Cash and Guidance

## Cash at March 29, 2019: $1,019.4M*

- As compared to $851.6M at December 31, 2018

## 2019 GAAP Financial Guidance

- COGS**: 4 - 5% of Net product revenue
- R&D Expenses: $285M - $315M, which includes $20M in non-cash share-based compensation
- SG&A Expenses: $220M - $240M, which includes $35M in non-cash share-based compensation
- Tax rate: 21 - 23%

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** Includes cash and cash equivalents, short- and long-term investments and long-term restricted cash and investments.*
*** COGS = Cost of goods sold*

# Commercial Update

PJ Haley

SVP, Commercial

# CABOMETYX Q1'19 Performance

## Strong Q1'19 business fundamentals

- 17% Q/Q growth in NRx and 3% Q/Q growth in demand
- NRx growth outpacing total demand growth
- Prescriber base increased by 10% Q/Q and 53% Y/Y
- RCC and HCC contributing equally to growth in demand and new patient starts

## Continued growth in RCC

- Growth in RCC demand and new patient starts
- Stable 1L share and increasing 2L share
- Large potential remains from 1L Ipi+Nivo patients yet to progress to 2L
- Leading sales force share of voice in RCC


## Positive early signs in HCC

- HCC launch exceeding expectations in terms of market share and new prescriptions
- Large physician overlap with RCC and synergy being seen in the CABOMETYX franchise
- Strong unaided awareness and leading sales force share of voice in 2L+ HCC

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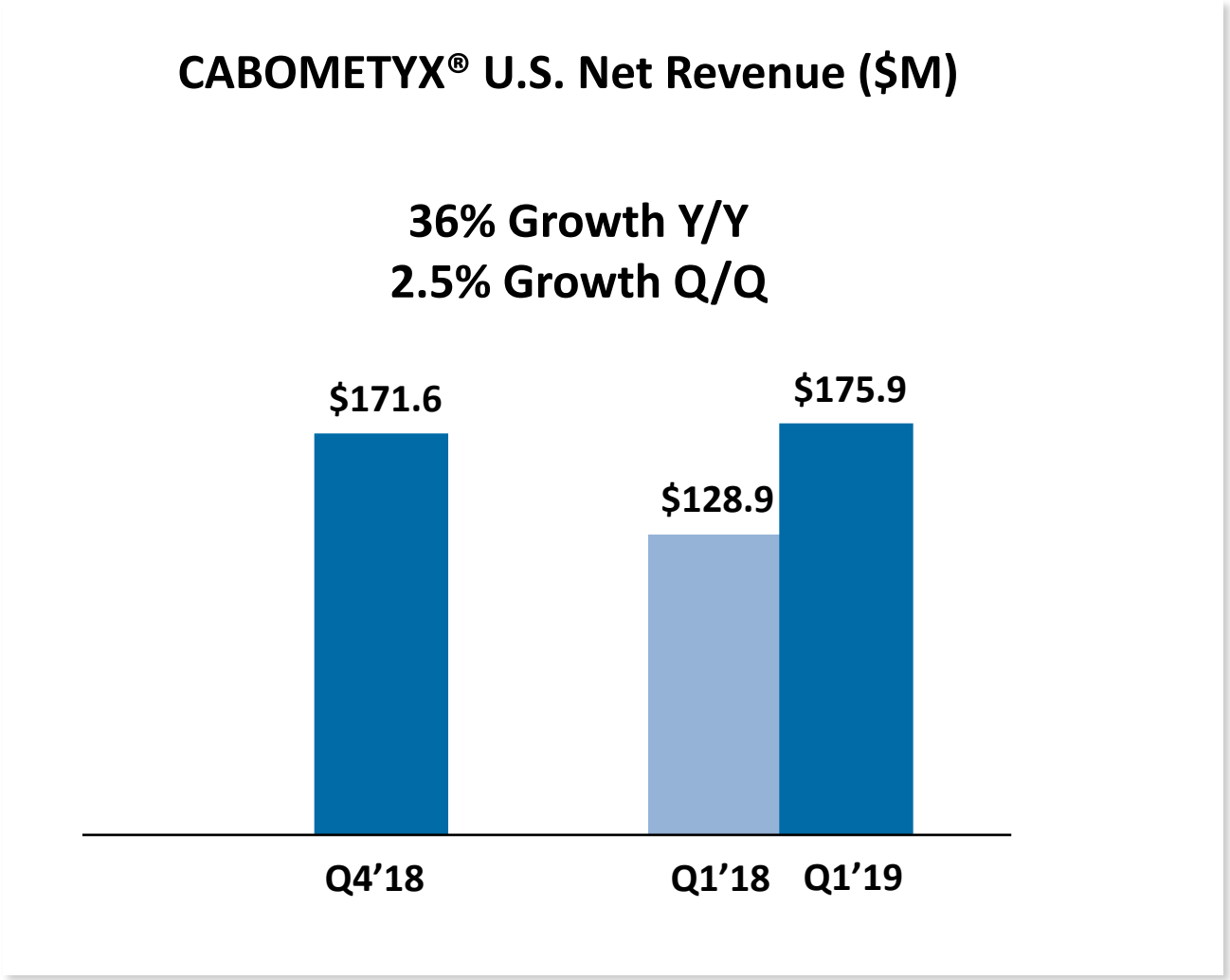
Sources: Exelixis Internal Data
IQVIA, IQVIA National Prescription Audit™, 03/2019
ZoomRX - February 2019

*NRx = new prescriptions; RCC = renal cell carcinoma; HCC = hepatocellular carcinoma; TKI = tyrosine kinase inhibitor*

# Cabozantinib Franchise Q1’19 U.S. Net Revenue: $179.6M




- Underlying product demand grew by 33% Y/Y and 3% Q/Q
- RCC and HCC contributed to nearly equal growth in demand and new patient starts during Q1’19
- Q1’19 net revenue growth impacted by inventory draw down, higher PHS utilization, and increase in Medicare coverage gap liability

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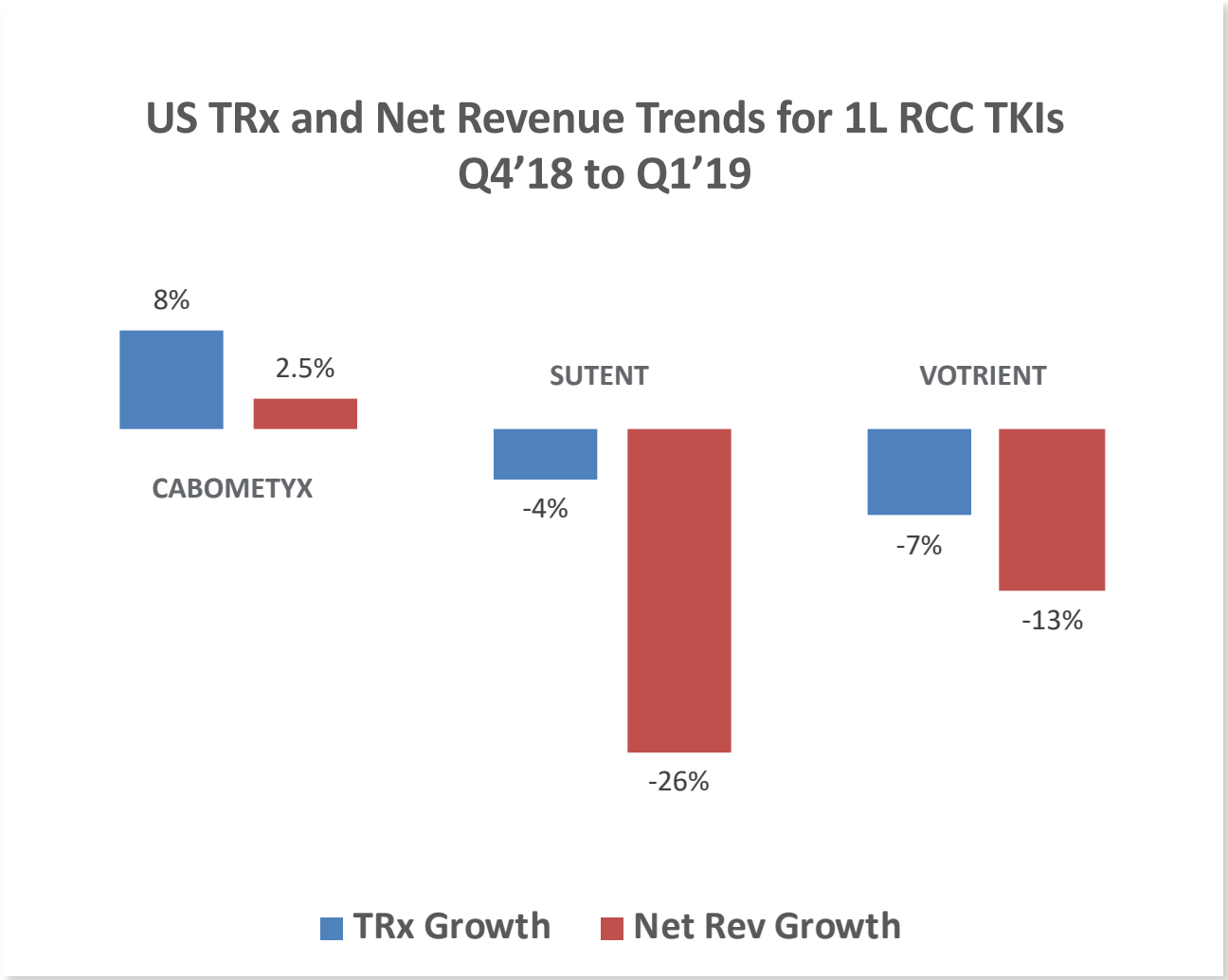
Sources: Exelixis Internal Data

*PHS = public health service*

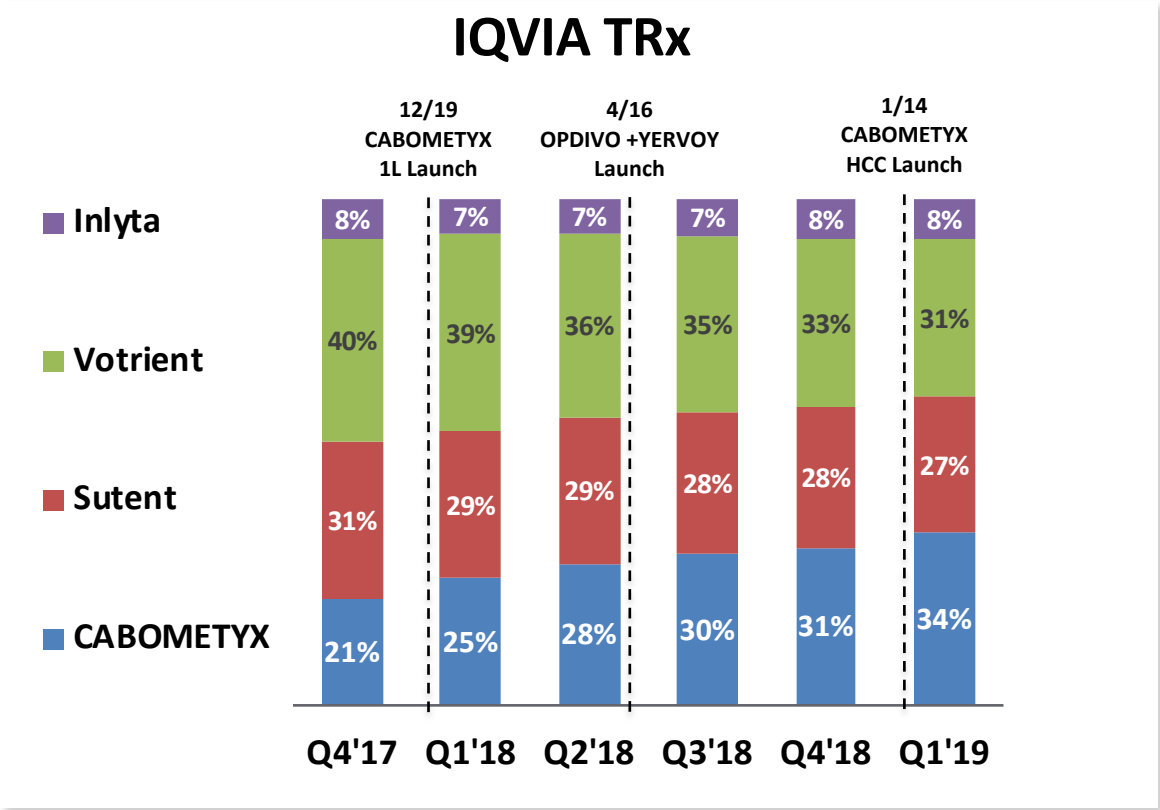
# Q1 2019 Industry Trends Impacted Reported Revenues

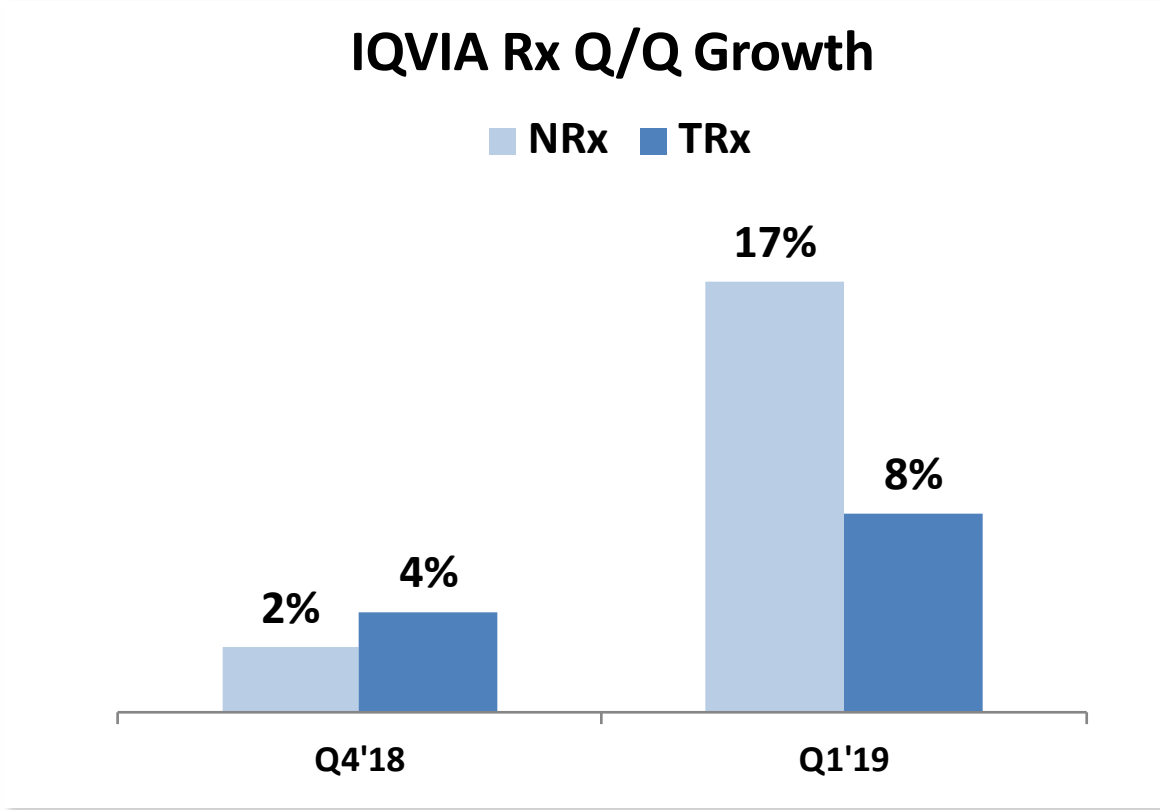



- Channel and end customer buying in Q4'18 increased year end inventory levels
- Increased Medicare Part D donut hole manufacturer responsibility: 50 to 70%

Sources: Exelixis Internal Data
IQVIA, IQVIA National Prescription Audit™, 03/2019
Q4'18 / Q1'19 Company earnings calls (includes all approved indications)
1L RCC TKI market defined as CABOMETYX, Sutent and Votrient, Rx data inclusive of all indications (not limited to RCC)

# CABOMETYX is the Leading TKI in RCC TRx and NRx



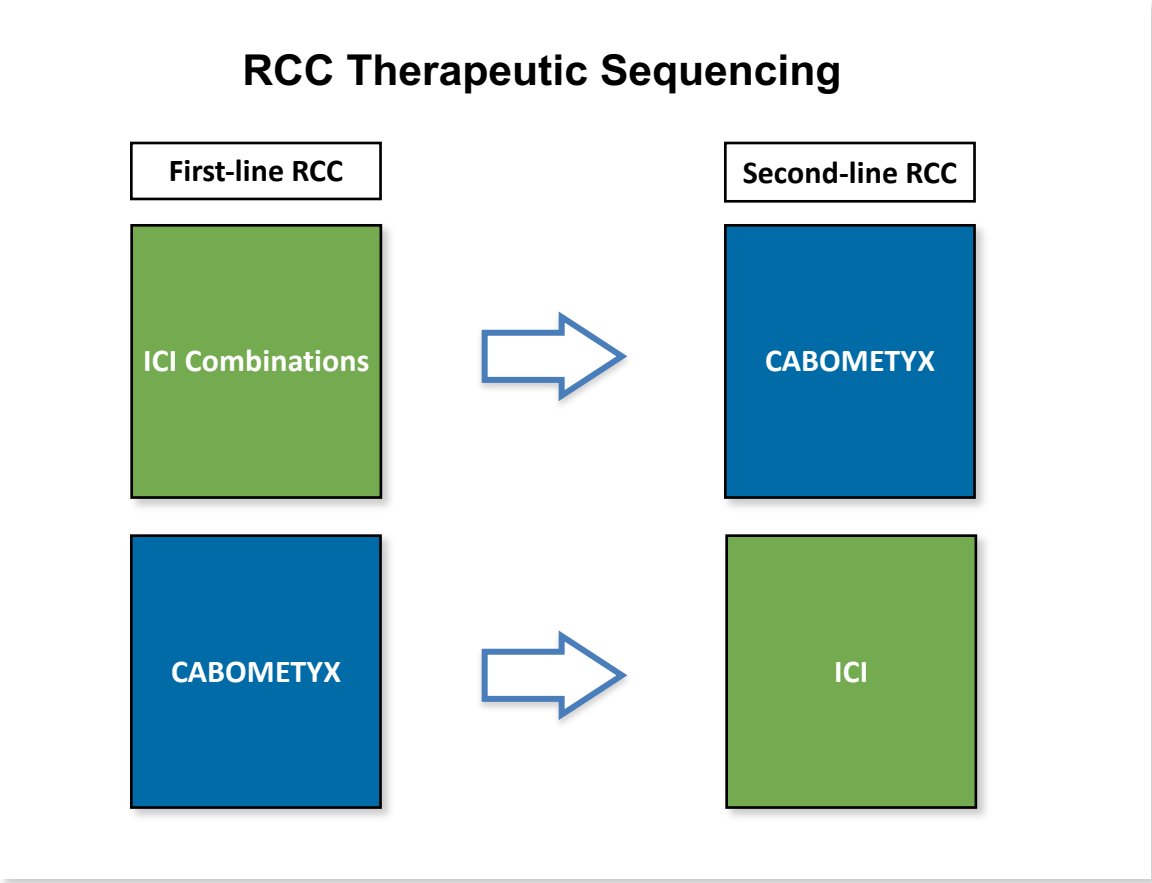




***NRx Growth Outpacing TRx Growth***

Sources: IQVIA, IQVIA National Prescription Audit™, 03/2019
TKI market defined as CABOMETYX, Inlyta, Sutent and Votrient, Rx data inclusive of all indications (not limited to RCC)

*TRx = total prescriptions; NRx = new prescriptions*

# RCC Therapeutic Sequencing Consistent with Expectations




- Stable 1L share and increasing 2L share
- Strong 2L adoption post Ipi+Nivo combination: CABOMETYX is capturing the majority of 1L Ipi+Nivo progressors
- Large group of 1L ICI patients yet to progress to 2L
- Strong academic and community support for CABOMETYX as TKI of choice after ICI combination

***Growth in CABOMETYX as More 2L Patients are ICI Experienced***

Sources: Exelixis Internal Data
IQVIA, IQVIA National Prescription Audit™, 03/2019
IQVIA, IQVIA BrandImpact, 2/2019

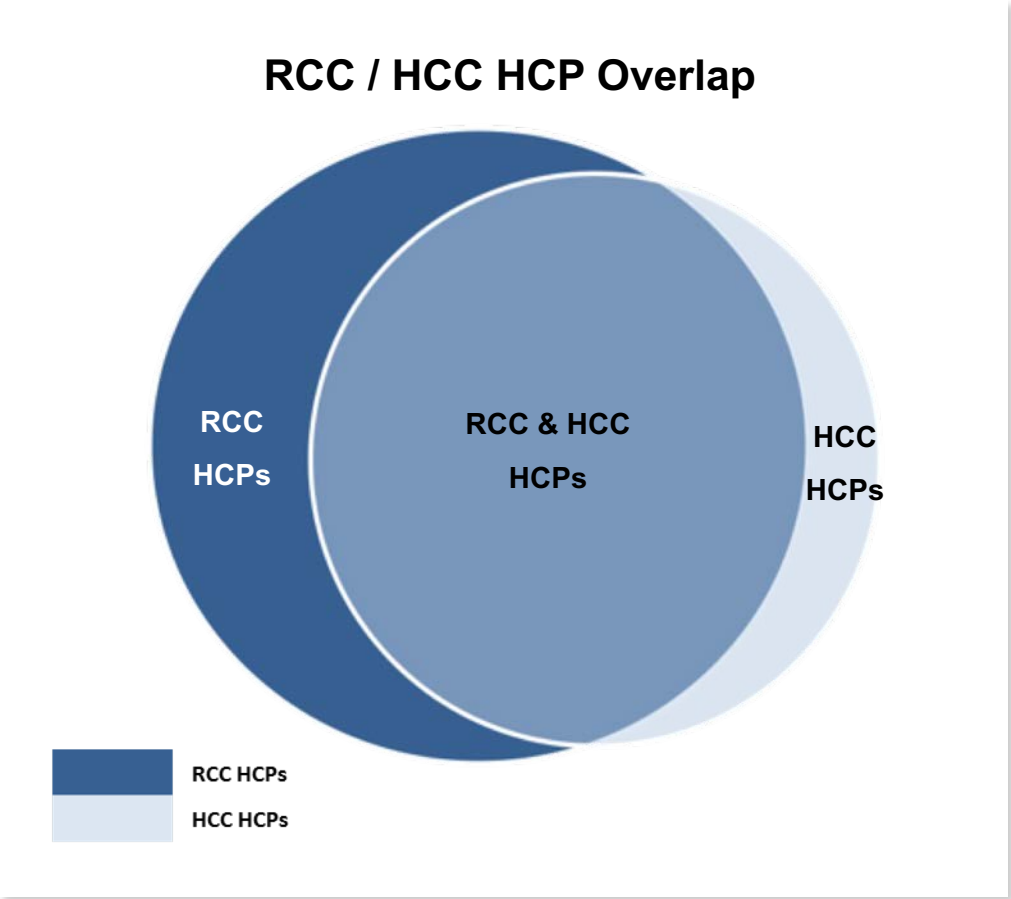
*ICI = immune checkpoint inhibitor*

# Strong Execution of 2L HCC CABOMETYX Launch


- Started promoting new HCC indication immediately after approval (January 14, 2019)
- The majority of surveyed oncologists indicate that CABOMETYX is their preferred 2L TKI
- Strong unaided awareness relative to other recently approved TKIs
- Vast majority of surveyed oncologists intend to prescribe when aware of CELESTIAL data
- Taking 2L+ market share from Stivarga

Source: Exelixis market research.

# 2L HCC is Adding to the Momentum of CABOMETYX




**Leading share of voice in 2L+ HCC**

**Post launch adoption has validated significant prescriber overlap**

- **~70% of demand from CABOMETYX experienced prescribers**
- **~30% of demand from CABOMETYX naïve prescribers**
- **New indication has increased access opportunities with existing customers and is driving prescriber growth**

**Strong adoption in community setting (~60% of HCC prescribers)**

**Launch metrics exceeding expectations in terms of new prescriptions and market share**

***2L HCC is Contributing to Growth in New Patient Starts and Demand***

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Sources: Exelixis Internal Data
ZoomRX - February 2019

*RCC = renal cell carcinoma; HCC = hepatocellular carcinoma; HCP = health care prescribers*

# CABOMETYX Q1'19 Performance

## Strong Q1'19 business fundamentals

- 17% Q/Q growth in NRx and 3% Q/Q growth in demand
- NRx growth outpacing total demand growth
- Prescriber base increased by 10% Q/Q and 53% Y/Y
- RCC and HCC contributing equally to growth in demand and new patient starts

## Continued growth in RCC

- Growth in RCC demand and new patient starts
- Stable 1L share and increasing 2L share
- Large potential remains from 1L Ipi+Nivo patients yet to progress to 2L
- Leading sales force share of voice in RCC


## Positive early signs in HCC

- HCC launch exceeding expectations in terms of market share and new prescriptions
- Large physician overlap with RCC and synergy being seen in the CABOMETYX franchise
- Strong unaided awareness and leading sales force share of voice in 2L+ HCC

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Sources: Exelixis Internal Data
IQVIA, IQVIA National Prescription Audit™, 03/2019
ZoomRX - February 2019

*NRx = new prescriptions; RCC = renal cell carcinoma; HCC = hepatocellular carcinoma; TKI = tyrosine kinase inhibitor*

# Clinical Development Update

Gisela Schwab, M.D.
President, Product Development and Medical Affairs & CMO

# Progress Evaluating Cabozantinib + Immune Checkpoint Inhibitors

## CheckMate 9ER phase 3 trial in treatment-naïve RCC now fully enrolled

- Last few patients in Japan in screening prior to randomization
- Results expected early next year*
- Sponsored by BMS, with co-funding from Exelixis, Ipsen and Takeda

## COSMIC-313 triplet combination trial now initiating

- The first phase 3 trial to compare TKI/ICI regimen to approved nivolumab + ipilimumab regimen in 1L RCC
- Builds on Exelixis' CABOSUN and BMS' CheckMate-214 clinical trial experience
- Sponsored by Exelixis, with BMS collaborating and providing its medicines free of charge

## Preliminary activity of cabozantinib/nivolumab and cabozantinib/nivolumab/ipilimumab regimens previously evaluated in phase 1b trial

- Tolerable dose of cabozantinib + nivolumab, or + nivolumab + ipilimumab established
- NCI-CTEP study led by Dr. Andrea Apolo in advanced GU tumors, including RCC

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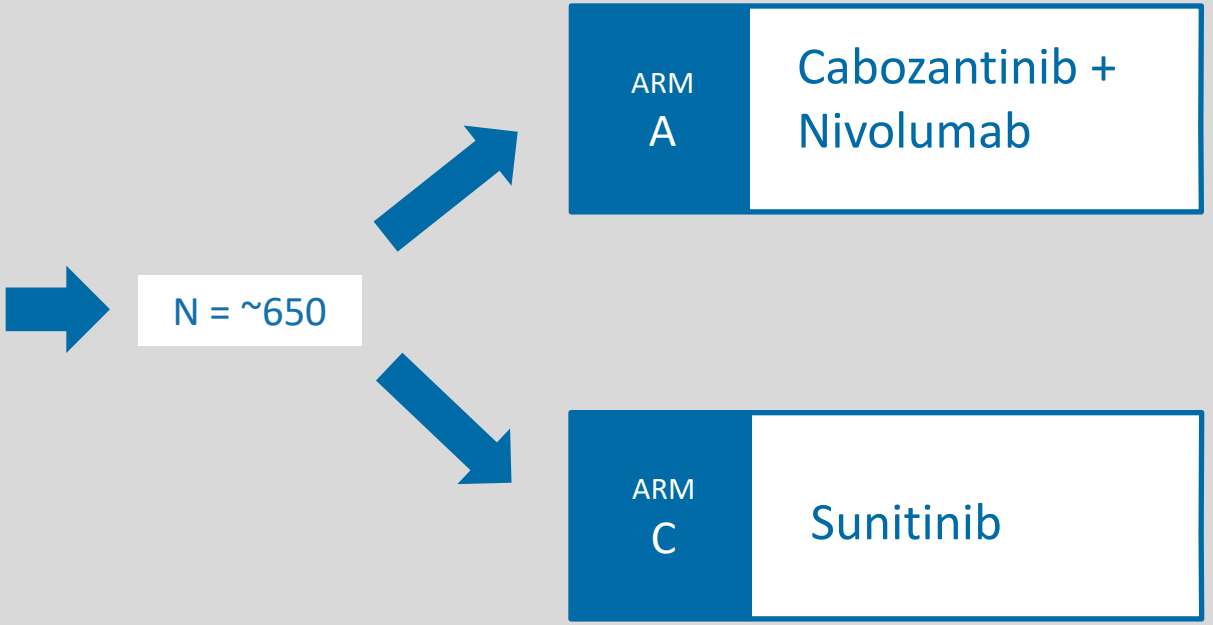
** As discussed on BMS' first quarter 2019 financial results call, April 25, 2019*
*BMS = Bristol-Myers Squibb Company, ICI = Immune Checkpoint Inhibitor, GU = Genitourinary, NCI-CTEP = National Cancer Institute Cancer Therapy Evaluation Program*

# CheckMate 9ER: Phase 3 Pivotal Trial of Cabozantinib + Nivolumab in First-line RCC

*(Sponsored by BMS, with co-funding from Exelixis, Ipsen and Takeda)*

## CheckMate 9ER (Ph 3)

- A study of cabo + nivo vs sunitinib in previously untreated advanced or metastatic RCC of all risk categories
- Requires histologically confirmed disease with a clear cell component




## Key Study Objectives

- **Primary:** PFS (assessed by blinded independent central review; BICR)
- **Secondary:** OS, ORR, safety

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*PFS = Progression-Free Survival, OS = Overall Survival, ORR = Overall Response Rate*

**First patient enrolled July 2017; enrollment now complete with last Japanese patients in screening before randomization**

# Progress Evaluating Cabozantinib + Immune Checkpoint Inhibitors

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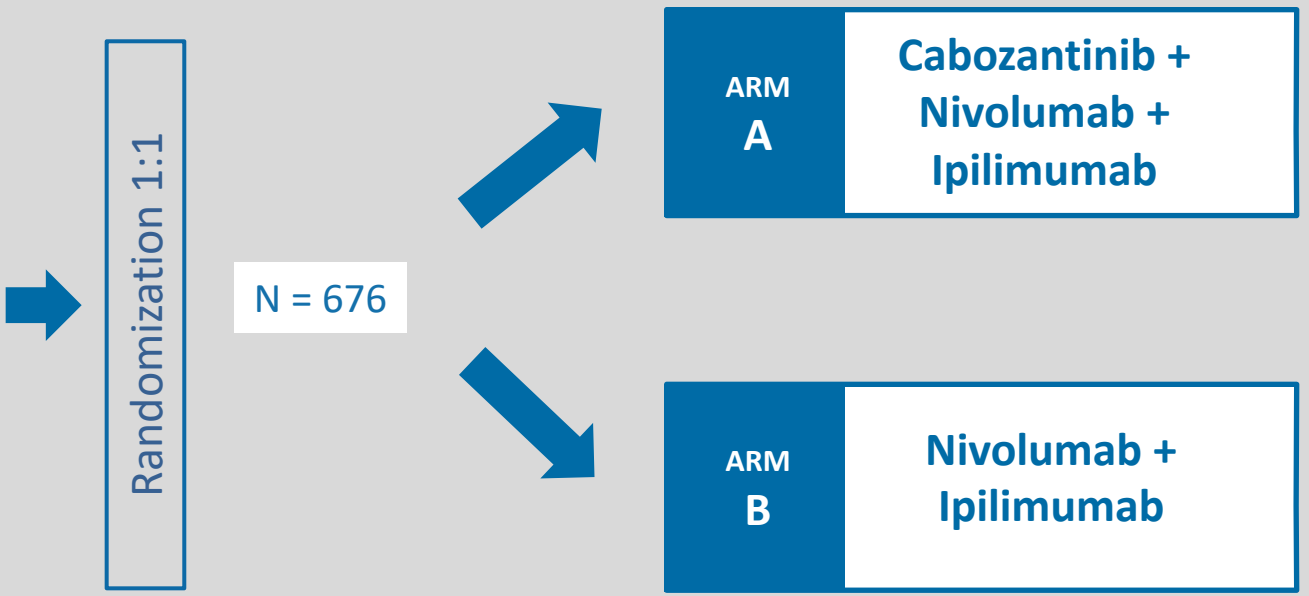
# COSMIC-313 Initiated: Phase 3 Pivotal Trial of Cabozantinib + Nivolumab + Ipilimumab in 1L RCC *(Exelixis-sponsored study in collaboration with BMS)*

COSMIC -313

**COSMIC-313 (Ph 3)**

- A randomized, double-blind, controlled study of cabozantinib + nivolumab + ipilimumab in patients with previously untreated advanced or metastatic RCC of immediate or poor risk
- Subjects must have measurable disease




**Key Study Objectives**

- **Primary Endpoint:** PFS
- **Secondary Endpoints:** OS and ORR

**Announced initiation today, May 1, 2019**

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# Progress Evaluating Cabozantinib + Immune Checkpoint Inhibitors

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# Now Enrolling: COSMIC-021 Phase 1b Trial of Cabozantinib + Atezolizumab in Multiple Tumors

*(Exelixis-sponsored study in collaboration with Roche)*

## Dose Escalation (RCC)

- Oral cabozantinib in combination with IV atezolizumab
- Recommended dose for expansion: cabozantinib 40 mg/day + atezolizumab 1200mg Q3W

**** Cabozantinib active as a single agent in this histology***

## 20 Expansion Cohorts

| | |
|---|---|
| **UC*** (n=30)<br>Prior platinum-chemotherapy | **UC*** (n=30)<br>Cis-ineligible, treatment naïve |
| **UC*** (n=30)<br>Cis-eligible, treatment naïve | **UC*** (n=30-80)<br>Prior ICI therapy |
| **ccRCC*** (n=30)<br>Clear cell, treatment naïve | **CRPC*** (n=30)<br>Prior enzalutamide or abiraterone |
| **NSCLC*** (n=30)<br>Treatment naïve | **NSCLC* (n=30-80)**<br>Prior ICI therapy |
| **NSCLC* (n=30)**<br>Prior EGFR-targeting TKI | **nccRCC* (n=30)**<br>Non-clear cell, treatment naïve |
| **TNBC* (n=30)**<br>Prior systemic therapy | **EOC* (n=30)**<br>Platinum-resistant or refractory |
| **EC* (n=30)**<br>Prior systemic therapy | **HCC* (n=30)**<br>Child-Pugh score of A; systemic therapy naive |
| **GEJ* Carcinoma (n=30)**<br>Prior platinum or fluoropyrimidine chemotherapy | **Colorectal adenocarcinoma (n=30)**<br>Prior fluoropyrimidine chemotherapy |
| **Head & neck cancer of squamous cell histology (n=30)**<br>Prior platinum chemotherapy | **DTC* (n=30)**<br>Radio-refractory or iodine-131 ineligible |
| **CABOMETYX Single Agent Arm: UC***<br>Prior ICI therapy | **CABOMETYX Single Agent Arm: NSCLC***<br>Prior ICI therapy |

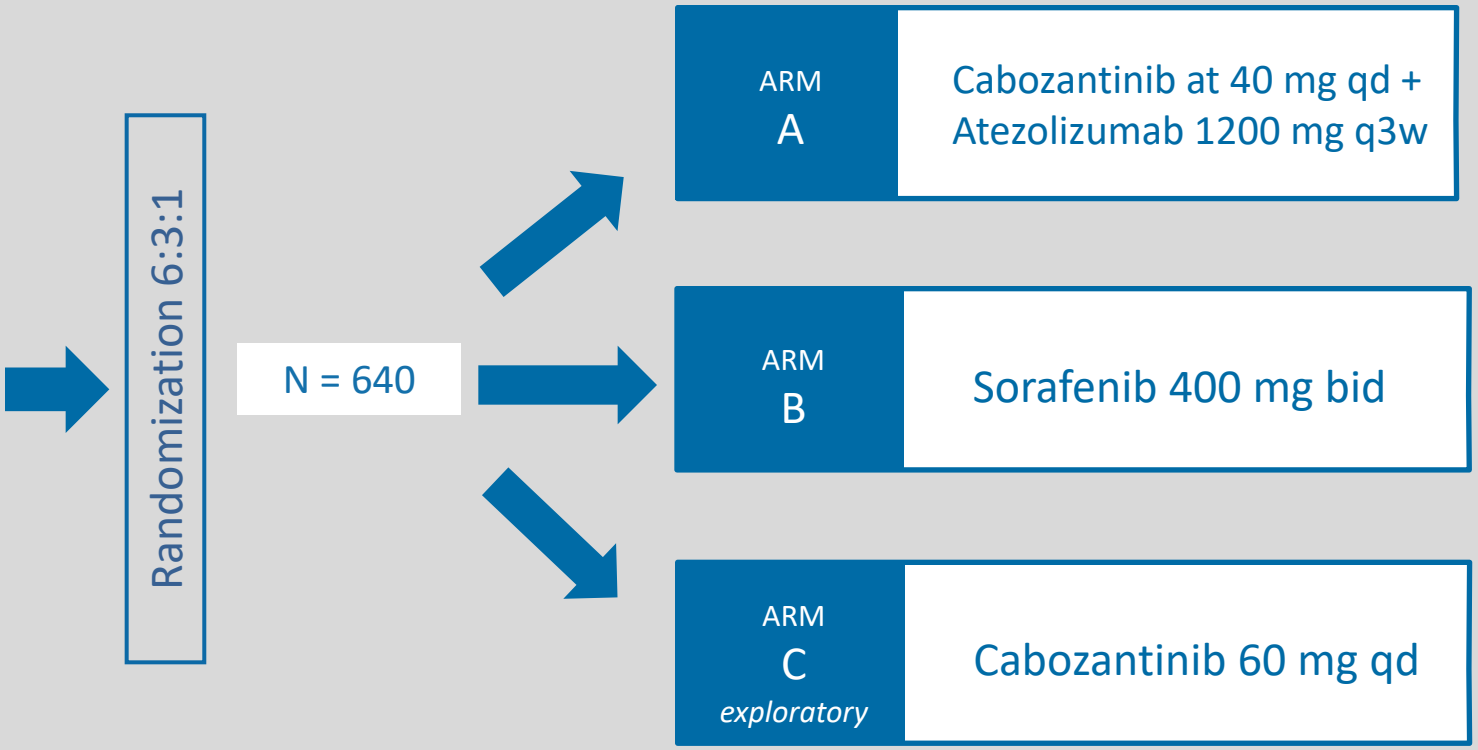
*UC: urothelial carcinoma*
*ccRCC: clear cell renal cell carcinoma*
*TKI: tyrosine kinase inhibitor*
*NSCLC: non-small cell lung cancer*
*Cis: cisplatin*
*nccRCC: non-clear cell renal cell carcinoma*
*TNBC: triple-negative breast cancer*
*CRPC: castration-resistant prostate cancer*
*ICI: immune checkpoint inhibitor*
*EOC: epithelial ovarian cancer*
*EC: endometrial cancer*
*HCC: hepatocellular carcinoma*
*GEJ: gastric or gastroesophageal junction*
*DTC: differentiated thyroid cancer*

# COSMIC-312: Phase 3 Pivotal Trial of Cabozantinib + Atezolizumab vs. Sorafenib in 1L Advanced HCC *(Exelixis-sponsored study in collaboration with Roche)*

COSMIC -312

## COSMIC-312 (Ph 3)

- Randomized, open-label study of cabo + atezo vs. sorafenib in previously untreated advanced HCC
- Target enrollment of 640 patients at up to 200 sites globally
- Exelixis-sponsored, with co-funding from Ipsen and atezolizumab provided by Genentech




## Key Study Objectives

- **Co-Primary Endpoints:** PFS by IRC; OS
- **Secondary:** ORR, safety

**Announced initiation on Dec. 5, 2018**

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*IRC = independent radiology committee*

# Additional Development Updates

## Additional late-stage ICI combination trials planned

- Potential bladder cancer and non-small cell lung cancer trials
- Potential tumor types from COSMIC-021 study

## Takeda's Japanese regulatory application has been filed

- Seeking approval for cabozantinib as a treatment for advanced RCC
- Triggered $10 million milestone payment to Exelixis

## Phase 1 clinical development of XL092 underway

- Next generation TKI targeting VEGFR and MET; subject of IND filed in December 2018
- Data-dependent clinical plans could include single agent and combination testing

## Nine cabozantinib and two cobimetinib abstracts accepted to 2019 ASCO Annual Meeting

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*VEGFR = vascular endothelial growth factor receptors*
*IND = investigational new drug application*

# Roche/Genentech Partnership for COTELLIC® (cobimetinib)

**Two fully enrolled phase 3 pivotal trials in previously untreated melanoma**

- IMspire150 TRILOGY: cobimetinib + vemurafenib + atezolizumab in BRAF mutation-positive, locally advanced or metastatic disease
- IMspire170: cobimetinib + atezolizumab in BRAF wild-type metastatic disease

**Potential regulatory filings later this year, if data are supportive**

- Per Roche's FY 2018 results call on January 31, 2019

**Multiple Roche-sponsored earlier stage trials ongoing**

- Studies in 13 different tumor types

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# Closing

Michael M. Morrissey, Ph.D.

President and CEO

# Strong Momentum in the First Quarter of 2019

**Continued to grow the business Q/Q and Y/Y**

- Driven by the strength of the CABOMETYX launch, ex-U.S. deals, and disciplined expense management

**Cabozantinib vectoring toward $1B run rate globally**

- Helping tens of thousands with RCC and HCC worldwide

**Strong foundation = Further investment in R&D**

- Additional cabozantinib label-enabling trials
- Add new product candidates from both internal discovery and business development efforts

***We remain committed to making every day count as we discover, develop and commercialize the next generation of our medicines for cancer patients***

25 YEARS Resilient Together

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# Question and Answer Session

# Financial Appendix

# GAAP to Non-GAAP Reconciliation

*(in millions, except per share amounts)*

**Non-GAAP Financial Measures**

To supplement Exelixis' financial results presented in accordance with GAAP, Exelixis uses certain non-GAAP financial measures in this presentation and the accompanying tables. This presentation and the tables that follow present certain financial information on a GAAP and a non-GAAP basis for Exelixis for the periods specified, along with reconciliations of the non-GAAP financial measures presented to the most directly comparable GAAP measures. Exelixis believes that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, Exelixis believes that each of these non-GAAP financial measures, when considered together with its financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare Exelixis' results from period to period, and to identify operating trends in Exelixis' business. Exelixis also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate its business and to make operating decisions.

These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. Exelixis encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand Exelixis' business. Reconciliations between GAAP and non-GAAP results are presented in the tables that follow.

| | Q1'18 | Q2'18 | Q3'18 | Q4'18 | Q1'19 |
|---|---|---|---|---|---|
| **Research and development expense reconciliation:** | | | | | |
| GAAP Research and development expense | $ 37.8 | $ 42.5 | $ 44.7 | $ 57.3 | $ 63.3 |
| Adjustments: | | | | | |
| Stock-based compensation[1] | 3.0 | 2.9 | 3.2 | 4.0 | 4.3 |
| Non-GAAP Research and development expense | $ 34.8 | $ 39.6 | $ 41.5 | $ 53.3 | $ 59.0 |
| **Selling, general and administrative expense reconciliation:** | | | | | |
| GAAP Selling, general and administrative expense | $ 54.0 | $ 51.9 | $ 48.1 | $ 52.4 | $ 60.1 |
| Adjustments: | | | | | |
| Stock-based compensation[1] | 6.3 | 6.4 | 6.6 | 8.3 | 8.2 |
| Non-GAAP Selling, general and administrative expense | $ 47.7 | $ 45.5 | $ 41.5 | $ 44.1 | $ 51.9 |
| **Operating expense reconciliation:** | | | | | |
| GAAP Operating expense | $ 97.4 | $ 100.3 | $ 100.2 | $ 117.0 | $ 130.9 |
| Adjustments: | | | | | |
| Stock-based compensation - Research and development[1] | 3.0 | 2.9 | 3.2 | 4.0 | 4.3 |
| Stock-based compensation - Selling, general and administrative[1] | 6.3 | 6.4 | 6.6 | 8.3 | 8.2 |
| Total adjustments | 9.3 | 9.3 | 9.8 | 12.3 | 12.5 |
| Non-GAAP Operating expense | 88.1 | 91.0 | 90.4 | 104.7 | 118.4 |
| **Provision for income tax reconciliation:** | | | | | |
| GAAP Provision for income tax | $ (2.5) | $ (0.9) | $ (2.3) | $ 243.7 | $ (14.9) |
| Adjustments: | | | | | |
| Income tax benefit resulting from the release of the valuation allowance[2] | - | - | - | (244.1) | - |
| Income tax effect of stock-based compensation - Research and development[3] | (0.1) | (0.1) | (0.1) | (0.1) | (1.0) |
| Income tax effect of stock-based compensation - Selling, general and administrative[3] | (0.1) | (0.1) | (0.1) | (0.1) | (1.8) |
| Non-GAAP Provision for income tax | $ (2.7) | $ (1.1) | $ (2.5) | $ (0.6) | $ (17.7) |

*Amounts may not sum due to rounding.*

# GAAP to Non-GAAP Reconciliation (continued)

*(in millions, except per share amounts)*

| | | | | | |
|---|---|---|---|---|---|
| **Net Income reconciliation:** | | | | | |
| GAAP Net Income | $ 115.9 | $ 87.5 | $ 126.6 | $ 360.1 | $ 75.8 |
| Adjustments: | | | | | |
| Stock-based compensation - Research and development | 3.0 | 2.9 | 3.2 | 4.0 | 4.3 |
| Stock-based compensation - Selling, general and administrative | 6.3 | 6.4 | 6.6 | 8.3 | 8.2 |
| Income tax effect of the stock-based compensation adjustments | (0.2) | (0.2) | (0.2) | (0.2) | (2.8) |
| Income tax effect of releasing the valuation allowance | - | - | - | (244.1) | - |
| Total adjustments | $ 9.1 | $ 9.1 | $ 9.6 | $ (232.0) | $ 9.7 |
| Non-GAAP Net Income | $ 125.0 | $ 96.6 | $ 136.2 | $ 128.1 | $ 85.5 |
| **Net Income per share - diluted:** | | | | | |
| GAAP Net Income per share - diluted | $ 0.37 | $ 0.28 | $ 0.41 | $ 1.15 | $ 0.24 |
| Adjustments: | | | | | |
| Stock-based compensation - Research and development | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Stock-based compensation - Selling, general and administrative | 0.02 | 0.02 | 0.02 | 0.03 | 0.03 |
| Income tax effect of the stock-based compensation adjustments | - | - | - | - | (0.01) |
| Income tax effect of releasing the valuation allowance | - | - | - | (0.78) | - |
| Total adjustments | $ 0.03 | $ 0.03 | $ 0.03 | $ (0.74) | $ 0.03 |
| Non-GAAP Net Income per share - diluted | $ 0.40 | $ 0.31 | $ 0.44 | $ 0.41 | $ 0.27 |
| Shares used in computing net income per share, diluted | 313,691 | 312,241 | 312,346 | 312,443 | 314,644 |

(1) Non-cash stock-based compensation expense used for GAAP reporting in accordance with ASC 718

(2) Represents the non-cash income tax benefit related to the release of substantially all of the valuation allowance against the company's deferred tax assets on December 31, 2018.

(3) Income tax effect on the non-cash stock-based compensation expense adjustments

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*Amounts may not sum due to rounding.*

# Collaboration Revenue

## Royalty & Collaboration Revenue Detail

*Amounts in millions*

| Partner | Compound | Description | Q118 | Q218 | Q318 | Q418 | Q119 |
|---|---|---|---|---|---|---|---|
| | | | Revenue under 606 | | | | |
| **Roche (Genentech)** | **Cotellic** | **Profit Share & Royalties on Ex-U.S. sales** | **2.7** | **4.2** | **3.3** | **3.4** | **2.5** |
| **Ipsen Royalties** | **Cabozantinib** | **Royalties on Ex-U.S. sales** | **4.4** | **5.4** | **10.3** | **12.3** | **14.0** |
| **Milestones:** | | | | | | | |
| Ipsen | Cabozantinib | Amortization of Milestones Triggered prior to Q1'18 | 0.7 | 0.7 | 0.6 | 1.0 | 0.3 |
| Ipsen | Cabozantinib | $50M M/S 1LRCC Approval | 45.8 | 0.2 | 0.2 | 0.4 | 0.1 |
| Ipsen | Cabozantinib | $25M M/S - Sales >$100M in 4 conseq. qtrs | - | 25.0 | - | - | - |
| Ipsen | Cabozantinib | $5M M/S 2LRCC Canada Approval | - | - | 5.0 | - | - |
| Ipsen | Cabozantinib | $40M M/S EMA 2LHCC Approval | - | - | 36.9 | 0.3 | 0.1 |
| Ipsen | Cabozantinib | $20M M/S initiation Phase 3 1LHCC | - | - | - | 18.6 | 0.1 |
| Takeda | Cabozantinib | $10M M/S initiation of Phase 3 1LRCC | - | - | - | 9.3 | - |
| Takeda | Cabozantinib | $10M M/S Japan NDA filing | - | - | - | - | 9.4 |
| Daiichi Sankyo | MR CS-3150/MINNEBRO | | 20.0 | - | - | - | - |
| | | **Subtotal Milestones** | **66.5** | **25.9** | **42.7** | **29.6** | **10.0** |
| **R&D Reimbursements & Other:** | | | | | | | |
| Ipsen | Cabozantinib | R&D reimbursement and Product Supply | 2.0 | 2.1 | 3.7 | 3.9 | 6.7 |
| Ipsen | Cabozantinib | $200M Upfront fee | 0.9 | 0.8 | 0.6 | 1.4 | 0.6 |
| Takeda | Cabozantinib | R&D reimbursement and Product Supply | 2.7 | 1.8 | 1.8 | 1.6 | 2.0 |
| Takeda | Cabozantinib | $50M Upfront fee | 0.2 | 0.1 | 0.1 | 0.2 | 0.1 |
| | | **Subtotal R&D Reimbursments & Other** | **5.8** | **4.8** | **6.2** | **7.1** | **9.4** |
| **TOTAL COLLABORATION REVENUE** | | | **79.4** | **40.3** | **62.5** | **52.4** | **35.9** |

*Amounts may not sum due to rounding.*
*On January 1, 2018, we adopted Accounting Standards Codification Topic 606 which impacts the timing of revenue recognition related to contracts with our collaboration partners.*

# First Quarter 2019 Financial Results

**Exelixis, Inc.**
**Nasdaq: EXEL**

**Wednesday, May 1, 2019**

EXELIXIS®