WEDNESDAY, NOVEMBER 1, 2023

# Third Quarter 2023 Financial Results

Nasdaq: EXEL





## **Today's Agenda**

#### Introduction

**Third Quarter 2023 Highlights** 

**Financial Results & Guidance** 

**Commercial Update** 

**Development Update** 

**Pipeline & Discovery Update** 

Q&A

**Susan Hubbard** EVP, Public Affairs & Investor Relations

Michael M. Morrissey, Ph.D. President and CEO

**Chris Senner** EVP and CFO

**PJ Haley** EVP, Commercial

**Amy Peterson, M.D.** EVP, Product Development & Medical Affairs and CMO

**Dana T. Aftab, Ph.D.** EVP, Discovery & Translational Research and CSO

All, joined by: **Peter Lamb, Ph.D.** EVP, Scientific Strategy



# Safe Harbor Statement

This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' expectation for the cabozantinib franchise to continue to grow while advancing a range of discovery and development programs to build the Exelixis pipeline of the future; Exelixis' top R&D priority to deliver clinically and commercially differentiated medicines for large populations of cancer patients with high unmet medical need that may benefit from those medicines; Exelixis' plans to highlight its integrated strategy spanning drug discovery, development and commercialization activities at its R&D Day in December 2023, as well as elaborate on multiple opportunities to both serve more patients and generate sustainable, long-term value for shareholders; Exelixis' BD efforts to access assets with potential to generate differentiated clinical data in solid tumor indications; Exelixis' belief that clinical trial sales may continue to be choppy between quarters; Exelixis' commitment to repurchase up to \$550 million of its common stock before the end of 2023; Exelixis' updated 2023 financial guidance; the beliefs of physicians and other prescribers that the favorable toxicity profile, QoL and low discontinuation rate experienced with the combination of CABOMETYX and nivolumab can enable patients to remain on therapy longer and potentially achieve long-term survival; Exelixis' belief that the CONTACT-02 and CABINET studies could provide the opportunity for the continued growth for CABOMETYX in the coming years; Exelixis' plans to discuss a potential regulatory submission for the combination of cabozantinib and atezolizumab in mCRPC with the FDA when the OS results from CONTACT-02 are more mature, as well as present detailed findings from CONTACT-02 at a future medical meeting; Exelixis' plans to discuss findings from CABINET with the FDA once the data are in-house; Exelixis' development plans for zanzalintinib across its ongoing studies (STELLAR-001, STELLAR-002, STELLAR-303) and STELLAR-304), including with respect to the amendment to the pivotal trial design for STELLAR-303 to increase the probability of success, as well as the potential for data from the early-stage trials to support expanded development opportunities for zanzalintinib; Exelixis' plans to present data from the ccRCC expansion cohort of STELLAR-001 at the 2023 IKCS; Exelixis' plans to initiate additional pivotal studies of zanzalintinib as part of a broad development program that will address patients with unmet need, including the initiation of STELLAR-305, which will evaluate the combination of zanzalintinib and pembrolizumab in certain SCCHN patients and may provide opportunity to improve outcomes compared with single-agent pembrolizumab and offer patients a chemo-free option; Exelixis' development plans for XB002, including leveraging the various dosing and combinations in the ongoing JEWEL-101 study to inform future registrational trials; Exelixis' expectation it will complete the transfer of obligations for XL309 from Insilico by the end of 2023 and belief that XL309 is a potentially best-in-class small molecule inhibitor of USP1, with the potential to broaden the addressable patient population beyond those who carry a BCRA mutation; Exelixis' beliefs regarding the therapeutic potential of three biotherapeutics DCs (XB010, XB371 and XB628) and that it is on track to file INDs for each of them in mid-to-late 2024; the potential for XL495 to be a best-in-class small molecule inhibitor of PKMYT1 and Exelixis' expectation for an IND filing in mid-2024; Exelixis' belief that it is on track to achieve its stated goal of advancing up to five new DCs total during 2023, including from both biotherapeutics and small molecules programs, and the potential for those programs to meaningfully contribute towards Exelixis' mission; and Exelixis' list of anticipated milestones for 2023. 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 and other Exelixis products in the indications for which they are approved and in the territories where they are approved, and Exelixis' and its partners' ability to obtain or maintain coverage and reimbursement for these products; the effectiveness of CABOMETYX and other Exelixis products 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; Exelixis' ability to maintain and scale adequate sales, marketing, market access and product distribution capabilities for its products or to enter into and maintain agreements with third parties to do so; the availability of data at the referenced times; the potential failure of cabozantinib, zanzalintinib 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; complexities and the unpredictability of the regulatory review and approval processes in the U.S. and elsewhere; 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 and other Exelixis product candidates; Exelixis' dependence on third-party vendors for the development, manufacture and supply of its products and product candidates; 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 detailed from time to time under the caption "Risk Factors" in Exelixis' most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in Exelixis' other future filings with the Securities and Exchange Commission (SEC). All forward-looking statements in this presentation are based on information available to Exelixis as of the date of this presentation, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein, except as required by law.

This presentation includes certain non-GAAP financial measures as defined by the SEC rules. As required by Regulation G, we have provided a reconciliation of those measures to the most directly comparable GAAP measures, which is available in the appendix.



# **Third Quarter 2023 Highlights**

## Michael M. Morrissey, Ph.D. President and CEO



## **Active Third Quarter 2023 Across All Components of Exelixis Business**



#### Strong cabozantinib performance with continued growth in demand and revenue

- CABOMETYX<sup>®</sup> maintained status as leading TKI in RCC
- Cabozantinib franchise Q3 2023 NPR: ~\$426M in U.S. and ~\$586M globally, generated by Exelixis and partners

# Prioritizing pipeline of clinically and commercially differentiated medicines for large populations of cancer patients with high unmet medical need

- R&D Day on December 12<sup>th</sup> in New York City: highlight integrated R&D strategy spanning drug discovery, development and commercialization
- Plan to elaborate on multiple opportunities to both serve more patients and generate sustainable, long-term value for Exelixis shareholders

#### **BD** efforts focused on accessing potentially differentiated clinical-stage assets

• In September, announced exclusive, global license agreement with Insilico Medicine for XL309, a small molecule inhibitor of USP1, an emerging synthetic lethal target in BRCA-mutated tumors

#### MSN II cabozantinib intellectual property trial took place Oct. 23-26 at U.S. District Court in Delaware



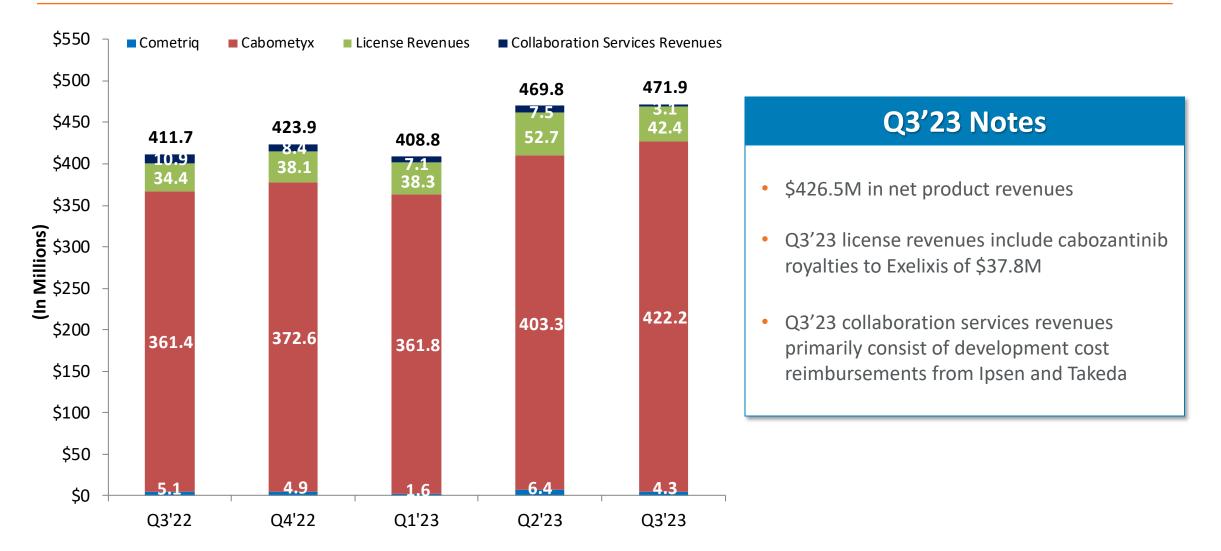
# **Financial Results & Guidance**

Chris Senner EVP and CFO



# Q3'23 Total Revenues

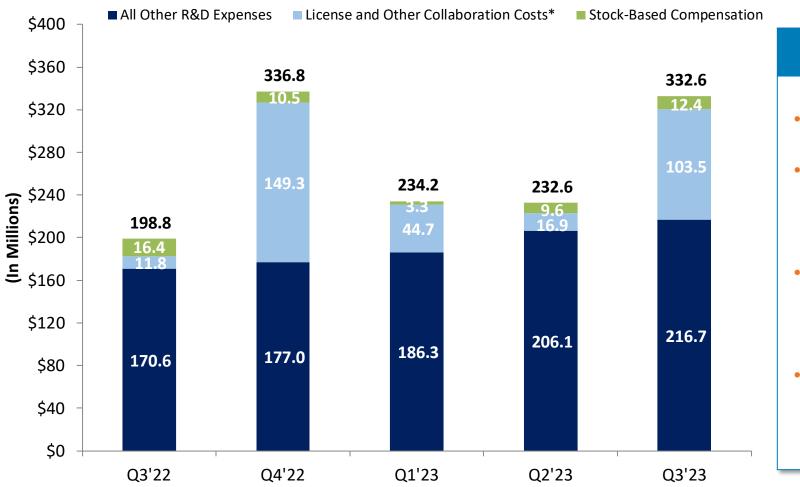
(See press release at www.exelixis.com for full details)





# Q3'23 R&D Expenses

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



#### Q3'23 Notes

- GAAP R&D expenses of \$332.6M
- Increase in R&D expenses vs. Q2'23 primarily due to higher license and other collaboration costs
- License and other collaboration costs includes a \$80.0M upfront payment to Insilico Medicine
- Non-GAAP R&D expenses of \$320.1M (excludes stock-based compensation expenses, before tax effect)

Amounts may not sum due to rounding.

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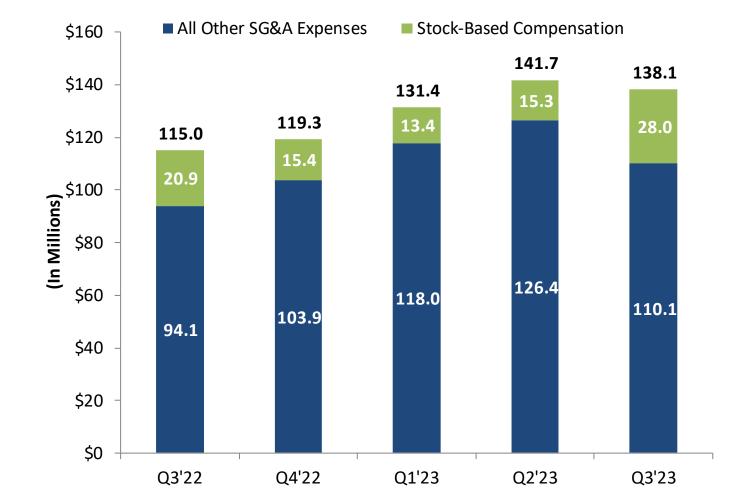
A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

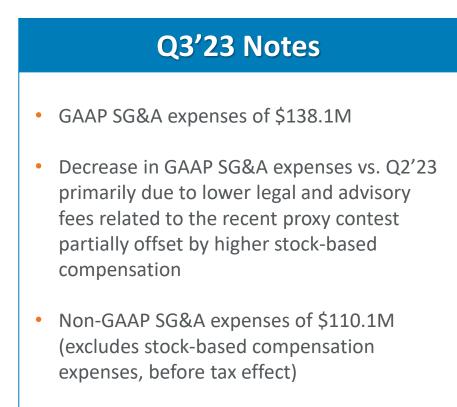
\*License and other collaboration costs include upfront, program initiation, development milestone fees, and other fees; in-process research and development assets acquired; and R&D funding for our collaboration and licensing agreements and assets purchase agreements.



# Q3'23 SG&A Expenses

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



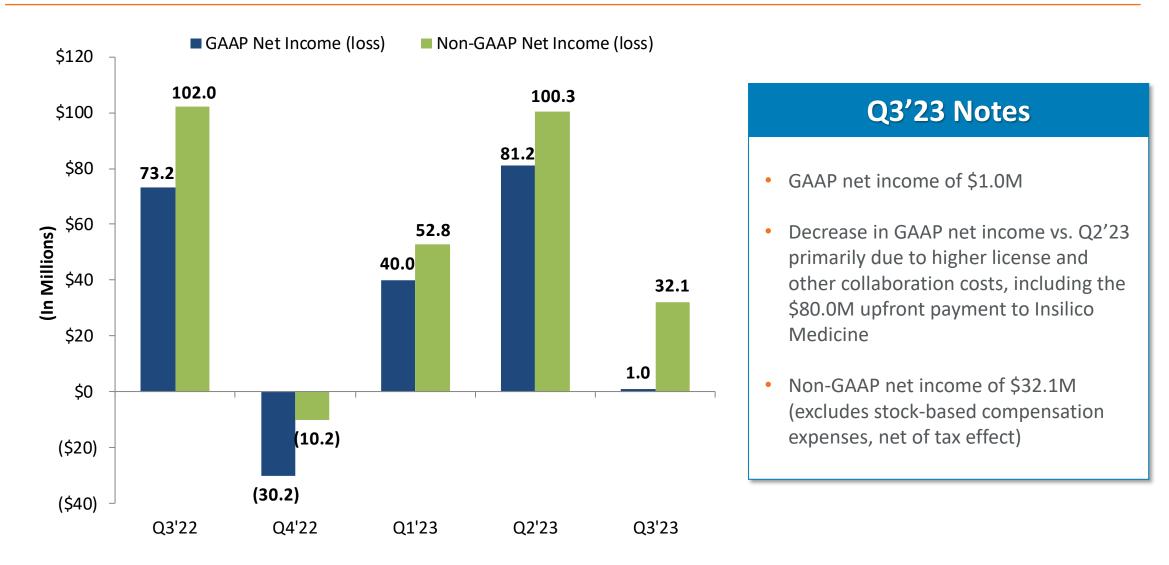


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# Q3'23 Net Income (Loss)

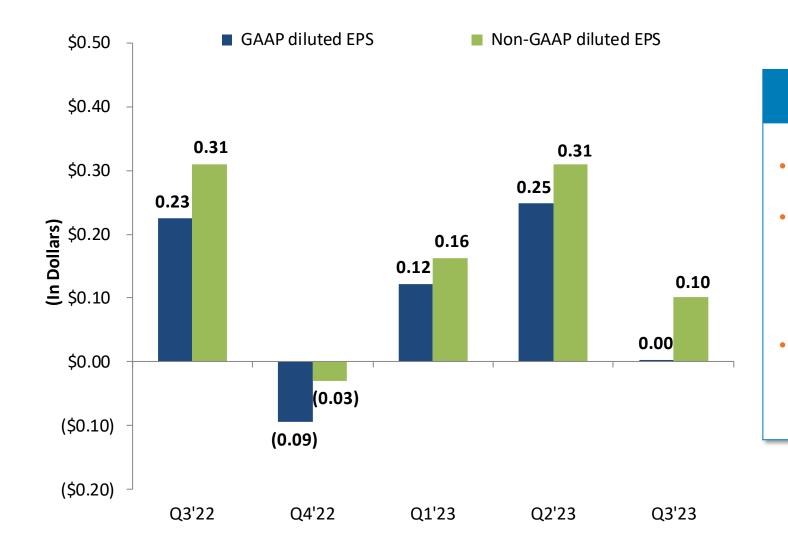
(See press release at www.exelixis.com for full details)





# Q3'23 Diluted Earnings (Loss) Per Share

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



#### Q3'23 Notes

- GAAP diluted earnings per share of \$0.00
- Decrease in GAAP EPS vs. Q2'23 primarily due to higher license and other collaboration costs, including the \$80.0M upfront payment to Insilico Medicine
- Non-GAAP diluted earnings per share of \$0.10 (excludes stock-based compensation expenses, net of tax effect)

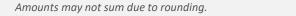




# **GAAP Financial Highlights: Q3'23**

(in millions, except per share amounts)

	Q3'22	Q2'23	Q3'23	YoY Delta	QoQ Delta
Total revenues	\$411.7 M	\$469.8 M	\$471.9 M	+15%	+0%
Cost of goods sold	\$15.3 M	\$17.7 M	\$18.8 M	+23%	+6%
R&D expenses	\$198.8 M	\$232.6 M	\$332.6 M	+67%	+43%
SG&A expenses	\$115.0 M	\$141.7 M	\$138.1 M	+20%	-3%
Total operating expenses	\$329.1 M	\$392.0 M	\$489.5 M	+49%	+25%
Other income, net	\$9.4 M	\$22.5 M	\$23.4 M	+148%	+4%
Income tax provision	\$18.8 M	\$19.2 M	\$4.8 M	-75%	-75%
Net income	\$73.2 M	\$81.2 M	\$1.0 M	-99%	-99%
Net income per share, diluted	\$0.23	\$0.25	\$0.00	-100%	-100%
Ending cash and investments <sup>(1)</sup>	\$2,100.2 M	\$2,105.4 M	\$1,915.1 M	-9%	-9%



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<sup>(1)</sup> Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments. Since Q2'23, there are no restrictions on cash, cash equivalents and investments.



# **2023 Share Repurchase Program Activity**

(in millions, except per share amounts)

	Amount Repurchased	Shares Repurchased	Average Purchase Price per Share
Q2 2023	\$127.0	6.608	\$19.22
Q3 2023	\$217.8	10.335	\$21.08
Total	\$344.8	16.943	\$20.35

\*\$550M share repurchase program authorized in March 2023, with \$205.2M remaining as of September 30, 2023.



# **Full Year 2023 Financial Guidance<sup>\*</sup>**

	<b>Current Guidance</b> (Provided November 1, 2023)	<b>Previous Guidance</b> (Provided January 8, 2023)
<b>Total Revenues</b>	\$1.825B - \$1.850B	\$1.775B - \$1.875B
Net Product Revenues	\$1.625B - \$1.650B	\$1.575B - \$1.675B
Cost of Goods Sold	4% - 5% of net product revenues	4% - 5% of net product revenues
R&D Expenses	<b>\$1.050B - \$1.075B</b> Includes <b>\$35M</b> of non-cash stock-based compensation expense	<b>\$1.000B - \$1.050B</b> Includes <b>\$45M</b> of non-cash stock-based compensation expense
SG&A Expenses	<b>\$525M - \$550M</b> Includes <b>\$70M</b> of non-cash stock-based compensation expense	<b>\$475M - \$525M</b> Includes <b>\$55M</b> of non-cash stock-based compensation expense
Effective Tax Rate	20% - 22%	20% - 22%



# **Commercial Update**

PJ Haley EVP, Commercial



## **CABOMETYX: Q3 2023 Performance**

#### **Strong execution continued in Q3 2023**

- \$426.5M in franchise net product revenues
- Strong demand and new patient starts continue to drive growth

#### **CABOMETYX** remains the #1 prescribed TKI in RCC and 2L HCC

# CheckMate -9ER 44-month follow-up data (ASCO GU 2023) continues to resonate with prescribers

- Compelling CABOMETYX + nivolumab combination median OS of 49.5 months
- Combination improved median OS by 14 months relative to sunitinib

#### CABOMETYX + nivolumab remains the #1 prescribed TKI + IO in 1L RCC

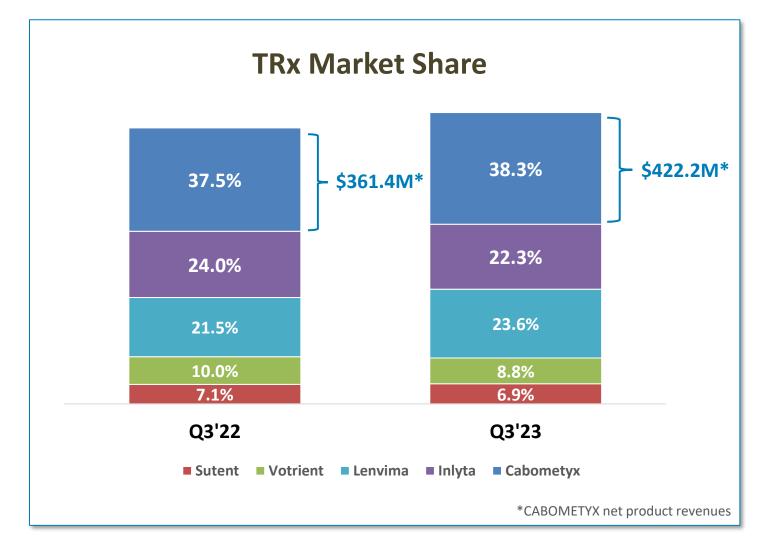
TKI = tyrosine kinase inhibitor1L = first-lineIO = immunotherapyRCC = renal cell carcinoma2L = second-lineASCO GU = American Society of Clinical Oncology Genitourinary SymposiumHCC = hepatocellular carcinomaOS = overall survival

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Sources: Internal Exelixis data IQVIA National Prescription Audit and BrandImpact data through 9/30/23



# **CABOMETYX Business Summary - #1 TKI in RCC**



# CABOMETYX continues to lead TRx market with over 38% share in Q3'23

- Broad uptake in the 1L RCC setting across clinical risk groups and practice settings
- Prescriber experience continues to be very positive

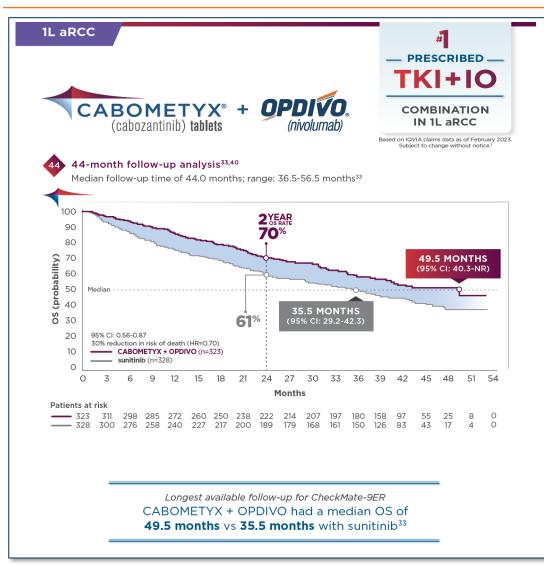
#### CABOMETYX in combination with nivolumab is the #1 prescribed TKI+IO regimen in 1L RCC

• 8% YoY TRx volume growth (Q3'23 vs. Q3'22)

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# CheckMate -9ER 44-month Follow-up OS Data Continue to Drive Meaningful Differentiation for CABOMETYX + Nivolumab vs. TKI+IO Competition



# Median OS over 4 years for CABOMETYX + nivolumab

- Prescribers are compelled by the median OS of 49.5 months of the combination
- CABOMETYX improved median OS by 14 months relative to sunitinib
- The CheckMate -9ER 44-month follow-up OS data are viewed as clinically meaningful and differentiating by oncologists

# Median OS of 49.5 months for CABOMETYX + nivolumab supports balance of data

- Prescribers believe that long-term survival may be achieved due to the ability to remain on therapy
- Physicians believe favorable toxicity profile, quality of life, and low discontinuation rate enable patients to remain on therapy

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#### **CABOMETYX + nivolumab remains the #1 prescribed 1L RCC TKI+IO combination therapy for** a fourth consecutive quarter

# Prescriber clinical experience continues to reflect the balance of superior efficacy, safety and tolerability, and QoL demonstrated in the CheckMate -9ER study

• 44-month follow-up data reinforce physician experience

#### CheckMate -9ER 44-month follow-up data: long-term OS now exceeds 4 years

• Prescribers are compelled by the median OS of 49.5 months for the combination of CABOMETYX + nivolumab, 14 months longer than sunitinib arm

#### CheckMate -9ER 44-month follow-up data reinforce CABOMETYX positioning



# **Development Update**

Amy Peterson, M.D. EVP, Product Development & Medical Affairs and CMO



# Cabozantinib 2<sup>nd</sup>-generation TKI targeting MET/VEGFR/AXL/MER

# **Positive Cabozantinib Phase 3 Data Readouts in Third Quarter 2023**

# 

#### 1L/2L mCRPC

#### **Key Endpoints**

- **Primary:** BICR-PFS, OS
- Secondary: BIRC-ORR, DOR, PSA

## CABINET

#### 2L pNET and epNET

#### **Key Endpoints**

- Primary: BICR-PFS
- Secondary: OS, ORR, Safety

#### **CONTACT-02:** Pivotal phase 3 study of cabozantinib + atezolizumab vs. 2<sup>nd</sup> NHT in patients with previously treated mCRPC

Top-line press release announcing positive results on August 21<sup>st</sup> 

#### **CABINET:** Pivotal phase 3 study conducted by The Alliance for Clinical Trials in Oncology evaluating cabozantinib vs. placebo in patients with advanced pNET and advanced epNET

- Top-line press release announcing positive results on August 24<sup>th</sup>
- Data presented by Dr. Jennifer Chan at 2023 ESMO Congress on October 22<sup>nd</sup>



#### 1L = first-line 22 2L = second-line

OS = overall survival *ORR* = *objective response rate PFS* = *progression-free survival* DOR = duration of response

PSA = prostate-specific antigen NHT = novel hormonal therapy *pNET* = *pancreatic neuroendocrine tumors*  *epNET = extra-pancreatic neuroendocrine tumors* mCRPC = metastatic castration-resistant prostate cancer BICR = blinded independent central radiology review

ESMO = European Society for Medical Oncology

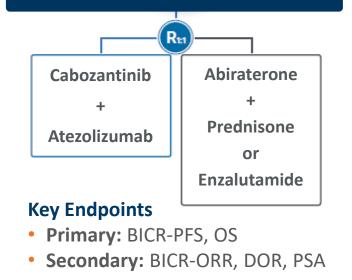


# **Positive CONTACT-02 Results Announced on August 21, 2023**

# CONTACT-02

#### **Metastatic CRPC**

- Measurable visceral disease or extrapelvic adenopathy
- 1 prior NHT



# **CONTACT-02:** Pivotal phase 3 study of cabozantinib + atezolizumab vs. 2<sup>nd</sup> NHT in patients with previously treated mCRPC

- Statistically significant PFS benefit for cabo+atezo and favorable trend in OS
- No new safety signals and AEs consistent with cabo or atezo monotherapy
- Plan to discuss potential regulatory submission when OS results are more mature, based on feedback from FDA

#### Detailed findings to be presented at a future medical meeting

PFS = progression-free survivalDOR = duration of responseOS = overall survivalPSA = prostate-specific antigenORR = objective response rateAEs = adverse events

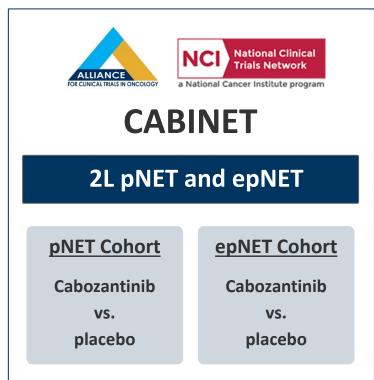
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NHT = novel hormonal therapy n BICR = blinded independent central radiology review FDA = U.S. Food and Drug Administration

mCRPC = metastatic castration-resistant prostate cancer



# **Positive CABINET Results Presented at 2023 ESMO Congress**



#### **Key Endpoints per Cohort**

- Primary: BICR-PFS
- Secondary: OS, ORR, Safety

**CABINET:** Pivotal phase 3 study conducted by The Alliance for Clinical Trials in Oncology evaluating cabozantinib vs. placebo in patients with advanced pNET and epNET

- Top-line press release announcing positive results on August 24<sup>th</sup>
- Data presented by Dr. Jennifer Chan at 2023 ESMO Congress:
  - pNET PFS HR: 0.27; pNET median PFS of 11.4 months vs. 3.0 months
  - epNET PFS HR: 0.45; epNET median PFS of 8.3 months vs. 3.2 months
  - No new safety signals identified for cabozantinib

#### Plan to discuss results with FDA once data are in-house

2L = second-line

OS = overall survival

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*ORR* = *objective response rate PFS* = *proaression-free survival* FDA = U.S. Food and Drua Administration HR = hazard ratio

pNET = pancreatic neuroendocrine tumors epNET = extra-pancreatic neuroendocrine tumors ESMO = European Society for Medical Oncology

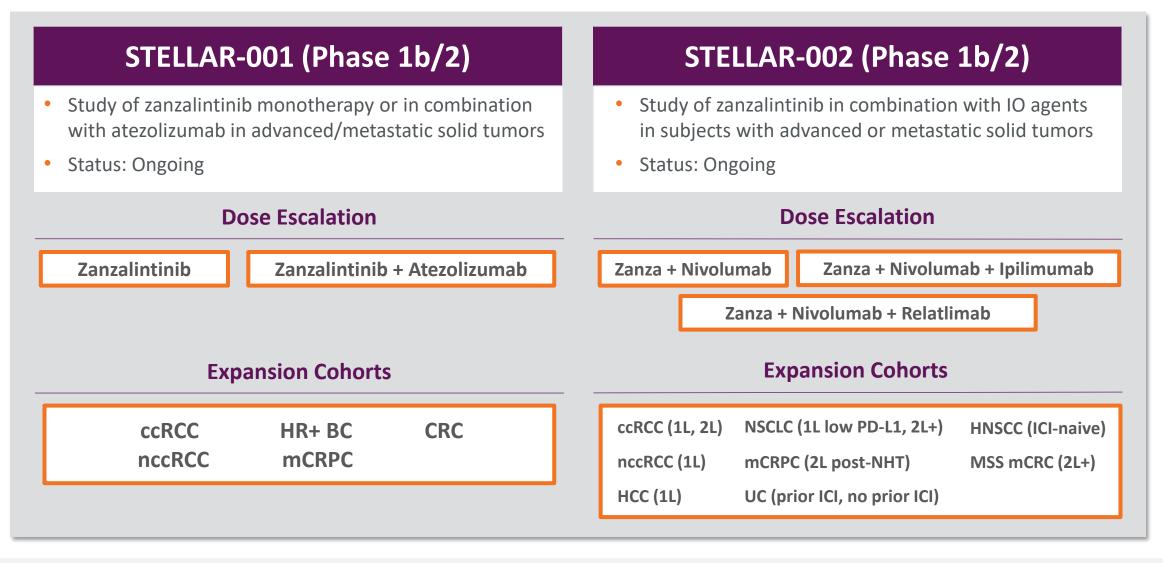
BICR = blinded independent central radiology review



# Zanzalintinib 3<sup>rd</sup>-generation TKI targeting MET/VEGFR/AXL/MER

## STELLAR-001/002: Phase 1b/2 Studies of Zanzalintinib ± ICI Combinations

Exelixis-sponsored Trials in Collaboration with Genentech/Roche and Bristol Myers Squibb



1L = first-line2L = second-linenccRCC = non-clear cell RCC IO = immunotherapvNHT = novel hormonal therapy

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ccRCC = clear cell renal cell carcinoma mCRPC = metastatic castration-resistant prostate cancer HNSCC = squamous cell carcinoma of the head and neck HR+ BC = hormone receptor positive breast cancer

UC = urothelial carcinoma ICI = immune checkpoint inhibitor *PD-L1* = *programmed death-ligand 1* 

MSS = microsatellite stable NSCLC = non-small cell lung cancer mCRC = metastatic colorectal cancer HCC = hepatocellular carcinoma

## Zanzalintinib: STELLAR-001 ccRCC Expansion Cohort to be presented at 2023 IKCS

#### Zanzalintinib (XL092)



- Next-generation, multi-targeted TKI
- Similar kinase inhibition profile to cabozantinib, with shorter clinical half-life
- Encouraging data presented at ESMO 2022 supports broad development

#### **Ongoing Clinical Trials**

Phase 1b/2:	STELLAR <sup>001</sup>
Phase 1b/2:	STELLAR <sup>002</sup>
Phase 3:	STELLAR 303
Phase 3:	STELLAR 304

#### Previously disclosed: Early, promising data from ccRCC cohort

- 2L+ ccRCC expansion cohort: 32 patients at 100 mg starting dose
- Compelling and durable responses observed in cabozantinib-naïve and cabozantinib-experienced patients
- Emerging safety profile continues to look encouraging
- Data provide evidence for activity of zanzalintinib in cabozantinibsensitive tumor type, and additional support for leveraging cabozantinib data to inform zanzalintinib development

Complete ccRCC dataset to be presented on Nov. 10<sup>th</sup> during Oral Abstracts Session at 2023 IKCS

#### 2L = second-line ccRCC = clear cell renal cell carcinoma TKI = tyrosine kinase inhibitor

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ESMO = European Society for Medical Oncology IKCS = International Kidney Cancer Symposium



## STELLAR-303: Pivotal Study of Zanzalintinib + Atezolizumab in 3L+ CRC

Exelixis-sponsored Trial with Atezolizumab Supplied by Genentech/Roche

#### STELLAR-303 (Phase 3)

 Study of zanzalintinib + atezolizumab in patients with MSS/MSI-low mCRC who have progressed after or are intolerant to the following SOC therapies:

Fluoropyrimidine, irinotecan and oxaliplatin based chemotherapy, +/- VEGFi, and, if RAS wt, anti-EGFR therapy.

- Primary population: non-liver metastases (NLM); pts w/o active LM at screening (by CT/MRI) including LM definitively treated at least 6 months prior to enrollment w/o evidence of progression
- Experimental Arm

  Zanzalintinib + Atezolizumab

  N = 874

  Control Arm

  Regorafenib

Status: Ongoing

#### **Key Study Objectives**

- **Primary:** OS in pts w/o liver metastases
- Secondary: OS (full ITT), PFS, ORR

Q2'23: announced protocol amendment to increase probability of success by changing primary endpoint to OS in patients without liver metastases

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 OS = overall survival
 ITT = intent to

 PFS = progression free survival
 w/o = without

 ORR = objective response rate
 pts = patients

ITT = intent to treat population w/o = without 3L = third-line CRC = colorectal cancer MSS = microsatellite stable MSI = microsatellite instability SOC = standard of care LM = liver metastases

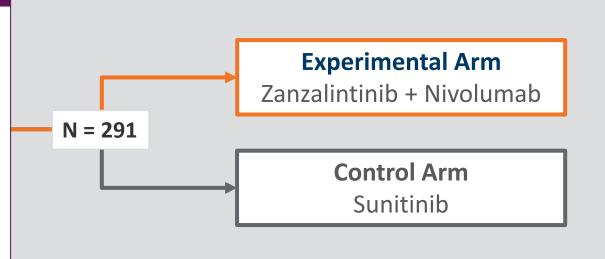


## **STELLAR-304: Pivotal Study of Zanzalintinib + Nivolumab in 1L nccRCC**

Exelixis-sponsored Trial with Nivolumab Supplied by Bristol Myers Squibb

#### STELLAR-304 (Phase 3)

- A study of zanzalintinib + nivolumab vs. sunitinib in 1L unresectable, advanced or metastatic nccRCC, including papillary, unclassified or translocation-associated histologies
- No prior treatment for nccRCC (adjuvant PD-1 allowed if >6 months ago)
- Status: Ongoing



#### **Key Study Objectives**

- **Primary:** PFS, ORR per RECIST v1.1
- Additional: OS

- Trial hypothesis based on NCI-sponsored phase 2 study of cabozantinib and phase 2 IST of cabozantinib + nivolumab
- Enrollment ongoing in multiple countries

1L = first-line PFS = progression-free survival ORR = objective response rate

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OS = overall survival NCI = National Cancer Institute IST = investigator-sponsored trial nccRCC = non-clear cell renal cell carcinoma RECIST = Response Evaluation Criteria in Solid Tumors



# STELLAR-305: Pivotal Study of Zanzalintinib + Pembrolizumab in 1L PD-L1<sup>+</sup> HNSCC

Exelixis-sponsored Trial

#### STELLAR-305 (Phase 2/3)

- A study of zanzalintinib + pembro vs. pembro ٠ alone in R/M HNSCC incurable by local therapies and no prior systemic therapy for R/M disease
- PD-L1 combined positive score (CPS)  $\geq$  1 ٠ RECIST v1.1 measurable disease
- Status: Initiating •

# **Experimental Arm** Zanzalintinib + Pembrolizumab N = 500**Control Arm** Pembrolizumab

#### **Key Study Objectives**

- **Primary:** PFS, OS
- Additional: ORR, DOR, QoL, • safety and tolerability
- Supported by data from a Phase 2 IST of cabozantinib + pembrolizumab (Saba, ASCO 2022)
- May provide opportunity to improve outcomes vs. single-agent pembro,  $\bullet$ based on emerging zanza activity + safety profile

1L = first-line 30 *OS* = *overall survival* 

ORR = objective response rate PFS = progression-free survival DOR = duration of response *QoL* = *quality* of *life* 

*PD-L1*<sup>+</sup> = programmed death-ligand 1 positive HNSCC = squamous cell carcinoma of the head and neck ASCO = American Society of Clinical Oncology Meeting

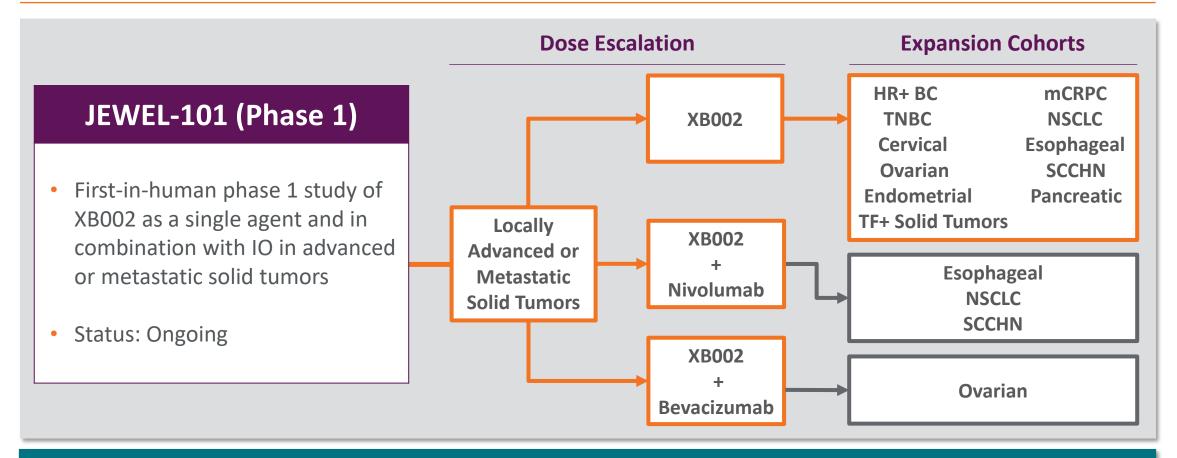
IST = investigator-sponsored trial *R/M* = *refractory* / *metastatic* RECIST = Response Evaluation Criteria in Solid Tumors



# XB002 Next-generation TF-targeting ADC

## JEWEL-101: Phase 1 Study of XB002 ± IO Combinations in Solid Tumors

Exelixis-sponsored Study with Nivolumab Supplied by BMS and Bevacizumab Supplied by Genentech/Roche



• Established RD for single agent XB002 and initiated multiple expansion cohorts. A lower dose is also being carried forward to fulfill FDA's Project Optimus requirements for dose optimization.

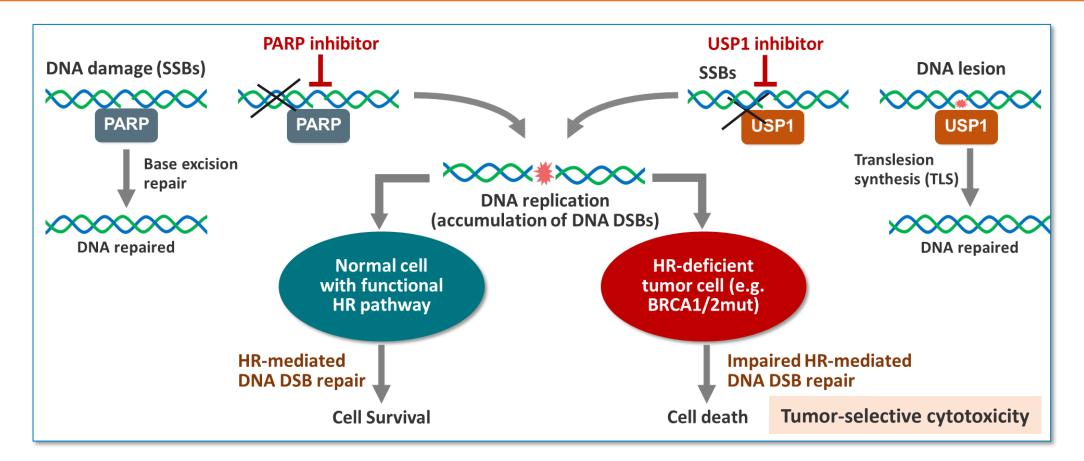
• Enrollment in dose escalation cohorts for nivolumab and bevacizumab combinations is ongoing.

32 IO = immunotherapy BMS = Bristol Myers Squibb TF = tissue factor HR+ BC = hormone receptor positive breast cancer mCRPC = metastatic castration-resistant prostate cancer TNBC = triple negative breast cancer NSCLC = non-small cell lung cancer SCCHN = squamous cell carcinoma of the head and neck FDA = U.S. Food and Drug Administration RD = recommended dose



# XL309 Small molecule USP1 inhibitor

# Rationale for XL309: Dual PARP and USP1 Inhibition Enhances Synthetic Lethality in BRCA-mutated Cells



XL309 Program Status: anticipating full transfer of obligations from Insilico by YE 2023

PARP = poly ADP ribose polymeraseSSB = single strand breakUSP1 = ubiquitin specific peptidase 1HR = homologous recombinationDSB = double strand break

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# Q3 2023 Development Summary

Advancing robust pipeline of molecules while maximizing potential of cabozantinib to benefit more patients in unmet need indications

Continue to expedite the development of promising pipeline assets into registrational trials for the benefit of patients with cancer

Plan to share more detailed information about progress and recent data at upcoming R&D Day on December 12<sup>th</sup> in New York City



# **Pipeline and Discovery Update**

Dana T. Aftab, Ph.D. EVP, Discovery & Translational Research and CSO



## **On Track to File 4 New IND Applications in 2024**

Program Name	Mechanism	Discovery / Preclinical	IND	Phase 1a	Phase 1b	Phase 2 / 3
Zanzalintinib (XL092)	Next-generation TKI targeting ME	T/VEGFR/AXL/MER				
XB002	Next-generation TF-targeting ADC	2				
XL102	Potent, selective, orally bioavailab	ble CDK7 inhibitor				
CBX-12 (Cybrexa)	Novel exatecan peptide-drug conj	jugate				
ADU-1805 (Sairopa)	Monoclonal antibody targeting SI	RPα				
XL309	Small molecule USP1 inhibitor					
XB010	Next-generation 5T4-targeting AD					
XB628	Bispecific antibody targeting PD-L	1 + NKG2A				
XB371	Next-generation TF-Topoisomeras	se ADC				
XL495	Small molecule PKMYT1 inhibitor					
XB014	Bispecific antibody targeting PD-L	1 + CD47				

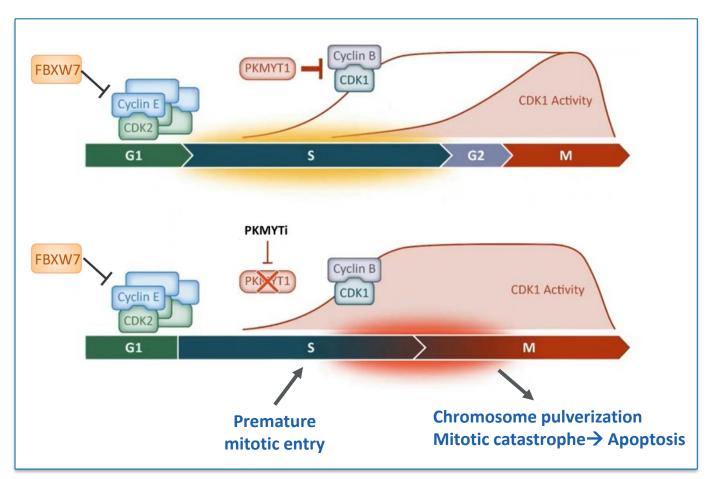
TKI = tyrosine kinase inhibitor TF = tissue factor ADC = antibody-drug conjugate

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CDK7 = cyclin-dependent kinase 7 SIRP $\alpha$  = signal-regulatory protein alpha NKG2A = natural killer cell receptor group 2A PD-L1 = programmed death-ligand 1 CD47 = cluster of differentiation 47 IND = Investigational New Drug status DC = development candidate USP1 = ubiquitin specific peptidase 1 PKMYT1 = protein kinase membrane associated tyrosine/threonine 1



## XL495: Small Molecule Inhibitor of PKMYT1



#### PKMYT1

- Increased Cyclin E levels cause genome instability and DNA damage across a wide range of tumors including ovarian, endometrial, and colorectal
- PKMYT1 inhibits CDK1, preventing mitotic entry for damaged genomes
- Inhibition of PKMYT1 in cancer cells with high Cyclin E allows mitosis before completion of DNA synthesis, with catastrophic consequences

#### **XL495**

- Potent and selective small molecule inhibitor of PKMYT1, designed to be best-in-class
- Shows synthetic lethality in preclinical models with increased Cyclin E levels

#### XL495 IND filing expected in 2024

CDK1 = cyclin-dependent kinase 1
 CDK2 = cyclin-dependent kinase 2
 IND = Investigational New Drug status

PKMYT1 = protein kinase membrane associated tyrosine/threonine 1

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# Closing

### Michael M. Morrissey, Ph.D. President and CEO



## **Anticipated Milestones for 2023**

Program	Milestone
Cabozantinib	Report top-line results from pivotal trial of cabozantinib + atezolizumab in RCC (CONTACT-03) in 1H 2023
Cabozantinib	Complete enrollment and report top-line results in pivotal trial of cabozantinib + atezolizumab in mCRPC (CONTACT-02) in 2H 2023
Zanzalintinib	Initiate multiple new phase 3 pivotal trials evaluating zanzalintinib across indications, tumor types and novel IO combinations
XB002	Accelerate development of XB002 TF ADC, as a monotherapy and in combination with IO and other targeted therapies, across a wide range of tumor types, with goal of moving into full development
	Initiate cohort expansion stage of phase 1 JEWEL-101 study after RD and/or MTD have been determined
XL102	Complete dose escalation, advance phase 1 QUARTZ-101 study into cohort expansion stage and initiate potential combination cohorts
CBX-12 (Cybrexa)	Cybrexa expected to continue to advance phase 1 clinical studies of CBX-12 PDC, including dose-expansion cohorts
ADU-1805 (Sairopa)	Sairopa to file IND for ADU-1805 SIRP $\alpha$ -targeting monoclonal antibody program in Q1 2023
DCs	Advance XB010 (5T4-targeting ADC), XB628 (PD-L1 x NKG2A bsAb), XB371 (TF-Topoisomerase ADC) and XL495 (PKMYT1 inhibitor) DCs toward potential IND filings in 2024
Preclinical / Discovery	Advance up to five new development candidates across multiple modalities / mechanisms of small molecules and biologics

RCC = renal cell carcinomaADC = antibody-drug conjugateIO = immunotherapyMTD = maximum-tolerated doseTF = tissue factorPDC = peptide-drug conjugateRD = recommended dosebsAb = bispecific antibody

mCRPC = metastatic castration-resistant prostate cancer NKG2A = natural killer cell receptor group 2A IND = Investigational New Drug application

DC = development candidate SIRPα = signal-regulatory protein alpha PD-L1 = programmed death-ligand 1

CD47 = cluster of differentiation 47 PKMYT1 = protein kinase membrane associated tyrosine/threonine 1



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# **Q&A** Session



WEDNESDAY, NOVEMBER 1, 2023

# Third Quarter 2023 Financial Results

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## **Financial Appendix**



## **Non-GAAP Financial Highlights: Q3'23**

(in millions, except per share amounts)

	Q3'22	Q2'23	Q3'23	YoY Delta	QoQ Delta
Total revenues	\$411.7 M	\$469.8 M	\$471.9 M	+15%	+0%
Cost of goods sold	\$15.3 M	\$17.7 M	\$18.8 M	+23%	+6%
R&D expenses (a)(b)	\$182.4 M	\$223.0 M	\$320.1 M	+76%	+44%
SG&A expenses (a)(b)	\$94.1 M	\$126.4 M	\$110.1 M	+17%	-13%
Total operating expenses (a)(b)	\$291.8 M	\$367.1 M	\$449.0 M	+54%	+22%
Other income, net	\$9.4 M	\$22.5 M	\$23.4 M	+148%	+4%
Income tax provision <sup>(a)</sup>	\$27.3 M	\$25.0 M	\$14.2 M	-48%	-43%
Net income <sup>(a)</sup>	\$102.0 M	\$100.3 M	\$32.1 M	-69%	-68%
Net income per share, diluted <sup>(a)</sup>	\$0.31	\$0.31	\$0.10	-68%	-68%
Ending cash and investments <sup>(c)</sup>	\$2,100.2 M	\$2,105.4 M	\$1,915.1 M	-9%	-9%

Amounts may not sum due to rounding.

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<sup>(a)</sup> A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

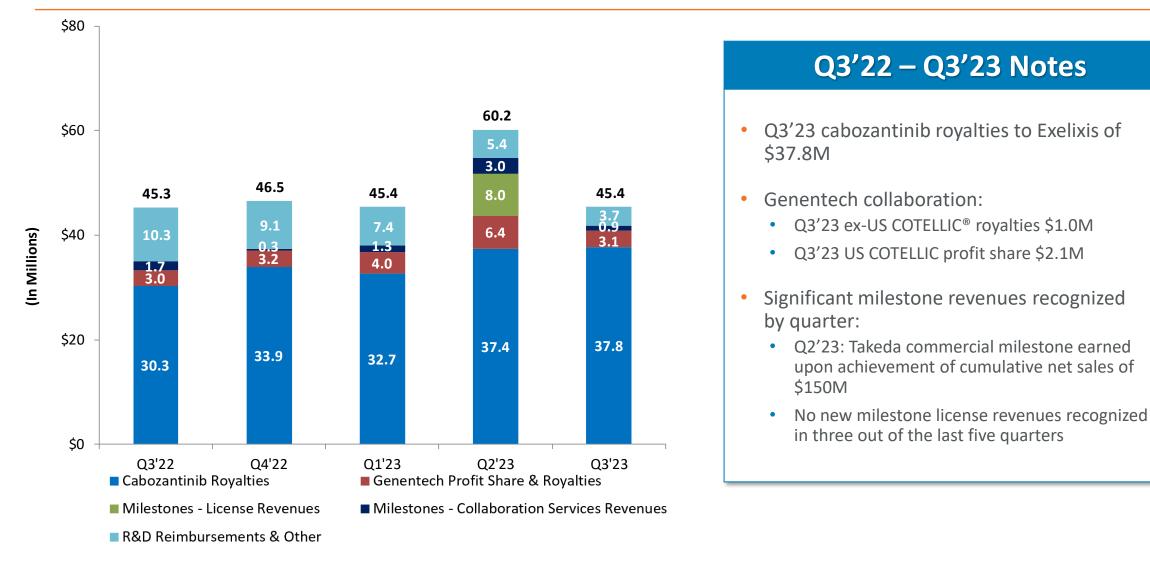
(b) Amounts reflect non-GAAP adjustment before tax effect.

(c) Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments. Since Q2'23, there are no restrictions on cash, cash equivalents and investments.



## **Collaboration Revenues Detail**

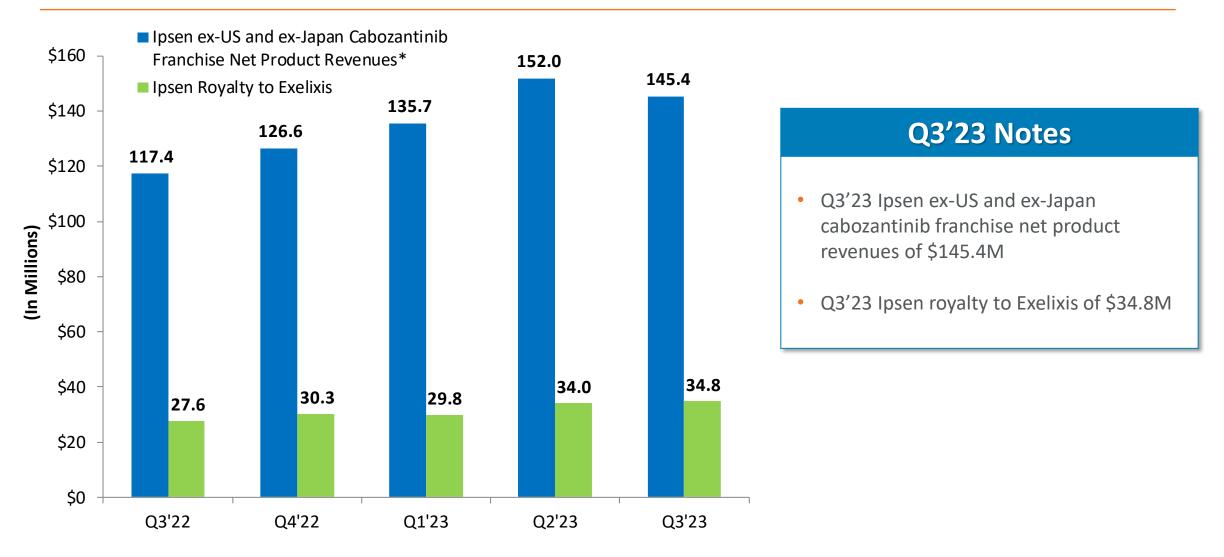
(See press release at www.exelixis.com for full details)





## **Ipsen Royalties**

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





### **GAAP to Non-GAAP Reconciliation**

#### (in millions, except per share amounts)

#### **Non-GAAP Financial Measures**

To supplement Exelixis' financial results presented in accordance with U.S. Generally Accepted Accounting Principles (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.

	(	Q3'22		Q4'22		Q1'23		Q2'23		23'23
Research and development expenses reconciliation:										
GAAP Research and development expenses	\$	198.8	\$	336.8	\$	234.2	\$	232.6	\$	332.6
Stock-based compensation expenses <sup>(1)</sup>		(16.4)		(10.5)		(3.3)		(9.6)		(12.4)
Non-GAAP Research and development expenses	\$	182.4	\$	326.4	\$	231.0	\$	223.0	\$	320.1
Selling, general and administrative expenses reconciliation:										
GAAP Selling, general and administrative expenses	\$	115.0	\$	119.3	\$	131.4	\$	141.7	\$	138.1
Stock-based compensation expenses <sup>(1)</sup>		(20.9 <u>)</u>		(15.4)		(13.4)		(15.3 <u>)</u>		(28.0)
Non-GAAP Selling, general and administrative expenses	\$	94.1	\$	103.9	\$	118.0	\$	126.4	\$	110.1
Operating expenses reconciliation:										
GAAP Operating expenses	\$	329.1	\$	472.0	\$	380.0	\$	392.0	\$	489.5
Stock-based compensation - Research and development expenses <sup>(1)</sup>		(16.4)		(10.5)		(3.3)		(9.6)		(12.4)
Stock-based compensation - Selling, general and administrative ${\sf expenses}^{(1)}$		(20.9)		(15.4)		(13.4)		(15.3)		(28.0)
Non-GAAP Operating expenses	\$	291.8	\$	446.1	\$	363.3	\$	367.1	\$	449.0
Income tax provision										
GAAP Income tax provision	\$	18.8	\$	(1.3)	\$	8.3	\$	19.2	\$	4.8
Income tax effect of stock-based compensation - Research and development <sup>(2)</sup>		3.7		2.4		0.8		2.2		2.9
Income tax effect of stock-based compensation - Selling, general and administrative $^{(2)}$		4.8		3.5		3.1		3.6		6.5
Non-GAAP Income tax provision	\$	27.3	\$	4.6	\$	12.1	\$	25.0	\$	14.2



## **GAAP to Non-GAAP Reconciliation (continued)**

(in millions, except per share amounts)

	 Q3'22		Q4'22		Q1'23		Q2'23		23'23
Net Income reconciliation:									
GAAP Net Income	\$ 73.2	\$	(30.2)	\$	40.0	\$	81.2	\$	1.0
Stock-based compensation - Research and development $^{(1)}$	16.4		10.5		3.3		9.6		12.4
Stock-based compensation - Selling, general and administrative <sup>(1)</sup>	20.9		15.4		13.4		15.3		28.0
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>	 (8.5 <u>)</u>		(5.9)		(3.9 <u>)</u>		(5.8 <u>)</u>		(9.4)
Non-GAAP Net Income	\$ 102.0	\$	(10.2)	\$	52.8	\$	100.3	\$	32.1
Net Income per share, diluted:									
GAAP Net Income per share, diluted	\$ 0.23	\$	(0.09)	\$	0.12	\$	0.25	\$	0.00
Stock-based compensation - Research and development $^{(1)}$	0.05		0.03		0.01		0.03		0.04
Stock-based compensation - Selling, general and administrative $^{(1)}$	0.06		0.05		0.04		0.05		0.09
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>	 (0.03)		(0.02)		(0.01)		(0.02)		(0.03)
Non-GAAP Net Income per share, diluted	\$ 0.31	\$	(0.03)	\$	0.16	\$	0.31	\$	0.10
Weighted-average shares used to compute GAAP net income per share, diluted	325.1		323.3		326.3		327.3		319.2

<sup>(1)</sup> Non-cash stock-based compensation expense used for GAAP reporting in accordance with ASC 718.

<sup>(2)</sup> Income tax effect on the non-cash stock-based compensation expense adjustments.

## **Collaboration Revenues**

(in millions)

Partner	Compound	Description	23'22	Q4'22	Q1'23	C	22'23	(	Q3'23
Roche (Genentech)	COTELLIC	Profit Share & Royalties on Ex-U.S. sales	\$ 3.0	\$ 3.2	\$ 4.0	\$	6.4	\$	3.1
Partner Royalties	Cabozantinib	Royalties on ex-U.S.	30.3	33.9	32.7		37.4		37.8
Milestones:									
lpsen	Cabozantinib	Amortization of Milestones Triggered prior to Q1'18	0.3	0.3	0.2		0.2		0.2
lpsen	Cabozantinib	\$50M milestone - 1L RCC Approval	0.1	0.1	0.1		0.1		0.1
lpsen	Cabozantinib	\$40M milestone - EMA 2L HCC Approval	0.1	0.1	0.1		0.1		0.1
lpsen	Cabozantinib	\$2M milestone - Canada MAA Approval, 1st indication (DTC)	-	-	-		-		-
lpsen	Cabozantinib	\$25M milestone - MAA approval by EMA, tier 2 add'l indication (DTC)	0.1	0.1	-		-		-
Takeda	Cabozantinib	\$16M milestone - Japan regulatory filing 2L RCC	0.3	(0.1)	0.2		0.2		0.1
Takeda	Cabozantinib	\$26M milestone - 1st Commercial Sale in Japan - 2L RCC	0.3	(0.1)	0.2		0.2		0.2
Takeda	Cabozantinib	\$15M milestone - 1st Commercial Sale in Japan - 2L HCC	0.1	-	0.1		-		-
Takeda	Cabozantinib	\$20M milestone - 1st Commercial Sale in Japan - 1L RCC	0.1	-	0.1		0.1		-
Takeda	Cabozantinib	\$11M milestone - Cumulative Net Sales >\$150M	-	-	-		9.8		0.1
		Subtotal Milestones	\$ 1.7	\$ 0.3	\$ 1.3	\$	11.0	\$	0.9
		Milestones License revenues	\$ -	\$ -	\$ -	\$	8.0	\$	-
		Milestones Collaboration services revenues	\$ 1.7	\$ 0.3	\$ 1.3	\$	3.0	\$	0.9
R&D Reimbursements & O	ther:								
lpsen	Cabozantinib	R&D reimbursement and Product Supply	\$ 6.1	\$ 5.7	\$ 2.9	\$	1.9	\$	0.6
lpsen	Cabozantinib	\$200M Upfront fee	0.4	0.4	0.3		0.3		0.2
Takeda	Cabozantinib	R&D reimbursement and Product Supply	2.5	2.1	2.5		2.2		1.2
Takeda	Cabozantinib	\$50M Upfront fee	0.1	-	0.1		0.1		0.1
Daiichi Sankyo & royalties	MR CS-3150/MI	NNEBRO	1.1	1.0	1.6		1.0		1.5
		Subtotal R&D Reimbursments & Other	\$ 10.3	\$ 9.1	\$ 7.4	\$	5.4	\$	3.7
Total License revenues			34.4	38.1	38.3		52.7		42.4
Total Collaboration servi	ces revenues		10.9	8.4	7.1		7.5		3.:
TOTAL COLLABORATION R	EVENUES		45.3	46.5	45.4		60.2		45.4

WEDNESDAY, NOVEMBER 1, 2023

# Third Quarter 2023 Financial Results

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