TUESDAY, MAY 9, 2023

# First Quarter 2023 Financial Results

Nasdaq: EXEL





## **Today's Agenda**

#### Introduction

**First Quarter 2023 Highlights** 

**Financial Results & Guidance** 

**Commercial Update** 

**Pipeline and Discovery Update** 

**Development Update** 

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

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

**Chris Senner** EVP and CFO

**PJ Haley** EVP, Commercial

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

Vicki Goodman, M.D. EVP, Product Development & Medical Affairs and CMO

**All Participants** 



Q&A

# Safe Harbor Statement

This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' commitment to creating long-term value for shareholders by advancing clinically and commercially differentiated medicines designed to improve outcomes for patients in meaningful indications, and by maximizing the number of patients that may benefit from those medicines; Exelixis' belief that it has the insights and discipline to successfully explore targets and develop medicinal compounds as it did with cabozantinib, while avoiding less productive avenues, repeatedly in the future; Exelixis' plans to return capital to its shareholders during 2023 through the \$550 million share repurchase program; Exelixis' 2023 financial guidance; the beliefs of physicians and other prescribers that the favorable toxicity profile, guality of life 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 44-month follow-up data from CheckMate -9ER position CABOMETYX for continued momentum and growth; Exelixis' overall strategy to maximize opportunity and reduce risk to address unmet need in solid tumors, focusing small molecule efforts on synthetic lethality and biotherapeutics efforts on ADCs and innate immunity, and Exelixis' belief that emphasizing a best-in-class approach informed by prior clinical data or clinical POC greatly reduces target risk; Exelixis' development plans for zanzalintinib and belief that it has the potential to be a more manageable and more combinable drug that allows Exelixis to explore the white space where there is evidence that cabozantinib is active, as well as Exelixis' belief it is on track to initiate additional phase 3 studies of zanzalintinib in 2023; Exelixis' development plans for XB002, including the initiation of multiple solid tumor expansion cohorts in the JEWEL-101 study that will allow a quick pivot into registrational trials, and the broader goal to accelerate XB002 development activities as a single agent and in combination regimens across a wide range of tumor types in 2023 and beyond; Exelixis' belief that XB002 has potential differentiation across all aspects of the ADC and presents an opportunity for broad activity with improved stability and exposure: Exelixis' future financial and other obligations under its agreements with Cybrexa and Sairopa; the therapeutic potential for ADU-1805 to be a best-in-class mAb that can treat a broad population of patients; Exelixis' plans to continue utilizing option-type deal structures for capital efficient access to compelling clinical-stage assets in a pay for success structure; Exelixis' discovery plans for 2023, including further advancement of its preclinical development programs (XB010, XB371, XB014 and XB628), and Exelixis' belief that it is on track to deliver several new DCs in 2023 from both biotherapeutics and small molecules programs; Exelixis' development plans for XL102, with a go/no-go decision expected by the end of 2023; Exelixis' plans to present emerging data for zanzalintinib (including from the ccRCC cohort of STELLAR-001), XB002 and other pipeline programs at upcoming medical conferences as the data mature; Exelixis' expectation that it will complete enrollment in CONTACT-02 and provide data for the primary endpoint of PFS in the second half of 2023, as well as plans to present the full data set for CONTACT-03 at ASCO 2023; Exelixis' belief that momentum from its cabozantinib franchise will translate to the critical growth drivers across all components of the business as Exelixis works to help many more cancer patients in the future; Exelixis' expectation that progress in the pipeline will continue in 2023 and for sharing its latest results and plans at an R&D day later in 2023; and Exelixis' list of anticipated milestones for 2023 and summary of key 2023 corporate objectives. 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, including as a result of the COVID-19 pandemic and other global events; 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 9, 2023, 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 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.



# First Quarter 2023 Highlights

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



## **Exelixis Is Committed to Creating Long-term Value for Shareholders by** Helping More Patients with Cancer



- CABOMETYX was the leading TKI in both 1L IO/TKI and 2L monotherapy RCC market segments
- Continues to fuel the development and expansion of our product pipeline

#### **R&D** efforts focused on improving standard of care for patients with cancer

- Advancing a pipeline of clinically and commercially differentiated medicines for large populations of cancer patients with high unmet medical need
- Driving growth and long-term value creation for shareholders by maximizing the number of cancer patients that may benefit from our medicines

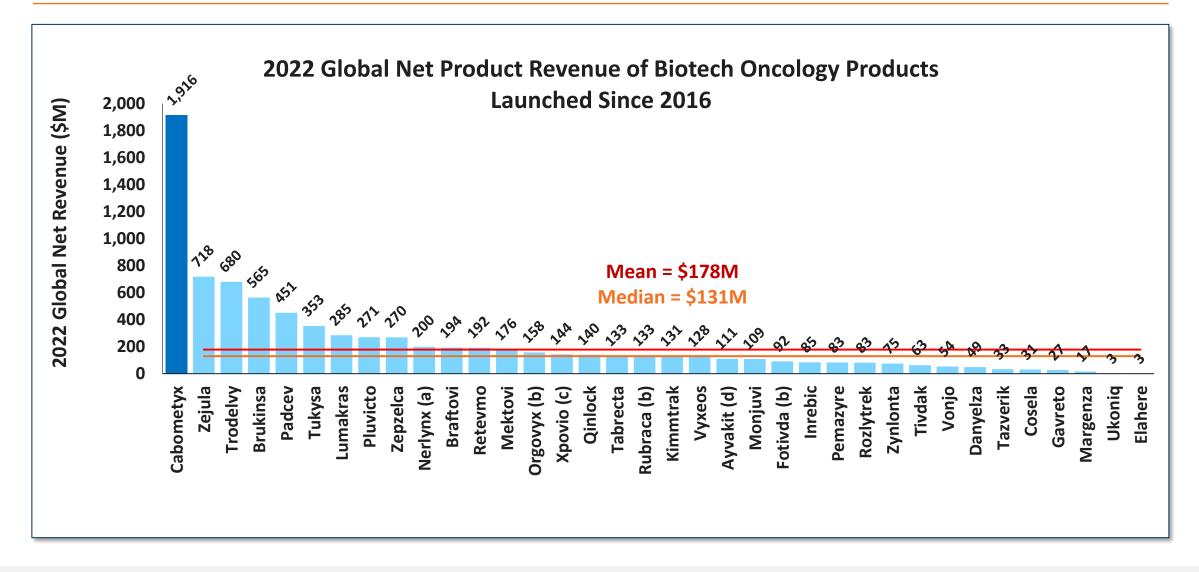
# Employing a biology-centric and modality-agnostic strategy within a narrow therapeutic framework in oncology

- Disciplined and integrated strategy spanning discovery, development and commercial functions
- Advancing medicines designed to improve outcomes for patients in meaningful indications in order to build value for shareholders

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## **CABOMETYX Success Relative to Biotech Oncology Launches Since 2016**



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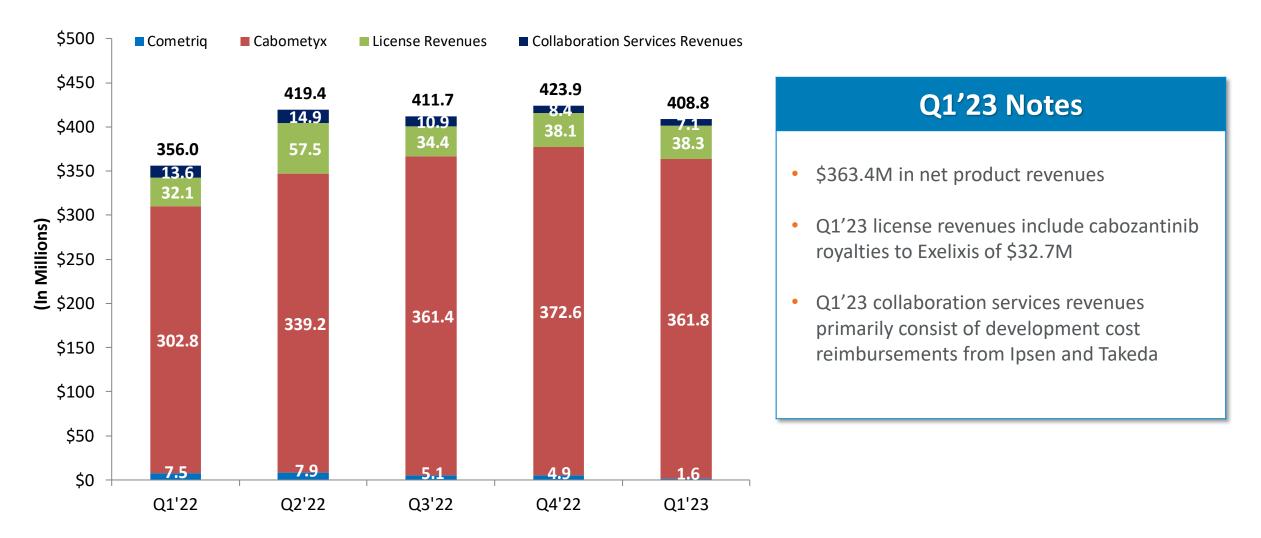
# **Financial Results & Guidance**

Chris Senner EVP and CFO



# Q1'23 Total Revenues

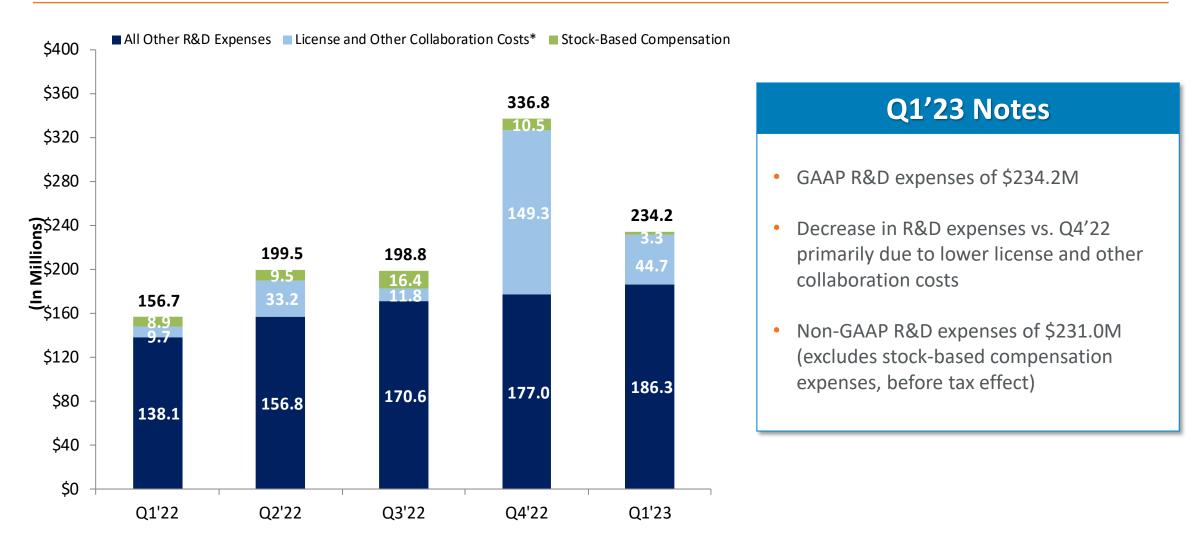
(See press release at www.exelixis.com for full details)





# Q1'23 R&D Expenses

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



Amounts may not sum due to rounding.

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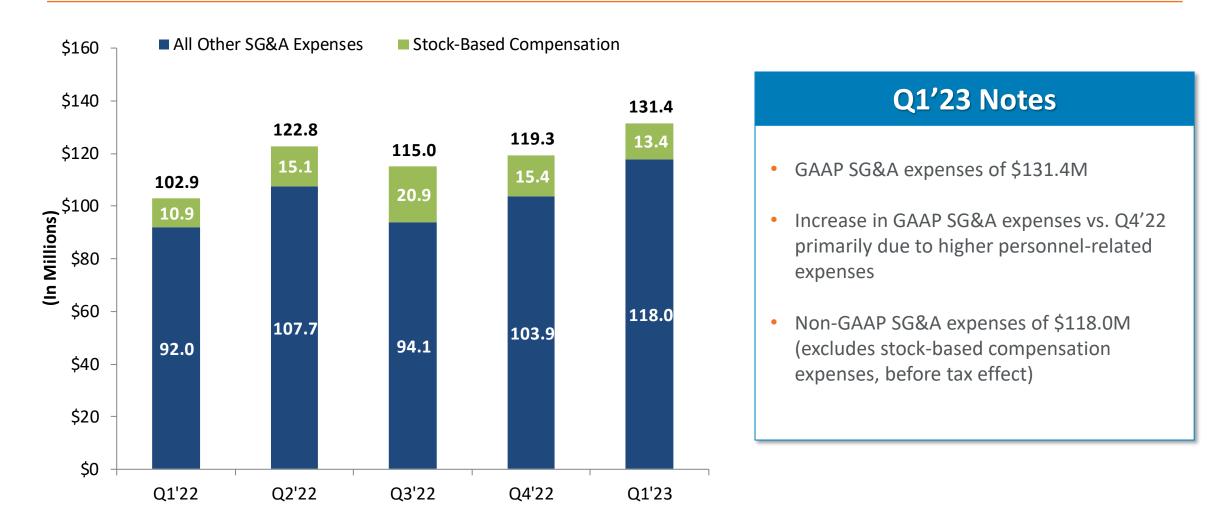
A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

\*License and other collaboration costs include upfront, option exercise, 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.



# Q1'23 SG&A Expenses

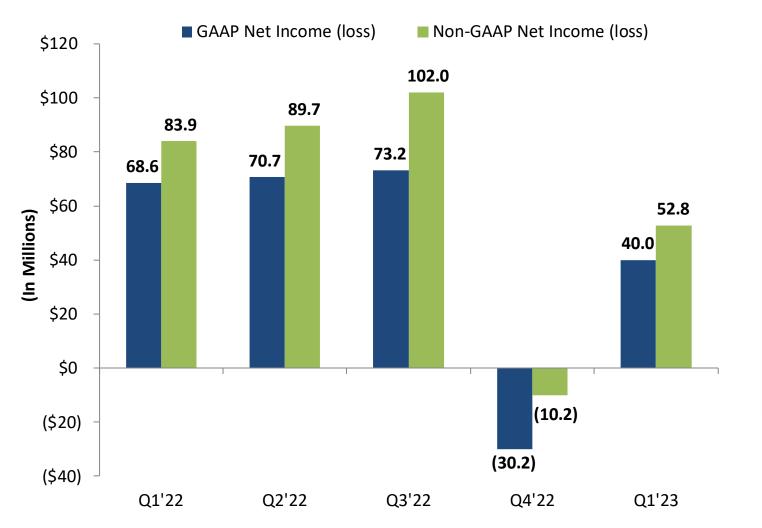
(See press release at www.exelixis.com for full details)

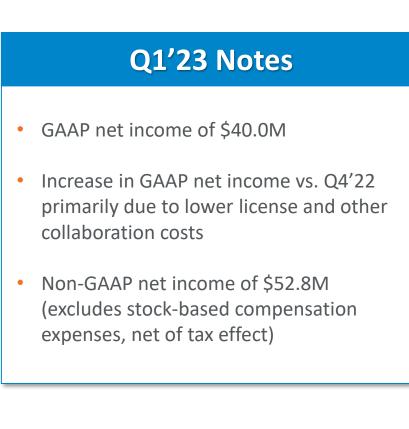




# Q1'23 Net Income (Loss)

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

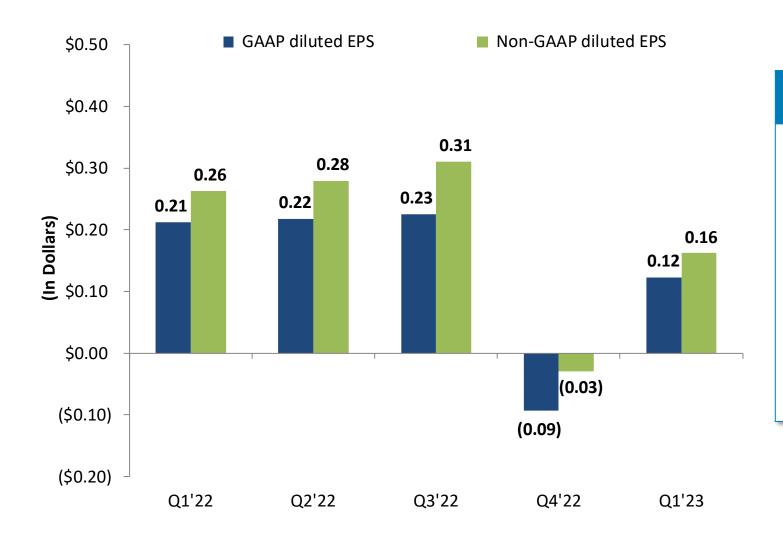






# Q1'23 Diluted Earnings (Loss) Per Share

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



## Q1'23 Notes

- GAAP diluted earnings per share of \$0.12
- Increase in GAAP EPS vs. Q4'22 primarily due to lower license and other collaboration costs
- Non-GAAP diluted earnings per share of \$0.16 (excludes stock-based compensation expenses, net of tax effect)



# **GAAP Financial Highlights: Q1'23**

(in millions, except per share amounts)

	Q1'22	Q4'22	Q1'23	YoY Delta	QoQ Delta
Total revenues	\$356.0 M	\$423.9 M	\$408.8 M	+15%	-4%
Cost of goods sold	\$13.2 M	\$15.9 M	\$14.3 M	+8%	-10%
R&D expenses	\$156.7 M	\$336.8 M	\$234.2 M	+50%	-30%
SG&A expenses	\$102.9 M	\$119.3 M	\$131.4 M	+28%	+10%
Total operating expenses	\$272.7 M	\$472.0 M	\$380.0 M	+39%	-19%
Other income, net	\$2.0 M	\$16.7 M	\$19.4 M	+879%	+17%
Income tax provision (benefit)	\$16.7 M	\$(1.3) M	\$8.3 M	-50%	n/a
Net income (loss)	\$68.6 M	\$(30.2) M	\$40.0 M	-42%	n/a
Net income (loss) per share, diluted	\$0.21	\$(0.09)	\$0.12	-43%	n/a
Ending cash and investments <sup>(1)</sup>	\$1,988.9 M	\$2,066.7 M	\$2,121.2 M	+7%	+3%

n/a = not applicable

13 Amounts may not sum due to rounding.

<sup>(1)</sup> Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments.



## **Full Year 2023 Financial Guidance**\*

**Financial Guidance** (Provided January 8, 2023)

Total Revenues	\$1.775B - \$1.875B
Net Product Revenues	\$1.575B - \$1.675B
Cost of Goods Sold	4% - 5% of net product revenues
R&D Expenses	<b>\$1.000B - \$1.050B</b> Includes <b>\$45M</b> of non-cash stock-based compensation expense
SG&A Expenses	<b>\$475M - \$525M</b> Includes <b>\$55M</b> of non-cash stock-based compensation expense
Effective Tax Rate	20% - 22%

# **Commercial Update**

PJ Haley EVP, Commercial



## **CABOMETYX: Q1 2023 Performance**

### **Strong execution continued in Q1 2023**

- >\$363M in franchise net product revenues
- 12% TRx growth YoY (Q1'23 vs. Q1'22)
- Strong demand and new patient starts

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

### CheckMate -9ER 44-month follow-up data from ASCO GU 2023 well received in marketplace

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

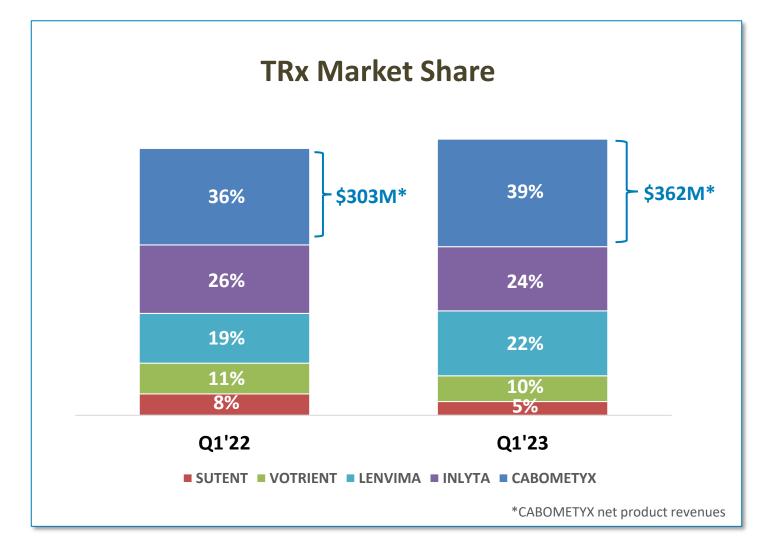
## CABOMETYX + nivolumab is the #1 prescribed TKI + IO in 1L RCC

TRx = total prescriptions1L = first-lineHCC = hepatocellular carcinomaTKI = tyrosine kinase inhibitor2L = second-lineIO = immunotherapyRCC = renal cell carcinomaOS = overall survivalASCO GU = American Society of Clinical Oncology Genitourinary Symposium

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



# CABOMETYX continues to lead TRx market with 39% share in Q1'23

- Uptake in the 1L RCC setting is broad across clinical risk groups and practice settings
- Prescriber experience to date continues to be very positive

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

• 12% YoY TRx volume growth (Q1'23 vs. Q1'22)

# Overall TRx market basket volume was stable in Q1'23 vs. Q4'22

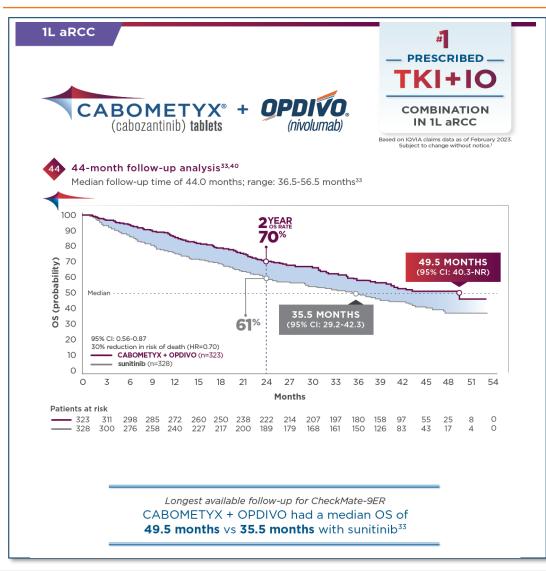
• CABOMETYX was stable, in line with market

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Source for TRx: IQVIA National Prescription Audit 3/31/23, including Cabometyx, Inlyta, Sunitinib, Votrient, Lenvima; Includes scripts across indications. Sutent includes volumes from generic. Source for 1L RCC share: IQVIA BrandImpact March 2023. Amounts in chart may not sum to 100% due to rounding.



# CheckMate -9ER 44-month Follow-up OS Data 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 is the #1 Prescribed TKI+IO Combination in 1L RCC**

### The #1 prescribed TKI+IO combination

• CABOMETYX + nivolumab remains the most prescribed 1L RCC TKI+IO combination therapy for a second consecutive quarter

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

• 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



# **Pipeline and Discovery Update**

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



## **Strategy Maximizes Opportunity and Reduces Risk to Address Unmet Needs in Solid Tumors**

- Reduce target/biology risk we are not dependent on one approach driving success
- Targets selected by strength of science vs. limited by platform
- Ability to address heterogenous tumors with complex biology

Small molecules focused on synthetic lethality

Biotherapeutics focused on antibody-drug conjugates and innate immunity

**Emphasis on best-in-class programs based on prior clinical POC** 



# **Robust Pipeline Beyond Cabozantinib**

Program Name	Mechanism	Discovery / Preclinical	IND	Phase 1a	Phase 1b	Phase 2 / 3
Zanzalintinib (XL092)	Next-generation TKI targeting I	Next-generation TKI targeting MET/VEGFR/AXL/MER				
XB002	Next-generation TF-targeting A	NDC				
XL102	Potent, selective, orally bioava	ilable CDK7 inhibitor				
CBX-12 (Cybrexa)	Novel exatecan peptide-drug co	onjugate				
ADU-1805 (Sairopa)	Monoclonal antibody targeting	; SIRPα				
XB010	Next-generation 5T4-targeting	ADC				
XB014	Bispecific antibody targeting PI	D-L1 + CD47				
XB628	Bispecific antibody targeting PI	D-L1 + NKG2A				
XB371	Next-generation TF-Topoisome	erase ADC				

 TKI = tyrosine kinase inhibitor
 CDK7 = 0

 TF = tissue factor
 SIRPα =

 ADC = antibody-drug conjugate
 NKG2A :

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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



## Profiles of Zanzalintinib and XB002 are Based on Prior Clinical Proof of Concept

### Zanzalintinib builds on our extensive experience with cabozantinib

Cabozantinib MET/VEGFR/AXL/MER

- Activity in 20 solid tumor types
- Combination activity with checkpoint inhibitors



### Zanzalintinib MET/VEGFR/AXL/MER

- Optimized pharmacokinetic profile
- Active in Phase 1
- Differentiated adverse event profile

#### **Development Strategy**

Develop in indications where cabozantinib has shown activity

**Develop in novel combinations** 

#### XB002 builds on the clinical experience of tisotumab vedotin

#### **Tisotumab Vedotin**

*Tissue factor ADC with monomethyl auristatin E payload* 

- Activity in cervical carcinoma
- Bleeding adverse events
- Opportunity for broader activity limited by dosing



#### XB002 Tissue factor ADC with

modified monomethyl auristatin E payload

- Reduced risk of bleeding events
- Opportunity for broad activity improved stability and exposure

Develop broadly in indications with tissue factor expression

**Develop in novel combinations** 

Retaining the same target profile mitigates biology risk and increases probability of clinical success



# **Robust Pipeline Beyond Cabozantinib**

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## **Strategic Business Development Efforts to Access Clinical Assets a Primary Focus in 2023**



- Exclusive collaboration agreement<sup>\*</sup> for CBX-12, a first-in-class peptide-drug conjugate
- CBX-12 delivers exatecan directly to tumor cells using a pH-sensitive peptide; designed to improve the TI of topoisomerase I inhibition
- Exelixis may exercise option to acquire CBX-12, pending certain phase 1 results; Exelixis and Cybrexa will advance CBX-12 based on an agreed clinical development plan



- Exclusive clinical development and option agreement<sup>\*</sup> for ADU-1805, a potentially best-in-class mAb that targets SIRPα
- ADU-1805 is active against all human alleles of SIRPα; may allow for treatment of a broad population of patients. Optimized for maximum potential benefit of blocking the SIRPα – CD47 checkpoint, while minimizing potential toxicities
- Exelixis may exercise option for ADU-1805 based on assessment of early clinical data; Sairopa will conduct prespecified phase 1 clinical studies

## Option-type structure allows for a capital-efficient way to access compelling clinical-stage assets in a pay for success structure

25 TI = therapeutic indexmAb = monoclonal antibody $SIRP\alpha = signal-regulatory protein alpha$ 

*CD*47 = *cluster of differentiation* 47

\*Agreement announced on November 1, 2022



# **Robust Pipeline Beyond Cabozantinib**

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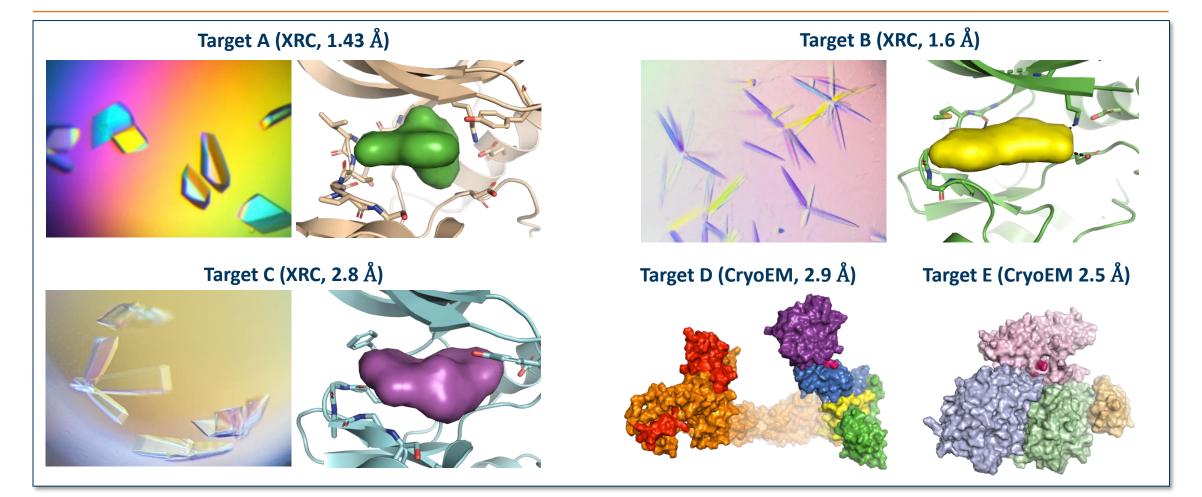
# **Exelixis Preclinical / Discovery Pipeline**

ADCs focused on next-gen opportunities	<ul> <li>XB002 and XB371 next-generation TF-targeting ADCs with different payloads</li> <li>XB010 next-generation 5T4 targeting ADC employing site specific conjugation</li> <li>Multiple additional programs combining novel mAbs with next-generation linker-payload technologies</li> </ul>
Bispecifics / mAbs focused on modulating tumor microenvironment	<ul> <li>Combine blocking a proven checkpoint (PD-L1) with a novel innate immune checkpoint</li> <li>Modulate PD-L1 plus a macrophage checkpoint (XB014, ADU-1805)</li> <li>Modulate PD-L1 plus an NK cell checkpoint (XB628)</li> </ul>
Small molecules focused on synthetic lethality	<ul> <li>Tumor alterations that provide tumor-specific vulnerabilities</li> <li>Maximizes opportunity for good therapeutic index</li> <li>Structure-enabled lead optimization improves probability of success</li> </ul>

TF = tissue factor NK = natural killer

EXELIXIS

## **CryoEM and X-Ray Crystallography for Structurally-Enabled Drug Discovery**



High-resolution structures are solved at project initiation to drive differentiated approaches



# **Development Update**

Vicki Goodman, M.D. EVP, Product Development & Medical Affairs and CMO



# **Progress Update on Internal Clinical Stage Pipeline Programs**

### 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**

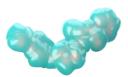
Phase 1a:	STELLAR <sup>001</sup>
Phase 1b:	STELLAR <sup>002</sup>
Phase 3:	STELLAR 303
Phase 3:	STELLAR 304



- Next-generation, TF-targeting ADC
- Potential differentiation across all aspects of the ADC
- Compelling early data presented at FNA 2022

#### **Ongoing Clinical Trials** Phase 1: **VI Jewel** 101

### **XL102**



- Potent, orally bioavailable and highly selective covalent CDK7 inhibitor
- Initial Phase 1 dose-escalation data presented at SABCS 2022
- Dose-escalation ongoing; go/no-go decision expected by year-end 2023

## **Ongoing Clinical Trials** Phase 1: Quartz 101

Retaining strong focus on clinical trial execution while continuing to refine strategic approach for each pipeline asset

ESMO = European Society for Medical Oncology



TF = tissue factor 30

TKI = tyrosine kinase inhibitor CDK7 = cyclin-dependent kinase 7 ENA = EORTC-NCI-AACR Symposium ADC = antibody-drug conjugate SABCS = San Antonio Breast Cancer Symposium

# Zanzalintinib: Update on STELLAR-001 ccRCC Expansion Cohort

- ccRCC 2L+ expansion cohort enrollment completed: 32 patients at 100 mg starting dose
- Preliminary efficacy data on-hand for full cohort of prior-ICI treated, including prior-cabo treated and cabo-naïve patients
- With a median follow-up of 7 months:
  - **34%** ORR for the full cohort
  - **50%** ORR for patients who were cabo-naïve
  - 1 unconfirmed PR in the cabo-naïve population; awaiting results of confirmatory scan
- Emerging safety profile continues to look encouraging
- Data planned for submission to an upcoming medical conference

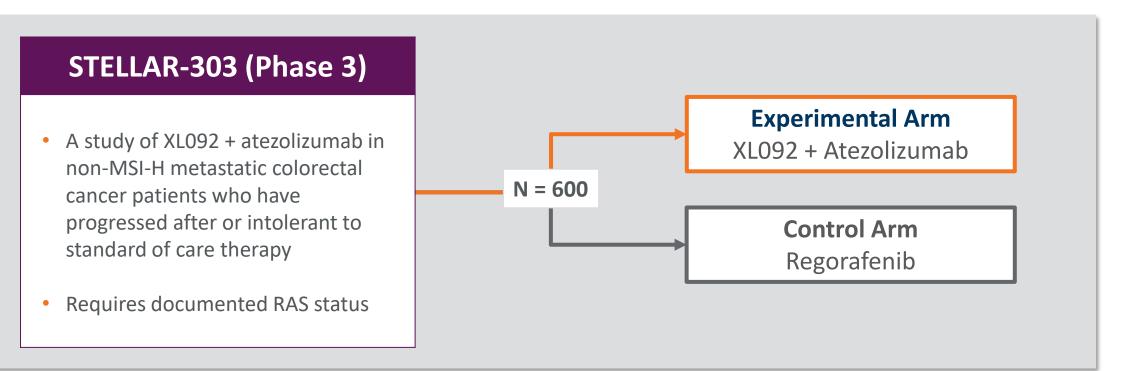
Data provide evidence for activity of zanza in a cabo-sensitive tumor type & provide additional support for leveraging cabo data to inform the zanza development program

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## STELLAR-303: Pivotal Study of XL092 + Atezolizumab in 3L+ CRC

Exelixis-sponsored Study with Atezolizumab Supplied by Genentech/Roche



#### **Key Study Objectives**

OS = overall survival

- **Primary:** OS (ITT RAS wild type)
- Additional: PFS, ORR, DOR, QoL •

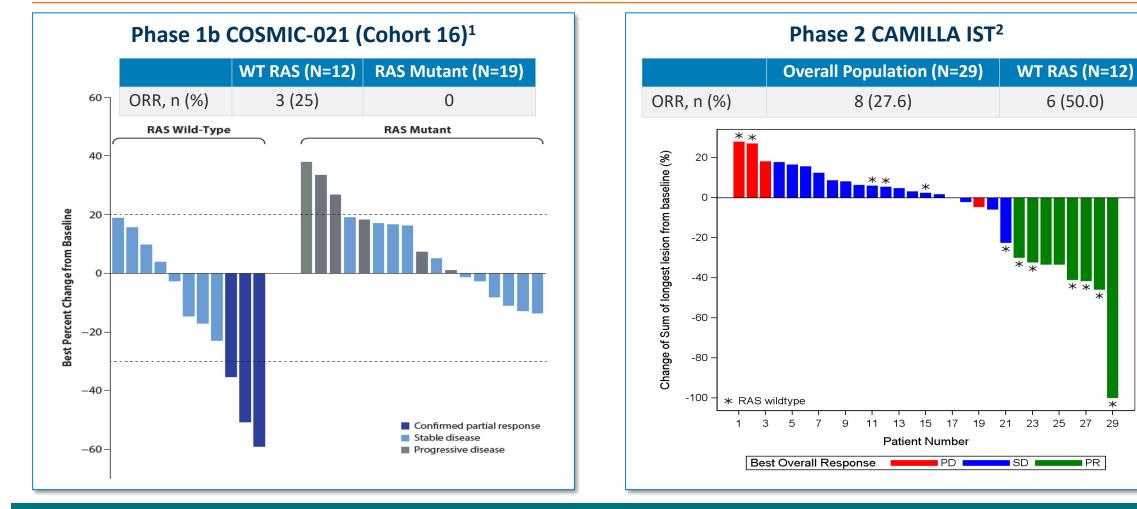
Trial hypothesis based on promising cabozantinib data from COSMIC-021 and CAMILLA clinical studies

ITT = intent to treat *PFS* = *progression* free survival DOR = duration of response *ORR* = *objective response rate* QoL = quality of life

3L = third-lineCRC = colorectal cancer *MSI-H = microsatellite instability-high* 



## STELLAR-303 Rationale is Supported by COSMIC-021 Cohort 16 and Phase 2 CAMILLA IST in Previously Treated MSS Colorectal Cancer



#### Both trials showed improved outcomes in patients with RAS wild-type vs those with RAS mutant disease

MSS = microsatellite stable WT = wild type ORR = objective response rate

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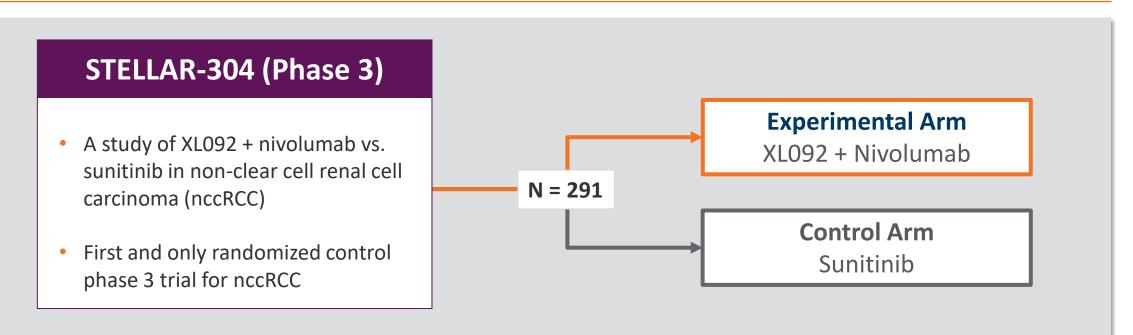
PD = progressive disease SD = stable disease PR = partial response IST = investigator-sponsored study

1. Abrams T et al. ASCO GI 2022. Abs 121. 2. Saeed A et al. ASCO GI 2022. Abs 135.



## **STELLAR-304: Pivotal Study of XL092 + Nivolumab in 1L nccRCC**

Exelixis-sponsored Study with Nivolumab Supplied by Bristol Myers Squibb



#### **Key Study Objectives**

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

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- Trial hypothesis based on NCI-sponsored phase 2 study of cabozantinib; and Phase 2 IST of cabozantinib + nivolumab
- Remain on track to initiate additional phase 3 studies by year-end 2023

 1L = first-line
 OS = overall survival

 PFS = progression-free survival
 NCI = National Cancer Institute

 ORR = objective response rate
 IST = investigator-sponsored study

*RECIST* = *Response Evaluation Criteria in Solid Tumors* 

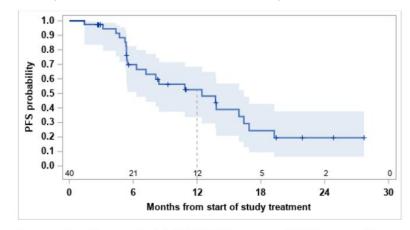


## STELLAR-304 Study Rationale Supported by Cabozantinib Data from Phase 2 Studies in nccRCC

Phase II Trial of Cabozantinib Plus Nivolumab in Patients With Non-Clear-Cell Renal Cell Carcinoma and Genomic Correlates.

Lee et al., J Clin Oncol. 2022 Jul 20; 40(21): 2333-2341.

A total of 47 patients were treated with a median follow-up of 13.1 months. Objective response rate for cohort 1 (n = 40) was 47.5% (95% CI, 31.5 to 63.9), with median progression-free survival of 12.5 months (95% CI, 6.3 to 16.4) and median overall survival of 28 months (95% CI, 16.3 to not evaluable).

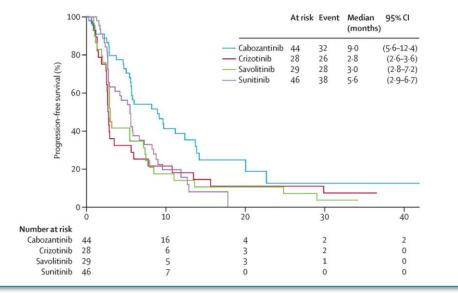


**Progression-free survival, irRECIST.** There were 20 PFS events (18 progressions and 2 deaths without progression). Median PFS is 12.5 months (95% CI: 6.3, 16.4). The PFS estimate is 52.6% (95% CI: 33.8, 68.3) at 12 months.

A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial.

Pal et al., Lancet. 2021 February 20; 397(10275): 695–703.

Overall, 152 patients were enrolled. PFS was longer with cabozantinib versus sunitinib (9.0 months vs. 5.6 months; hazard ratio for progression or death, 0.60; 95% CI 0.37–0.97, P=0.019 [1-sided]). Response rate for cabozantinib was 23% versus 4% for sunitinib (2-sided P=0.010).



# **Progress Update on Internal Clinical Stage Pipeline Programs**

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



- Next-generation, TF-targeting ADC
- Potential differentiation across all aspects of the ADC
- Compelling early data presented at FNA 2022

#### **Ongoing Clinical Trials** Phase 1: **VI Jewel** 101

## XI 102



- Potent, orally bioavailable and highly selective covalent CDK7 inhibitor
- Initial Phase 1 dose-escalation data presented at SABCS 2022
- Dose-escalation ongoing; go/no-go decision expected by year-end 2023

#### **Ongoing Clinical Trials** Phase 1: Quartzion

Retaining strong focus on clinical trial execution while continuing to refine strategic approach for each pipeline asset

ESMO = European Society for Medical Oncology

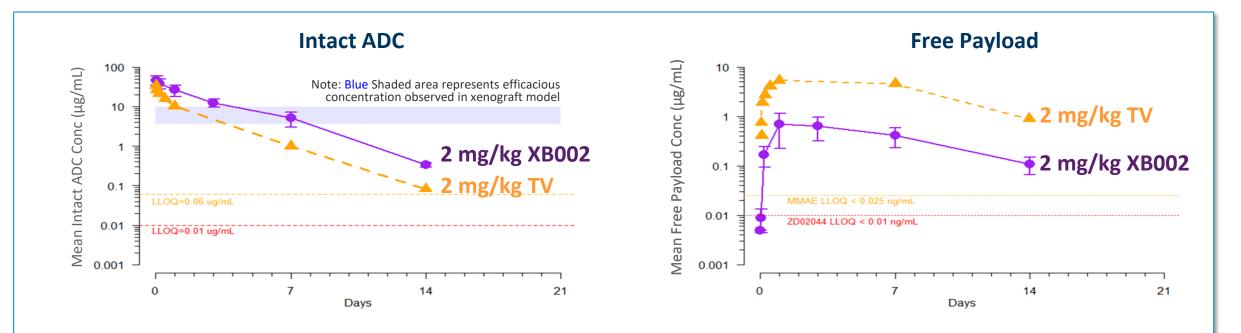


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TKI = tyrosine kinase inhibitor CDK7 = cyclin-dependent kinase 7 ENA = EORTC-NCI-AACR Symposium ADC = antibody-drug conjugate SABCS = San Antonio Breast Cancer Symposium

*TF* = *tissue factor* 

# XB002 TF-targeting ADC: Phase 1 JEWEL-101 Dose Escalation PK Data from ENA 2022 Presentation Relative to Tisotumab Vedotin Label PK Data



#### At 2.0 mg/kg XB002 or TV:

10X₽

XB002 has ~2X HIGHER EXPOSURE than TV AUC<sub>0-t</sub> (μg·day/mL): 121 XB002 vs 57.5 TV XB002 has 1/10<sup>TH</sup> THE FREE PAYLOAD than TV AUC<sub>0-t</sub> (μg·day/mL): 4.21 XB002 vs 50 TV

PK = pharmacokinetics ADC = antibody-drug conjugate AUC = area under the curve

**2X**企

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TV = tisotumab vedotin LLOQ = lower limit of quantification ENA = EORTC-NCI-AACR Symposium

Ulahannan S et al. ENA 2022. Abs 256. XB002 data cutoff: July 21, 2022
 PopPK Analysis in FDA Clin Pharm Review Package & TIVDAK Package Insert.



Plan to Accelerate XB002 Development Activities as a Single Agent and in **Combination Regimens Across a Wide Range of Tumor Types in 2023 and Beyond** 



First-in-human phase 1 study of XB002 as a single agent and in combination with immunotherapy

Dose-Escalation Stage Cohorts										
XB002 Mor Enrollmen		XB002 + N Enrollmen	ivolumab: t Ongoing	XB002 + Bevacizum Enrollment Ongoir						
9 Dose ( 0.16 - 3.0 mg (Advanced So	g/kg IV Q3W	Announced in Novem (Advanced S		ted in per 2022 olid Tumors)						
			– Planned Tu							
NSC	CLC	Ova	rian	Cervical						
Endor	netrial	HN	scc	Pancreatic						
Esoph	ageal	HR+	BC	mCRPC						
				ressing						

- Enrollment ongoing in monotherapy and combination dose-escalation cohorts
- Nearing declaration of RD for monotherapy dose-escalation cohort
- Initiation of cohort expansion stage planned after RD and/or MTD determined
- Initial dose-escalation data presented in Oct'22
  - PK analysis suggests XB002 remained stable after infusion with low levels of free circulating payload
  - XB002 was well-tolerated across multiple dose levels

TNBC = triple negative breast cancer TF = tissue factor



IV = intravenous Q3W = every three weeks *RD* = *recommended dose* 

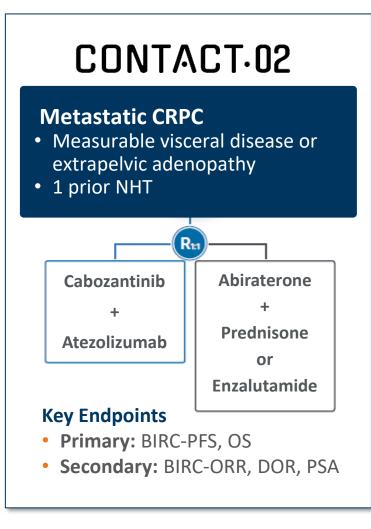
PK = pharmacokinetics

MTD = maximum-tolerated dose NSCLC = non-small cell lung cancer

HNSCC = head and neck squamous cell carcinoma *mCRPC* = *metastatic castration-resistant prostate cancer* HR+ BC = hormone receptor positive breast cancer

#### **CONTACT-02:** Pivotal Study of Cabozantinib + Atezolizumab in 1L/2L mCRPC

Clinical Collaboration between Exelixis and Roche/Genentech



#### Q1 2023 CONTACT Program Updates:

- **CONTACT-02** enrollment completion and readout of PFS • primary endpoint remains on track for second half of 2023
- **CONTACT-03** full dataset to be presented at ASCO 2023 •
  - Provides largest dataset on the performance of single agent cabozantinib in RCC patients who have previously received **ICI-based therapy**

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

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PFS = proaression-free survival OS = overall survival NHT = novel hormonal therapy *ORR* = *objective response rate* 

DOR = duration of response *PSA* = *prostate-specific antiaen* RCC = renal cell carcinoma

mCRPC = metastatic castration-resistant prostate cancer BIRC = blinded independent review committee ASCO = American Society of Clinical Oncology Annual Meeting ICI = immune checkpoint inhibitor



#### Q1 2023 Development Summary

Continue to advance pipeline molecules and believe emerging data for zanzalintinib and XB002 are encouraging

Plan to share emerging data from pipeline programs at upcoming medical conferences as the data mature

Aim to expedite the development of promising pipeline assets into registrational trials as rapidly as possible for the benefit of patients with cancer



## Closing

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



### **Anticipated Milestones for 2023**

Program	Milestone
	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
	Report next overall survival analysis from phase 3 COSMIC-313 pivotal trial evaluating triplet combination of cabozantinib + nivolumab + ipilimumab in advanced intermediate- or poor-risk first-line RCC
Zanzalintinib	Initiate multiple new phase 3 pivotal trials evaluating zanzalintinib across indications, tumor types and novel IO combinations
	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
XB002	Initiate cohort expansion stage of phase 1 JEWEL-101 study after RD and/or MTD have been determined
	Advance additional combination cohorts to identify sensitive tumor types
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), XB014 (PD-L1 x CD47 bsAb) and XB628 (PD-L1 x NKG2A bsAb) biotherapeutic DCs through preclinical and IND-enabling studies in 2023, toward potential IND filings in 2024
Preclinical / Discovery	Advance up to five new development candidates across multiple modalities / mechanisms of small molecules and biologics

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*mCRPC* = *metastatic castration-resistant prostate cancer PDC* = *peptide-drug conjugate* MTD = maximum-tolerated dose IND = Investigational New Drug application

bsAb = bispecific antibody NKG2A = natural killer cell receptor group 2A PD-L1 = programmed death-ligand 1 *DC* = *development candidate* 

SIRPα = signal-regulatory protein alpha CD47 = cluster of differentiation 47



## **Q&A** Session



TUESDAY, MAY 9, 2023

## First Quarter 2023 Financial Results

Nasdaq: EXEL





### **Financial Appendix**



### **Non-GAAP Financial Highlights: Q1'23**

(in millions, except per share amounts)

	Q1'22	Q1'22 Q4'22		YoY Delta	QoQ Delta
Total revenues	\$356.0 M	\$423.9 M	\$408.8 M	+15%	-4%
Cost of goods sold	\$13.2 M	\$15.9 M	\$14.3 M	+8%	-10%
R&D expenses <sup>(a)(b)</sup>	\$147.8 M	\$326.4M	\$231.0 M	+56%	-29%
SG&A expenses <sup>(a)(b)</sup>	\$92.0 M	\$103.9 M	\$118.0 M	+28%	+14%
Total operating expenses <sup>(a)(b)</sup>	\$253.0 M	\$446.1 M	\$363.3 M	+44%	-19%
Other income, net	\$2.0 M	\$16.7 M	\$19.4 M	+879%	+17%
Income tax provision (benefit) <sup>(a)</sup>	\$21.1 M	\$4.6 M	\$12.1 M	-43%	+161%
Net income (loss) <sup>(a)</sup>	\$83.9 M	\$(10.2) M	\$52.8 M	-37%	n/a
Net income (loss) per share, diluted <sup>(a)</sup>	\$0.26	\$(0.03)	\$0.16	-38%	n/a
Ending cash and investments <sup>(c)</sup>	\$1,988.9 M	\$2,066.7 M	\$2,121.2 M	+7%	+3%

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

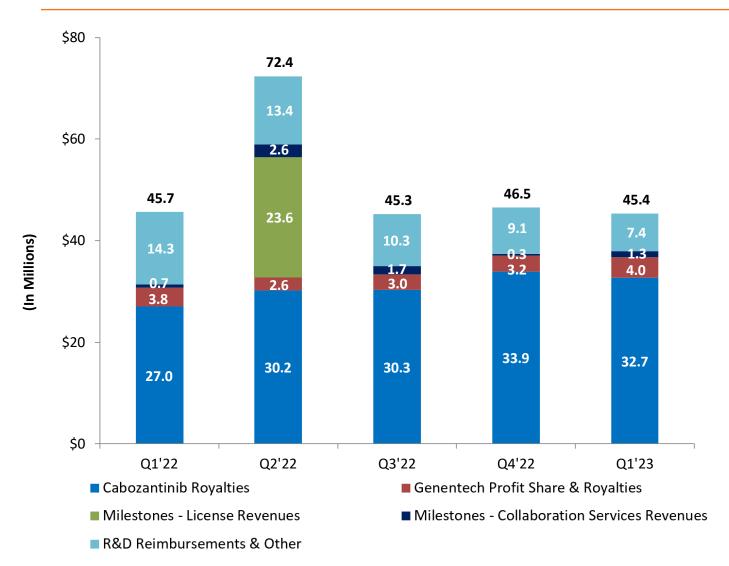
(b) Amounts reflect non-GAAP adjustment before tax effect.



<sup>(c)</sup> Cash and Investments is composed of cash, cash equivalents, restricted cash equivalents and investments.

### **Collaboration Revenues Detail**

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



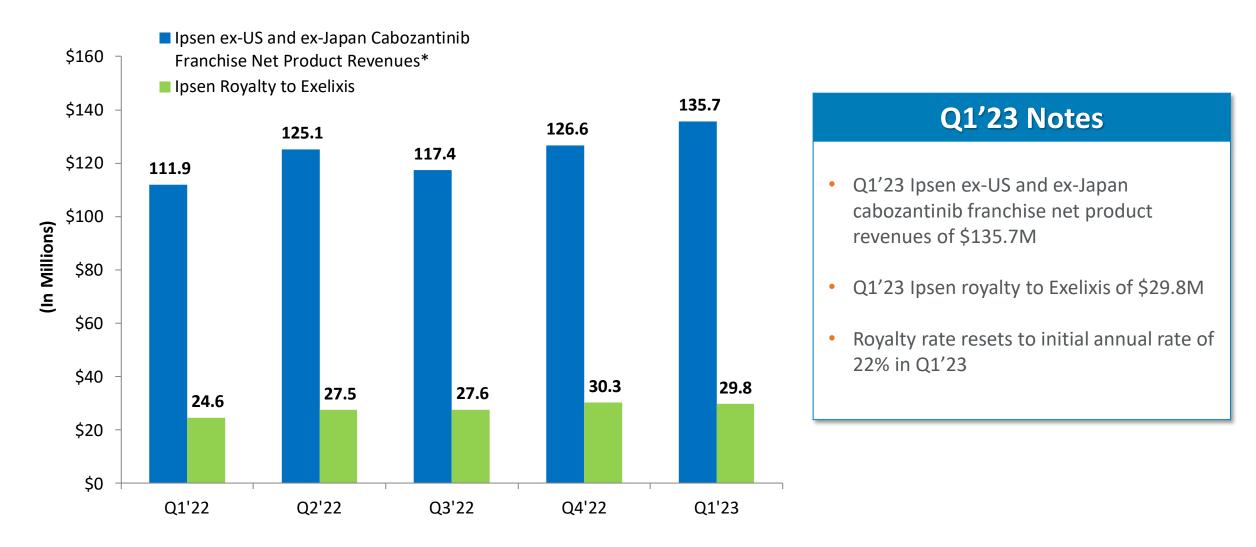
#### Q1'22 – Q1'23 Notes

- Q1'23 cabozantinib royalties to Exelixis of \$32.7M
- Genentech collaboration:
  - Q1'23 ex-US COTELLIC<sup>®</sup> royalties \$1.1M
  - Q1'23 US COTELLIC profit share \$2.9M
- Significant milestone revenues recognized by quarter:
  - Q2'22: Ipsen milestones for DTC (COSMIC-311) approval by EMA and Health Canada
  - No new milestone license revenues recognized in four out of the last five quarters



### **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.

	 Q1'22		Q2'22		Q3'22	(	Q4'22	 Q1'23
Research and development expenses reconciliation:								
GAAP Research and development expenses	\$ 156.7	\$	199.5	\$	198.8	\$	336.8	\$ 234.2
Stock-based compensation expenses <sup>(1)</sup>	 (8.9)		(9.5)		(16.4)		(10.5)	 (3.3)
Non-GAAP Research and development expenses	\$ 147.8	\$	189.9	\$	182.4	\$	326.4	\$ 231.0
Selling, general and administrative expenses reconciliation:								
GAAP Selling, general and administrative expenses	\$ 102.9	\$	122.8	\$	115.0	\$	119.3	\$ 131.4
Stock-based compensation expenses <sup>(1)</sup>	 (10.9)		(15.1)		(20.9)		(15.4)	 (13.4)
Non-GAAP Selling, general and administrative expenses	\$ 92.0	\$	107.7	\$	94.1	\$	103.9	\$ 118.0
Operating expenses reconciliation:								
GAAP Operating expenses	\$ 272.7	\$	335.7	\$	329.1	\$	472.0	\$ 380.0
Stock-based compensation - Research and development expenses <sup>[1]</sup>	(8.9)		(9.5)		(16.4)		(10.5)	(3.3)
Stock-based compensation - Selling, general and administrative expenses <sup>(1)</sup>	 (10.9)		(15.1)		(20.9)		(15.4)	 (13.4)
Non-GAAP Operating expenses	\$ 253.0	\$	311.1	\$	291.8	\$	446.1	\$ 363.3
Income tax provision								
GAAP Income tax provision	\$ 16.7	\$	17.8	\$	18.8	\$	(1.3)	\$ 8.3
Income tax effect of stock-based compensation - Research and development <sup>(2)</sup>	2.0		2.1		3.7		2.4	0.8
Income tax effect of stock-based compensation - Selling, general and administrative <sup>(2)</sup>	 2.5		3.4		4.8		3.5	 3.1
Non-GAAP Income tax provision	\$ 21.1	\$	23.4	\$	27.3	\$	4.6	\$ 12.1

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

(in millions, except per share amounts)

	0	1'22	Q2'22		C	Q3'22		Q4'22		1'23
Net Income reconciliation:										
GAAP Net Income	\$	68.6	\$	70.7	\$	73.2	\$	(30.2)	\$	40.0
Stock-based compensation - Research and development <sup>(1)</sup>		8.9		9.5		16.4		10.5		3.3
Stock-based compensation - Selling, general and administrative <sup>(1)</sup>		10.9		15.1		20.9		15.4		13.4
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>		(4.4)		(5.6)		(8.5)		(5.9)		(3.9)
Non-GAAP Net Income	\$	83.9	\$	89.7	\$	102.0	\$	(10.2)	\$	52.8
Net Income per share, diluted:										
GAAP Net Income per share, diluted	\$	0.21	\$	0.22	\$	0.23	\$	(0.09)	\$	0.12
Stock-based compensation - Research and development <sup>(1)</sup>		0.03		0.03		0.05		0.03		0.01
Stock-based compensation - Selling, general and administrative <sup>(1)</sup>		0.03		0.05		0.06		0.05		0.04
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>		(0.01)		(0.02)		(0.03)		(0.02)		(0.01
Non-GAAP Net Income per share, diluted	\$	0.26	\$	0.28	\$	0.31	\$	(0.03)	\$	0.16
Weighted-average shares used to compute GAAP net income per share, diluted		323.3		324.9		325.1		323.3		326.3

<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		Q1'22	(	Q2'22	Q	3'22	C	4'22	(	Q1'23
Roche (Genentech)	COTELLIC	Profit Share & Royalties on Ex-U.S. sales	\$	3.8	\$	2.6	\$	3.0	\$	3.2	\$	4.0
Partner Royalties	Cabozantinib	Royalties on ex-U.S.		27.0		30.2		30.3		33.9		32.7
Milestones:												
lpsen	Cabozantinib	Amortization of Milestones Triggered prior to Q1'18		(0.1)		(0.2)		0.3		0.3		0.2
lpsen	Cabozantinib	\$50M M/S 1L RCC Approval		-		(0.1)		0.1		0.1		0.1
psen	Cabozantinib	\$40M M/S EMA 2L HCC Approval		-		(0.1)		0.1		0.1		0.1
lpsen	Cabozantinib	\$12.5M M/S MAA filing DTC		-		-		-		-		-
lpsen	Cabozantinib	\$100M Net sales 4 consecutive quarters >\$400M		-		-		-		-		-
Ipsen	Cabozantinib	\$2M M/S Canada MAA Approval, 1st indication (DTC)		-		2.0		-		-		-
lpsen	Cabozantinib	\$25M M/S MAA approval by EMA, tier 2 add'l indication (DTC)		-		23.7		0.1		0.1		-
Takeda	Cabozantinib	\$16M M/S Japan regulatory filing 2L RCC		0.3		0.3		0.3		(0.1)		0.2
Takeda	Cabozantinib	\$26M M/S 1st Commercial Sale in Japan - 2L RCC		0.3		0.3		0.3		(0.1)		0.2
Takeda	Cabozantinib	\$15M M/S 1st Commercial Sale in Japan - 2L HCC		0.1		0.1		0.1		-		0.1
Takeda	Cabozantinib	\$20M M/S 1st Commercial Sale in Japan - 1L RCC		0.1		0.1		0.1		-		0.1
		Subtotal Milestones	\$	0.7	\$	26.2	\$	1.7	\$	0.3	\$	1.3
		Milestones License revenues	\$	-	\$	23.6	\$	-	\$	-	\$	-
		Milestones Collaboration services revenues	\$	0.7	\$	2.6	\$	1.7	\$	0.3	\$	1.3
R&D Reimbursements & Ot	ther:											
lpsen	Cabozantinib	R&D reimbursement and Product Supply	\$	10.3	\$	9.7	\$	6.1	\$	5.7	\$	2.9
lpsen	Cabozantinib	\$200M Upfront fee		(0.2)		(0.3)		0.4		0.4		0.3
Takeda	Cabozantinib	R&D reimbursement and Product Supply		2.7		2.7		2.5		2.1		2.5
Takeda	Cabozantinib	\$50M Upfront fee		0.1		0.1		0.1		-		0.1
Daiichi Sankyo & royalties	MR CS-3150/MINNEBRO			1.3		1.1		1.1		1.0		1.6
		Subtotal R&D Reimbursments & Other	\$	14.3	\$	13.4	\$	10.3	\$	9.1	\$	7.4
Total License revenues			\$	32.1	\$	57.5	\$	34.4	\$	38.1	\$	38.3
Total Collaboration servic	es revenues			13.6		14.9		10.9		8.4		7.1
TOTAL COLLABORATION RE	VENUES		Ś	45.7	\$	72.4	Ś	45.3	Ś	46.5	Ś	45.4

TUESDAY, MAY 9, 2023

## First Quarter 2023 Financial Results

Nasdaq: EXEL



