# Fourth Quarter and Full Year 2020 Financial Results

Wednesday, February 10, 2021

Nasdaq: EXEL





### **Today's Agenda**

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Q4 and Full Year 2020 Highlights

**Financial Results & Guidance** 

**Clinical Development Update** 

**Commercial Update** 

Q&A

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

**Michael M. Morrissey, Ph.D.** President & CEO

**Chris Senner** EVP & CFO

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

**PJ Haley** EVP, Commercial

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



### Safe Harbor Statement

This presentation, including any oral presentation accompanying it, contains forward-looking statements, including, without limitation, statements related to: Exelixis' anticipation of a projected annualized runrate of approximately \$1.5 billion for U.S. RCC business by the end of 2022; potential clinical and regulatory milestones for Exelixis in 2021, including three potential sNDA submissions, up to two additional IND filings, advancing COSMIC and CONTACT trials for cabozantinib, progress on the XL092 development program, early evaluations of XL102 and XB002, planned initiation of a phase 1 clinical trial for XB002 and moving discovery programs towards development candidate status; Exelixis' 2021 financial guidance; the potential for HRQoL data from the CheckMate -9ER trial to provide additional differentiation for the combination of cabozantinib and nivolumab compared to other TKI-immunotherapy options in 1L RCC; Exelixis' expectations for, and the related anticipated timelines for, completing enrollment in, conducting analyses of and obtaining top-line results from its ongoing potential label-enabling clinical studies evaluating cabozantinib, and if supported by the data, pursuing potential regulatory approvals; Exelixis' expectations regarding the clinical and therapeutic potential of XL092, including in combination with ICIs, and development plans for XL092; Exelixis' plans to initiate late-stage XL092 trials as soon as 2021, with some indications having the potential for accelerated development; planned cabozantinib presentations at ASCO GU 2021; the potential for 2021 to be a transformative year for CABOMETYX driven by the recent approval of the combination of CABOMETYX and OPDIVO and its potential for broad use in the 1L RCC setting, with market share and duration of therapy creating significant revenue growth in 2021 and beyond, as well as potential label expansions for CABOMETYX following upcoming data readouts; market trends and sequencing dynamics in the RCC market and the commercial potential for CABOMETYX in the various RCC settings; the potential for significant growth in 2021 and beyond for CABOMETYX in multiple therapeutic areas with multiple ICI combination partners, as well as potential for additional growth from XL092, XL102, XB002, near-term INDs and discovery efforts and collaborations; and Exelixis' anticipated milestones and expectations for 2021. 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. Forwardlooking 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 continuing COVID-19 pandemic and its impact on Exelixis' clinical trial, drug discovery and commercial activities; 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 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 products; 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 discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2020, and in Exelixis' future filings with the SEC, including, without limitation, Exelixis' Annual Report on Form 10-K expected to be filed with the SEC in February 2021. 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.



# Fourth Quarter and Full Year 2020 Highlights

# Michael M. Morrissey, Ph.D.

President & CEO



### Strong Execution in 2020 with a Focus on Revenue Growth in 2021



#### FDA approval for CABOMETYX<sup>®</sup> + OPDIVO<sup>®</sup> combination in 1L RCC

- Based on CheckMate -9ER pivotal trial, with doubling of PFS and ORR, significant improvement in OS, extended DOR, and improved QOL vs sunitinib
- Key RCC revenue growth driver, supporting potential \$1.5B annualized run-rate in the U.S. by the end of 2022

#### A year of important clinical and regulatory milestones in 2021

- Three potential sNDA submissions and up to two additional IND filings by year-end
- Advancing COSMIC and CONTACT clinical trials for cabozantinib
- Progress on development of XL092, currently enrolling single-agent and ICI combination cohorts
- Phase 1 trial for XL102 underway; XB002 Phase 1 trial initiation planned shortly

#### Strong presence at the 2021 ASCO GU Symposium, Feb. 11-13<sup>th</sup>

- Multiple important updates for cabozantinib in RCC
- Exelixis Investor Briefing on Saturday, Feb. 13<sup>th</sup> at 5:30 p.m. ET

FDA = U.S. Food and Drug Administration 1L = first-line RCC = renal cell carcinoma

PFS = progression-free survival ORR = objective response rate OS = overall survival

DOR = duration of response QOL = quality of life sNDA = supplemental New Drug Application IND = Investigational New Drug application ICI = immune checkpoint inhibitor



# **Financial Results & Guidance**

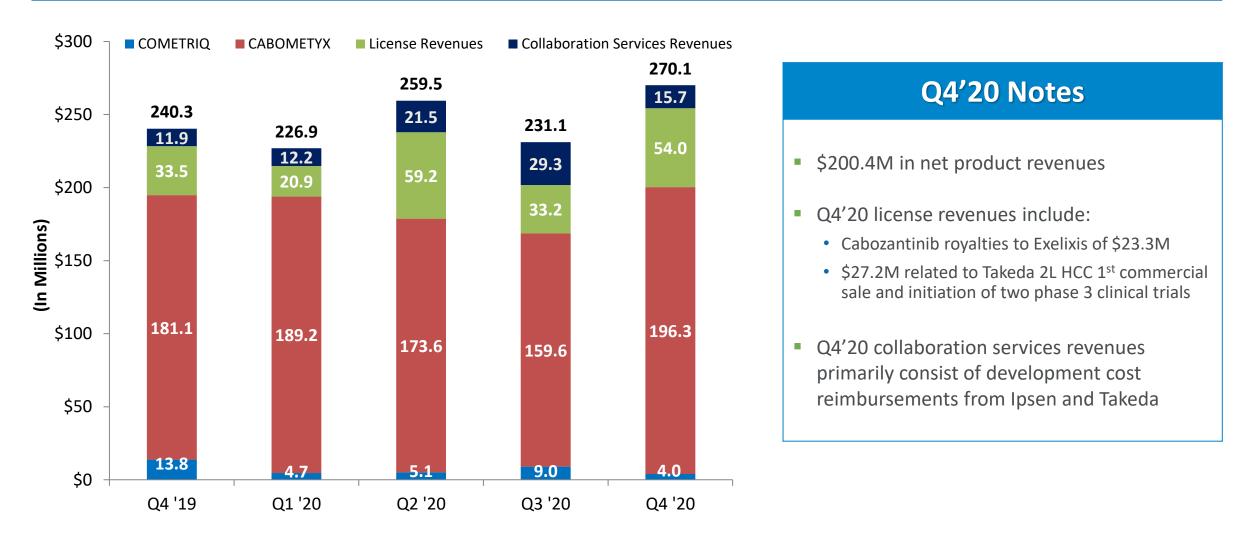
Chris Senner

EVP & CFO



### Q4'20 Total Revenues

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



Amounts may not sum due to rounding

HCC = hepatocellular carcinoma

2L = second-line

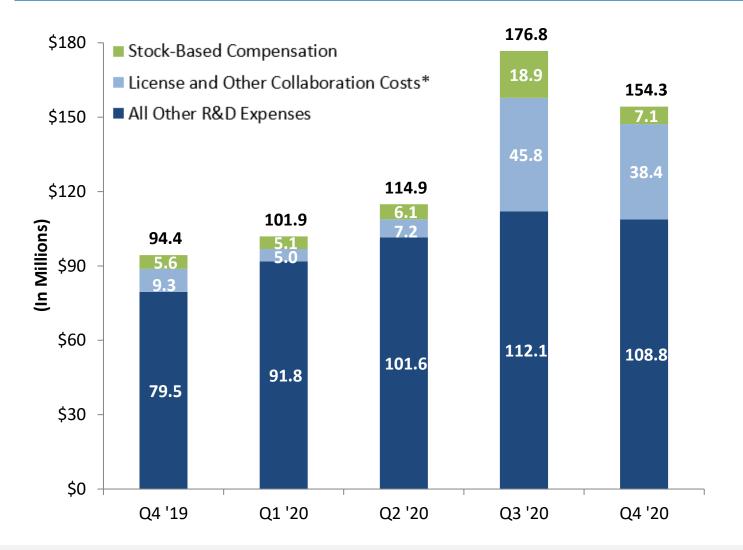
Adoption of ASU 2018-18 in Q1'20 impacted the presentation of our revenues. Net product revenues and License revenues are recorded in accordance with Topic 606 and presented separately from Collaboration services revenues which are recorded in accordance with Topic 808.



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### Q4'20 R&D Expenses

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



#### Q4'20 Notes

- GAAP R&D expenses of \$154.3M
- Decrease in R&D expenses vs. Q3'20 primarily due to lower stock-based compensation expenses, as well as lower license and other collaboration costs
- License and other collaboration costs include \$20M Iconic option exercise fee and \$12M Aurigene option exercise fee
- Non-GAAP R&D expenses of \$147.2M (excludes stock-based compensation expenses, before tax effect)



Amounts may not sum due to rounding

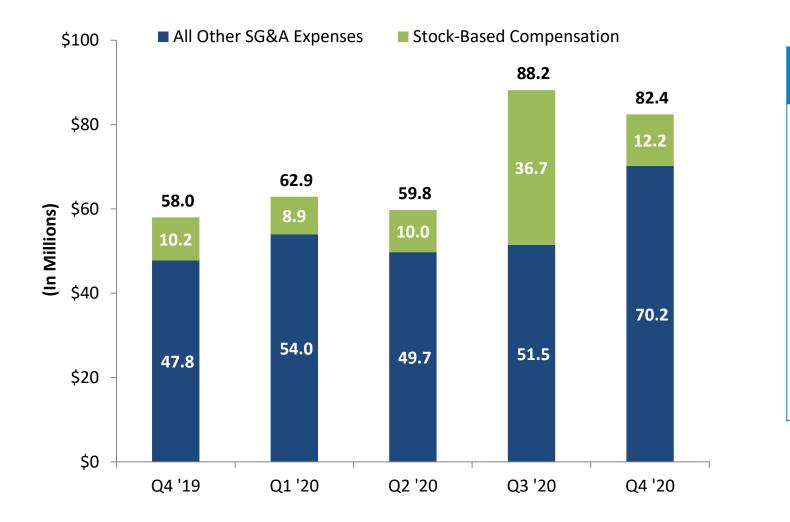
A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

\*License and other collaboration costs includes upfront, option exercise fee, program initiation, development milestone and R&D funding for our research collaboration and in-licensing agreements

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### Q4'20 SG&A Expenses

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



#### Q4'20 Notes

GAAP SG&A expenses of \$82.4M

 Decrease in GAAP SG&A expenses vs. Q3'20 primarily due to lower stock-based compensation expenses, partially offset by increased corporate giving

 Non-GAAP SG&A expenses of \$70.2M (excludes stock-based compensation expenses, before tax effect)

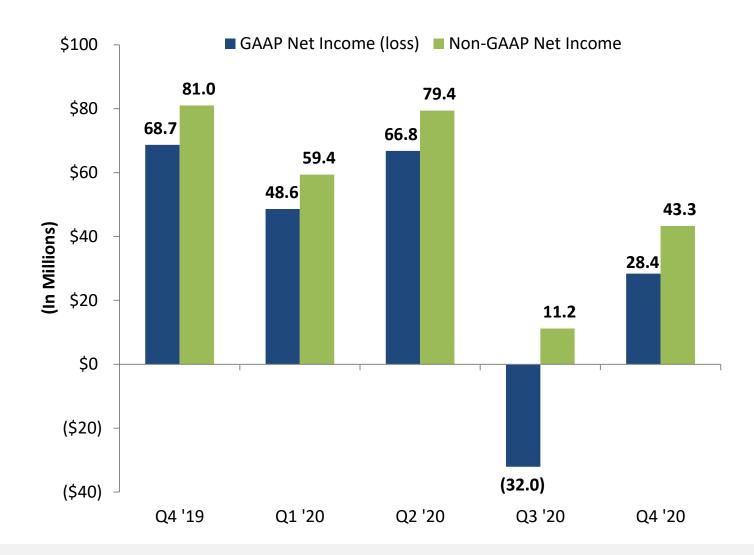


Amounts may not sum due to rounding

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

### Q4'20 Net Income (Loss)

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



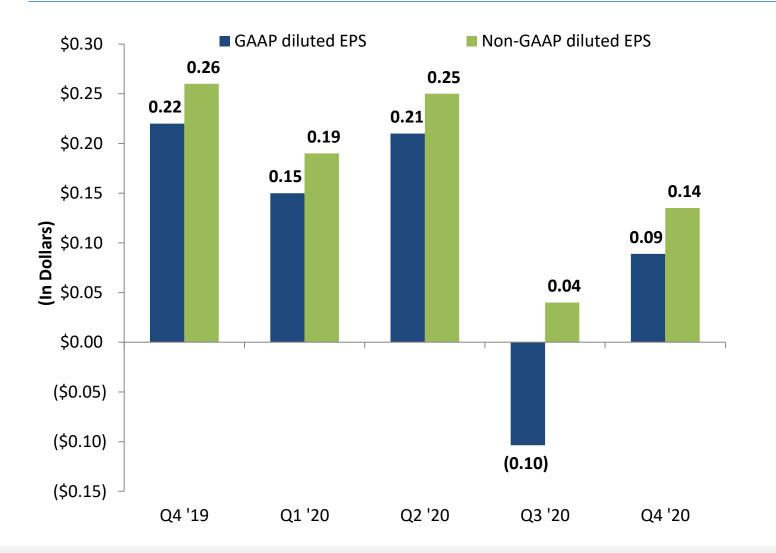
#### Q4'20 Notes

- GAAP net income of \$28.4M
- Increase in GAAP net income vs. Q3'20 primarily due to higher total revenues and lower stock-based compensation expenses
- Non-GAAP net income of \$43.3M (excludes stock-based compensation expenses, net of tax effect)



### Q4'20 Diluted Earnings (Loss) Per Share

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



#### Q4'20 Notes

- GAAP diluted earnings per share of \$0.09
- Increase in GAAP diluted EPS vs. Q3'20 primarily due to higher total revenues and lower stock-based compensation expenses
- Non-GAAP diluted EPS of \$0.14 (excludes stock-based compensation expenses, net of tax effect)



### **GAAP Financial Highlights: Q4'20**

(in millions, except per share amounts)

	<u>Q4'19</u>	<u>Q3'20</u>	<u>Q4'20</u>	YoY Delta	QoQ Delta
Total revenues	\$240.3 M	\$231.1 M	\$270.1 M	+12%	+17%
Cost of goods sold	\$10.5 M	\$8.7 M	\$9.0 M	-14%	+4%
R&D expenses	\$94.4 M	\$176.8 M	\$154.3 M	+63%	-13%
SG&A expenses	\$58.0 M	\$88.2 M	\$82.4 M	+42%	-7%
Total operating expenses	\$163.0 M	\$273.7 M	\$245.8 M	+51%	-10%
Other income, net	\$7.7 M	\$4.6 M	\$3.8 M	-50%	-16%
Income tax provision (benefit)	\$16.3 M	\$(6.0) M	\$(0.3) M	n/a	-96%
Net income (loss)	\$68.7 M	\$(32.0) M	\$28.4 M	-59%	n/a
Net income (loss) per share, diluted	\$0.22	\$(0.10)	\$0.09	-59%	n/a
Ending cash and investments	\$1,388.6 M	\$1,546.0 M	\$1,538.8 M	+11%	0%



### **GAAP Financial Highlights: Fiscal Year 2020**

(in millions, except per share amounts)

	<u>FY 2019</u>	<u>FY 2020</u>	YoY Delta
Total revenues	\$967.8 M	\$987.5 M	+2%
Cost of goods sold	\$33.1 M	\$36.3 M	+10%
R&D expenses	\$337.0 M	\$547.9 M	+63%
SG&A expenses	\$228.2 M	\$293.4 M	+29%
Total operating expenses	\$598.3 M	\$877.5 M	+47%
Other income (expense), net	\$28.6 M	\$20.8 M	-27%
Income tax provision (benefit)	\$77.1 M	\$19.1 M	-75%
Net income	\$321.0 M	\$111.8 M	-65%
Net income per share, diluted	\$1.02	\$0.35	-66%
Ending cash and investments	\$1,388.6 M	\$1,538.8 M	+11%



### **Fiscal Year 2021 Financial Guidance**\*

	Guidance
Total Revenues	\$1,150M - \$1,250M
Net Product Revenues	\$950M - \$1,050M
Cost of Goods Sold	5% - 6% of net product revenues
R&D Expenses	<b>\$600M - \$650M</b> Includes <b>\$45M</b> in non-cash stock-based compensation
SG&A Expenses	\$375M - \$425M Includes \$60M in non-cash stock-based compensation
Effective Tax Rate	20% - 22%
Cash and Investments** (at year-end 2021)	\$1.6B - \$1.7B



\*The financial guidance reflects U.S. GAAP amounts.

\*\*This cash and investments guidance does not include any potential new business development activity.

# **Clinical Development Update**

# Gisela Schwab, M.D.

President, Product Development and Medical Affairs & CMO



### **Development Updates: 2020 Achievements Set Up Impactful 2021**

#### Regulatory and development progress for cabozantinib

- FDA approval on January 22, 2021 of cabozantinib plus nivolumab combination for 1L treatment of advanced RCC, based on CheckMate -9ER pivotal Phase 3 study
- COSMIC and CONTACT clinical development program updates

#### Advancing the development of XL092 and early-stage pipeline assets

- XL092 currently in Phase 1b clinical development in combination with atezolizumab
- Progress with XL102 and XB002 programs

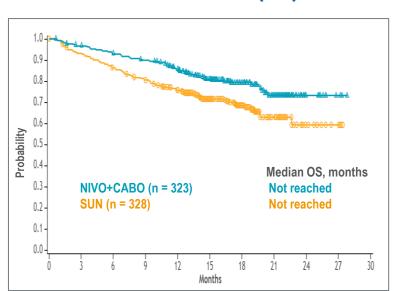
#### Preview of upcoming clinical data to be presented at ASCO GU 2021, Feb. 11-13<sup>th</sup>

• Updates from CheckMate -9ER and other cabozantinib clinical studies

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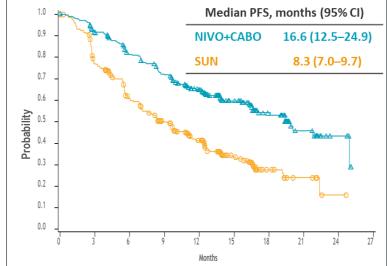


# Received U.S. FDA Approval on Jan. 22, 2021 for the Combination of Cabozantinib and Nivolumab in 1L Advanced RCC, Based on Results from CheckMate -9ER Study



**Overall Survival (OS)** 

#### **Progression-Free Survival (PFS)**



#### **Objective Response (ORR)**

Outcome, %	NIVO+CABO (n = 323)	SUN (n = 328)				
Confirmed ORR	55.7	27.1				
	<i>P</i> < 0.0001					
Complete response	8.0	4.6				
Partial response	47.7	22.6				
Stable disease	32.2	42.1				
Progressive disease	5.6	13.7				
Not evaluable/not assessed <sup>a</sup>	6.5	17.1				

The risk of death was reduced by 40% in patients with NIVO+CABO versus SUN The risk of disease progression or death was reduced by 49% in patients with NIVO+CABO versus SUN

Significantly more patients achieved an objective response with NIVO+CABO versus SUN

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<sup>a</sup>Includes patients who were never treated, those who discontinued/died before disease assessment, those without measurable disease at baseline per blinded independent central review, or other reason not reported/specified.

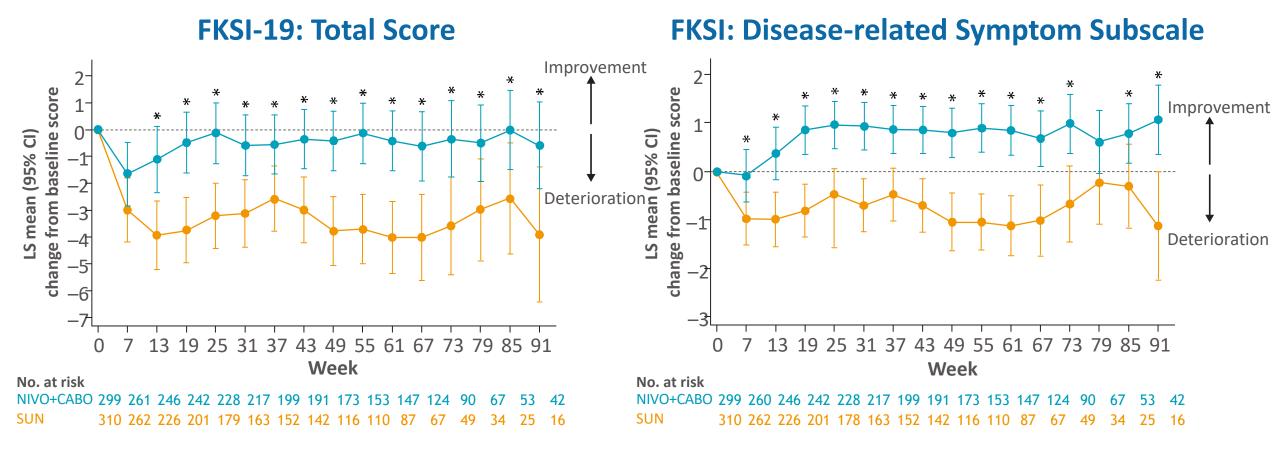


CheckMate -9ER: Combination of Cabozantinib 40 mg and Nivolumab was Generally Well-tolerated and Associated with Low Discontinuation Rate for Treatment-Related AEs

	NIVO+CABO (n = 320)	SUN (n = 320)
Median duration of therapy (range), months	<b>14.3</b> (0.2–27.3)	<b>9.2</b> (0.8–27.6)
Patients with at least 1 dose reduction (CABO or SUN), % <sup>a</sup>	56.3	51.6
Treatment discontinuation, % <sup>b</sup>	44.4	71.3
Treatment discontinuation due to disease progression, %	27.8	48.1
Any grade treatment-related AEs leading to discontinuation, % <sup>c</sup> NIVO only CABO only	<b>15.3</b> <sup>d</sup> 5.6 6.6	8.8 _ _
NIVO+CABO (both)	3.1	_

<sup>a</sup>No dose reductions were allowed for NIVO but were permitted for CABO and SUN per protocol; <sup>b</sup>Reasons were reported per investigator at the time of discontinuation and included disease progression, AEs of any cause, withdrawal of consent, death, request to discontinue treatment, patient no longer met study criteria, or other reason not reported/not specified; <sup>c</sup>Includes events that occurred on therapy or within 30 days after the end of the treatment period of all treated patients; <sup>d</sup>Includes events leading to discontinuation of either NIVO or CABO at any time; the assessment for discontinuation of NIVO and CABO were made separately for each drug, it was acceptable to continue treatment with only the study drug that was not related to the observed toxicity.

#### CheckMate -9ER: Analysis Demonstrated Improved HRQoL, Despite Enrolling a Higher Proportion of Intermediate / Poor Risk Patients Compared To Other 1L RCC Trials



\*Between-arm difference was statistically significant at this timepoint (P < 0.05).

Change from baseline was assessed using descriptive statistics and a mixed-model repeated measures analysis, which controlled for treatment arm, time point, baseline patient-reported outcomes score, IMDC prognostic score, PD-L1 tumor expression, and region. No. at risk denotes intention-to-treat patients with baseline plus at least 1 post-baseline HRQoL assessment with non-missing patient-reported outcome data. Time 0 indicates baseline.



### **Rapid Progress of Ongoing Phase 3 Development Program for Cabozantinib**

Study	Setting	Status Update	Next Milestone(s)
CSMIC (1) Cabozantinib	<b>DTC</b> RAI refractory, up to 2 prior VEGFR TKIs	Analysis in Q4 2020: Trial met primary endpoint of PFS, cabozantinib reduced the risk of death or PD by 78% (HR 0.22, p<0.0001)	File sNDA in 2021; Present detailed data at an upcoming medical meeting
CSMIC 312 Cabozantinib + Atezolizumab	1L aHCC	Global enrollment complete	Event-driven, top-line analysis of PFS and OS in 1H 2021; File sNDA in 2021, data-dependent
COSMIC (1) Cabozantinib + Nivolumab + Ipilimumab	<b>1L aRCC</b> IMDC intermediate and poor risk	Expanded enrollment to 840 patients to provide additional power to assess secondary endpoint OS	Event-driven analysis 2022
COSMIC 021 Cabozantinib + Atezolizumab	pretreated NSCLC (Cohort 7) tully enrolled		Final analysis of ORR by BIRC of Cohort 6 (mCRPC) in mid-2021; File sNDA in 2021, data-dependent
CONTACT-01 Cabozantinib + Atezolizumab	Metastatic NSCLC, after ICI and platinum chemo	Actively enrolling globally	Study enrollment ongoing
CONTACT-02 Cabozantinib + Atezolizumab	Actively enrolling globally		Study enrollment ongoing
CONTACT-03 Cabozantinib + Atezolizumab	<b>aRCC,</b> w/progression during or following ICI	Actively enrolling globally	Study enrollment ongoing

DTC = differentiated thyroid cancer RAI = radioactive iodine TKI = tyrosine kinase inhibitor PFS = progression-free survival PD = progressive disease HR = hazard ratio sNDA = supplemental New Drug Application 1L = first-line aHCC = advanced hepatocellular carcinoma OS = overall survival aRCC = advanced renal cell carcinoma IMDC = International Metastatic RCC Database Consortium mCRPC = metastatic castration-resistant prostate cancer NSCLC = non-small cell lung cancer ICI = immune checkpoint inhibitor ORR = objective response rate BIRC = blind independent review committee NHT = novel hormonal therapy



### **Development Updates: 2020 Achievements Set Up Impactful 2021**

Regulatory and development progress for cabozantinib

- FDA approval on January 22, 2021 of cabozantinib plus nivolumab combination for 1L treatment of advanced RCC, based on CheckMate -9ER pivotal Phase 3 study
- COSMIC and CONTACT clinical development program updates

#### Advancing the development of XL092 and early-stage pipeline assets

- XL092 currently in Phase 1b clinical development in combination with atezolizumab
- Progress with XL102 and XB002 programs
- Preview of upcoming clinical data to be presented at ASCO GU 2021, Feb. 11-13<sup>th</sup>
  - Updates from CheckMate -9ER and other cabozantinib clinical studies

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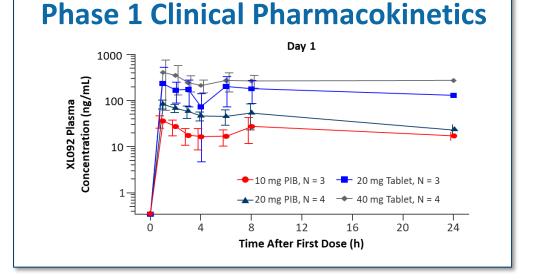


#### **XL092** target profile comparable to cabozantinib

Potent inhibitor of MET, VEGFR2, AXL and MER

#### **Structure intended to modulate half-life**

 Mean terminal half-life of 20-28 hours, based on Phase 1 PK profile

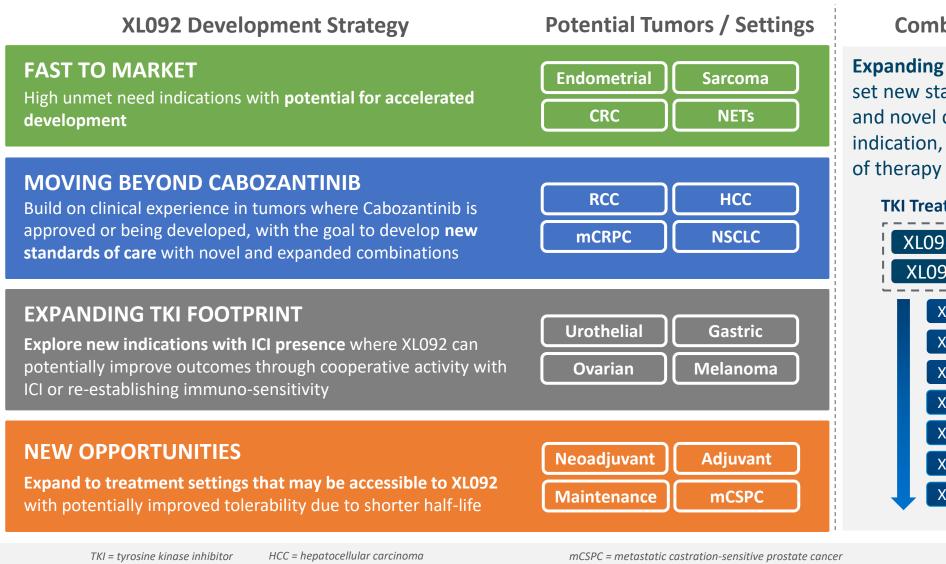


XL092 Phase 1b development advancing rapidly, evaluating in parallel as a single-agent and in combination with atezolizumab



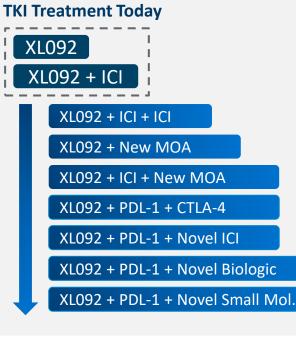
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# XL092: Extensive Development Plan Across a Wide Range of Tumor Types, Lines of Therapy and Therapeutic Settings – Potential to Initiate Late-Stage Studies in 2021



Combination Approaches

**Expanding Beyond ICI-TKI Success** to set new standards of care with triplet and novel combinations based on indication, therapeutic setting and line of therapy



HCC = hepatocellular carcinomamCSFmCRPC = metastatic castration-resistant prostate cancerICI = 1NSCLC = non-small cell lung cancerMOA

mCSPC = metastatic castration-sensitive prostate cancel ICI = immune checkpoint inhibitor MOA = mechanism of action



### **Early-stage Pipeline Assets Progressing into Clinical Development**

### XL102

- Potent, selective and orally bioavailable inhibitor of CDK7 (formerly AUR102)
- In-licensed from Aurigene in 2020

### XB002

- Rationally designed, next-generation ADC targeting Tissue Factor (formerly ICON-2)
- In-licensed from Iconic Therapeutics in 2020

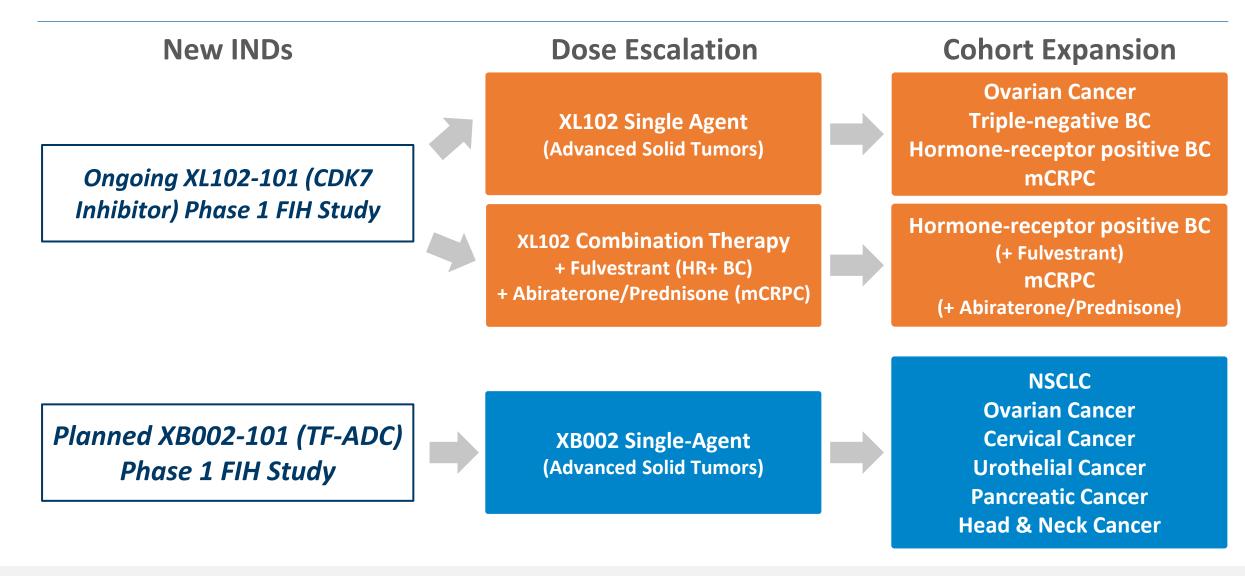
#### Phase 1 trial underway

IND filing planned shortly, once drug product release assays are finalized



CDK7 = Cyclin-dependent Kinase 7 ADC = antibody-drug conjugate IND = Investigational New Drug application

### XL102 and XB002 Phase 1a/b Development Plans



IND = Investigational New Drug application CDK7 = cyclin-dependent kinase 7 FIH = first-in-human

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TF = Tissue Factor ADC = antibody-drug conjugate HR+ = hormone-receptor positive BC = breast cancer mCRPC = metastatic castration-resistant prostate cancer NSCLC = non-small cell lung cancer



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#### Preview of upcoming clinical data to be presented at ASCO GU 2021, Feb. 11-13<sup>th</sup>

• Updates from CheckMate -9ER and other cabozantinib clinical studies

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### ASCO GU 2021: Summary of Key Data Presentations from Multiple Cabozantinib Clinical Studies

ASCO<sup>®</sup> AMERICAN SOCIETY OF CLINICAL ONCOLOGY Genitourinary Cancers Symposium

#### **CheckMate -9ER:**

- Abstract 308 Nivolumab + cabozantinib (NIVO+CABO) versus sunitinib (SUN) for advanced renal cell carcinoma (aRCC): Outcomes by sarcomatoid histology and updated trial results with extended follow-up of CheckMate 9ER.
  - Sustained efficacy across OS, PFS and ORR; increased CR rate demonstrated with further follow-up
- Abstract 285 Patient-reported outcomes of patients with advanced renal cell carcinoma (aRCC) treated with first-line nivolumab plus cabozantinib versus sunitinib: The CheckMate 9ER trial
  - Improved HRQoL, reduction in disease-related symptoms, extended time to confirmed deterioration

Exelixis Virtual Investor Briefing Saturday, Feb. 13<sup>th</sup> 5:30 pm ET / 2:30pm PT

#### **Other Cabozantinib Clinical Studies:**

- Abstract 3 Final results from a phase I trial and expansion cohorts of cabozantinib and nivolumab (CaboNivo) alone or with ipilimumab (CaboNivoIpi) for metastatic genitourinary tumors.
- Abstract 270 Sunitinib versus cabozantinib, crizotinib or savolitinib in metastatic papillary renal cell carcinoma (pRCC): Results from the randomized phase II SWOG 1500 study.
- Abstract 310 Activity and safety of cabozantinib (cabo) in brain metastases (BM) from metastatic renal cell carcinoma (mRCC): An international multicenter study.

OS = overall survival PFS = progression-free survival ORR = objective response rate CR = complete response HRQoL = health-related quality of life



# **Commercial Update**

# PJ Haley

EVP, Commercial





### **2021 Holds Potential to be a Transformative Year for CABOMETYX**

#### **CheckMate -9ER**

- Cabo + nivo combination in 1L RCC approved by U.S. FDA on January 22, 2021
- Study data compelling with potential for broad use in 1L setting
- Market share and duration of therapy from CheckMate -9ER may create significant revenue growth in 2021 and beyond

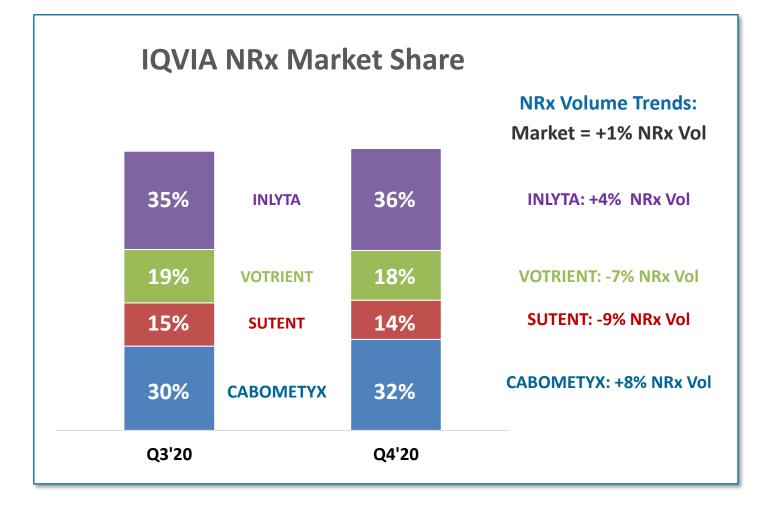
#### **Broader Development Program**

- CheckMate -9ER supported the first of several potential additional label expansions based on broad ongoing LCM program for CABOMETYX
- Upcoming data readouts may drive continued growth

Accelerate revenue growth in 2021 and beyond



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

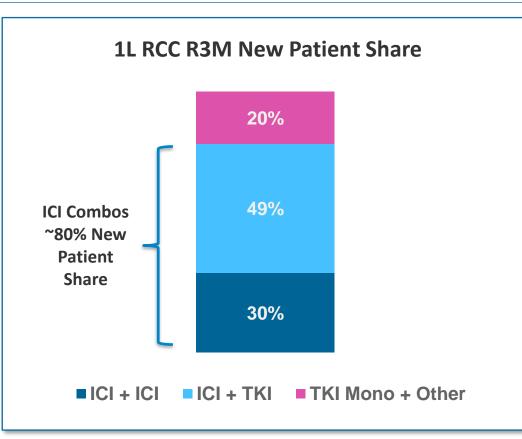


- CABOMETYX remains the #1 prescribed single-agent TKI in RCC market
- TKI NRx market was stable in Q4'20
- CABOMETYX had strong market share growth in 2L RCC



TKI = tyrosine kinase inhibitor RCC = renal cell carcinoma HCC = hepatocellular carcinoma 2L = second-line TRx = total prescriptions NRx = new prescriptions

# Commercial Opportunity Provided by FDA Approval of the Combination of CABOMETYX + Nivolumab in 1L RCC



- IL RCC market is >15,000 drug treatable patients annually\*
- ICI combos dominate 1L space at ~80% new patient share\*\*
- ICI + TKI new patient share ~50% and widely used across all clinical risk groups<sup>\*\*</sup>
- Broad potential for CABOMETYX with nivolumab in the 1L setting

#### With CheckMate -9ER results, CABOMETYX can target all three competitive segments of the current 1L market: ICI+ICI, ICI+TKIs, and TKI monotherapies

Sources: \*Decision Resources Group Renal Cell Carcinoma Epidemiology May 2020 \*\*IQVIA BrandImpact September 2020 RCC = renal cell carcinoma 1L = first-line R3M = rolling 3 months TKI = tyrosine kinase inhibitor ICI = immune checkpoint inhibitor



### **Commercial Opportunity Provided by FDA Approval of the Combination of CABOMETYX + Nivolumab in 1L RCC**

CheckMate 9ER Ph3: 1L RCC Cabo + Nivo Combination vs Sunitinib

Strong differentiation vs other ICI combination therapies currently available

- **Doubling of median PFS and ORR**
- Superior overall survival
- ✓ Clinical benefits regardless of IMDC risk status
- ✓ New 40mg starting dose optimized for combo therapy
- Compelling safety and tolerability
- Favorable quality of life

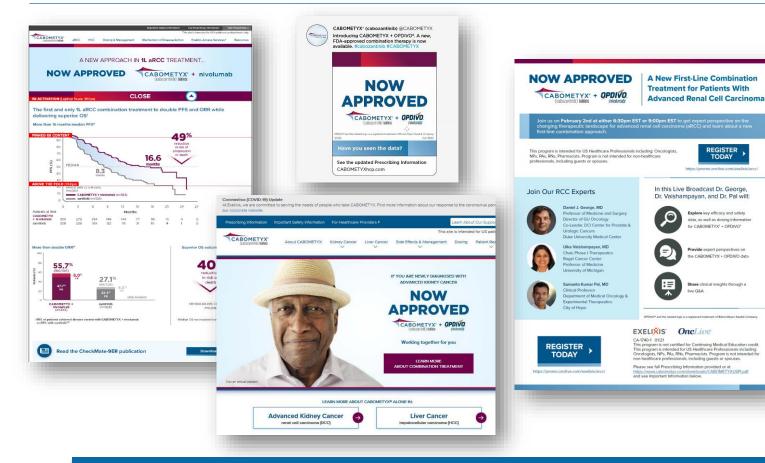
#### **Projected run-rate of ~\$1.5 billion for U.S. RCC business by the end of 2022**

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PFS = progression-free survival ORR = objective response rate IMDC = International Metastatic RCC Database Consortium



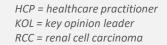
### Rapidly Driving Awareness of FDA Approval of CABOMETYX + Nivolumab Combination in 1L RCC



#### **Early Launch Execution**

- HCP and patient websites went live immediately
- Multi-channel targeted approach to reach key customers
- Launch broadcast with top KOLs executed
- Sales representatives engaging customers via virtual and live platforms

#### Leveraging the legacy of two proven agents in RCC to drive rapid awareness





# Potential Significant Growth in 2021 and Beyond, Driven by Expansion of the CABOMETYX Lifecycle



#### Growth across multiple therapeutic areas with multiple ICI combination partners

1L = first-line RCC = renal cell carcinoma DTC = differentiated thyroid cancer

mCRPC = metastatic castration-resistant prostate cancer NSCLC = non-small cell lung cancer aHCC = advanced hepatocellular carcinoma IND = Investigational New Drug application ICI = immune checkpoint inhibitor





# Michael M. Morrissey, Ph.D.

President and CEO



### **Anticipated Milestones for 2021**

Program		Milestone		
CheckMate -9ER		U.S. FDA approval of the combination of cabozantinib + nivolumab in 1L advanced RCC (Jan. 22, 2021)		
COSMIC-311		File sNDA for approval of cabozantinib in patients with radioactive iodine-refractory DTC		
COSMIC-312		Report top-line results for co-primary endpoints PFS and OS		
COSIVIIC-S12		File sNDA for approval of cabozantinib + atezolizumab in 1L HCC, if data supportive		
COSMIC-021 Gile sNDA for accelerated approval of cabozantinib + atezolizumab in mCRPC, if date		File sNDA for accelerated approval of cabozantinib + atezolizumab in mCRPC, if data supportive		
COSMIC-313		Complete expanded enrollment in phase 3 trial of triplet cabozantinib, nivolumab + ipilimumab vs combination of nivolumab + ipilimumab in 1L RCC		
CONTACT-01/02/03		Continue enrollment in pivotal trials of cabozantinib + atezolizumab in NSCLC, mCRPC and RCC		
		Continue enrollment in dose escalation cohort of Phase 1b trial of XL092 + atezolizumab		
XL092		Initiate enrollment of ccRCC, nccRCC, HR+ BC and mCRPC expansion cohorts of Phase 1a/b		
		Initiate further Phase 1b trial(s) with expansion cohorts in other tumor types and combinations		
XL102		Initiate Phase 1 trial of single-agent and combination therapy in solid tumors		
XB002		Initiate Phase 1 trial of single-agent in solid tumors		
Preclinical Advance up to two compounds currently in preclinical development				

1L = first-line RCC = renal cell carcinoma ccRCC = clear cell RCC nccRCC = non-clear cell RCC HCC = hepatocellular carcinoma DTC = differentiated thyroid cancer mCRPC = metastatic castration-resistant prostate cancer HR+ BC = hormone receptor positive breast cancer NSCLC = non-small cell lung cancer sNDA = supplemental New Drug Application PFS = progression-free survival OS = overall survival



# **Q&A Session**





# Fourth Quarter and Full Year 2020 Financial Results

Wednesday, February 10, 2021

Nasdaq: EXEL





# **Financial Appendix**



### **Non-GAAP Financial Highlights: Q4'20**

(in millions, except per share amounts)

	<u>Q4'19</u>	<u>Q3'20</u>	<u>Q4'20</u>	YoY Delta	QoQ Delta
Total revenues	\$240.3 M	\$231.1 M	\$270.1 M	+12%	+17%
Cost of goods sold	\$10.5 M	\$8.7 M	\$9.0 M	-14%	+4%
R&D expenses <sup>(a)(b)</sup>	\$88.8 M	\$157.8 M	\$147.2 M	+66%	-7%
SG&A expenses <sup>(a)(b)</sup>	\$47.8 M	\$51.5 M	\$70.2 M	+47%	+36%
Total operating expenses (a)(b)	\$147.1 M	\$218.0 M	\$226.5 M	+54%	+4%
Other income, net	\$7.7 M	\$4.6 M	\$3.8 M	-50%	-16%
Income tax provision <sup>(a)</sup>	\$19.8 M	\$6.4 M	\$4.1 M	-79%	-36%
Net income <sup>(a)</sup>	\$81.0 M	\$11.2 M	\$43.3 M	-47%	+286%
Net income per share, diluted <sup>(a)</sup>	\$0.26	\$0.04	\$0.14	-46%	+250%
Ending cash and investments	\$1,388.6 M	\$1,546.0 M	\$1,538.8 M	+11%	0%

Amounts may not sum due to rounding

39

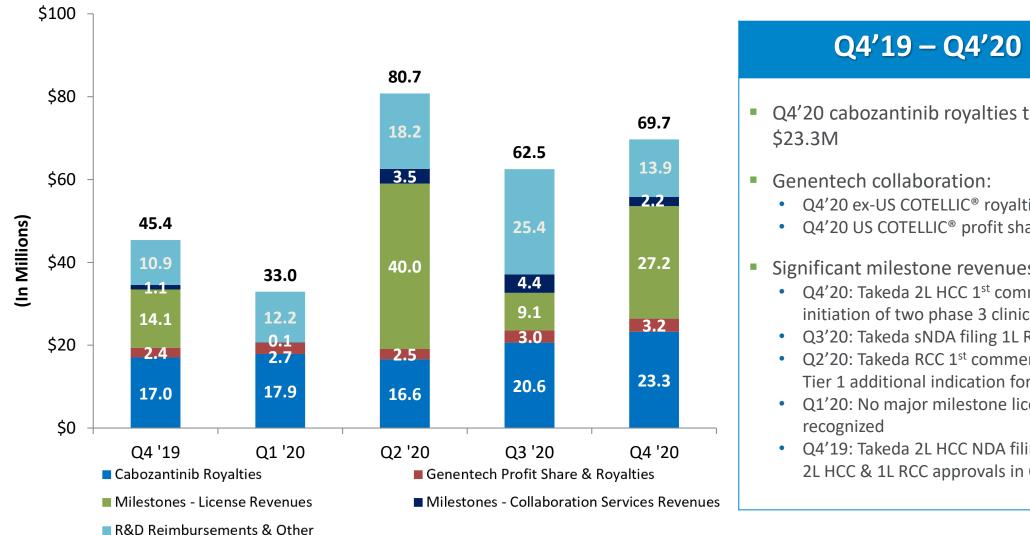
(a) A reconciliation of our GAAP to non-GAAP financial results is at the end of this presentation.

<sup>(b)</sup> Amounts reflect non-GAAP adjustment before tax effect



### **Collaboration Revenues Detail**

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



#### Q4'19 – Q4'20 Notes

- Q4'20 cabozantinib royalties to Exelixis of
  - Q4'20 ex-US COTELLIC<sup>®</sup> royalties \$1.3M
  - Q4'20 US COTELLIC<sup>®</sup> profit share \$1.9M
- Significant milestone revenues by quarter:
  - Q4'20: Takeda 2L HCC 1<sup>st</sup> commercial sale and initiation of two phase 3 clinical trials
  - Q3'20: Takeda sNDA filing 1L RCC (9ER)
  - Q2'20: Takeda RCC 1<sup>st</sup> commercial sale and Ipsen Tier 1 additional indication for initiation of phase 3
  - Q1'20: No major milestone license revenues
  - Q4'19: Takeda 2L HCC NDA filing in Japan and Ipsen 2L HCC & 1L RCC approvals in Canada



RCC = renal cell carcinoma 1L = first-line 2L = second-line

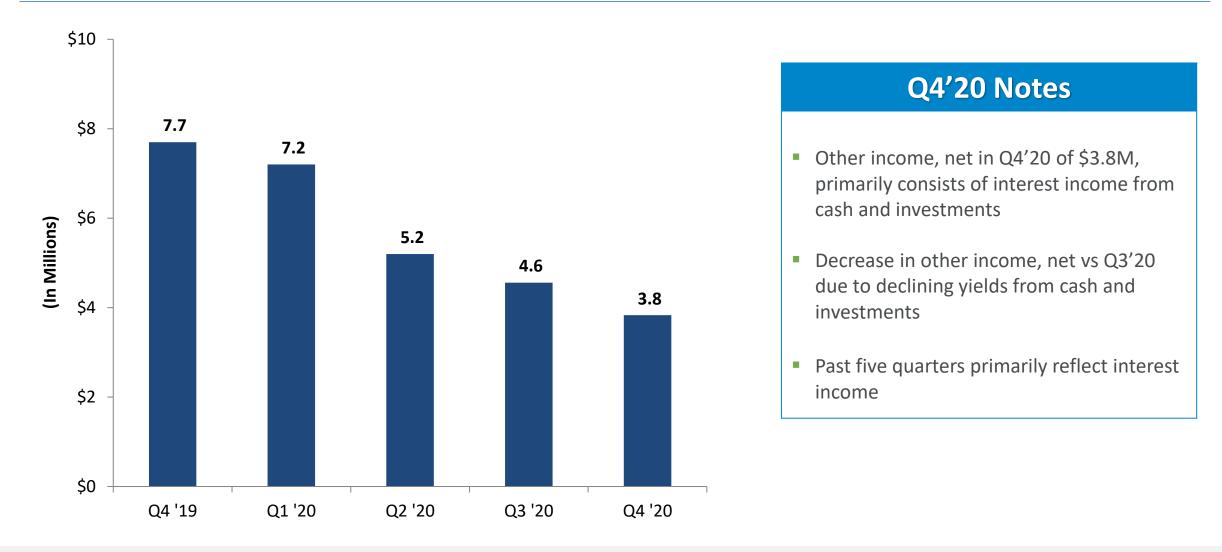
*NDA* = *new drug application* 

HCC = hepatocellular carcinoma MAA = marketing authorization application

Amounts may not sum due to rounding

### **Other Income, net**

(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.

	Q4'19 Q1'20		(	Q2'20 Q		Q3'20		Q4'20	F)		Y'19		FY'20		
Research and development expenses reconciliation:		-		-		-		-		-					
GAAP Research and development expenses	\$	94.4	\$	101.9	\$	114.9	\$	176.8	\$	154.3		\$	337.0	\$	547.9
Stock-based compensation expenses <sup>(1)</sup>	_	(5.6)	_	(5.1)	_	(6.1)	_	(18.9)		(7.1)			(19.4)	_	(37.2)
Non-GAAP Research and development expenses	\$	88.8	\$	96.8	\$	108.8	\$	157.8	\$	147.2		\$	317.6	\$	510.7
Selling, general and administrative expenses reconciliation:															
GAAP Selling, general and administrative expenses	\$	58.0	\$	62.9	\$	59.8	\$	88.2	\$	82.4		\$	228.2	\$	293.4
Stock-based compensation expenses <sup>(1)</sup>		(10.2)		(8.9)		(10.0)		(36.7)		(12.2)			(37.2)		(67.9)
Non-GAAP Selling, general and administrative expenses	\$	47.8	\$	54.0	\$	49.7	\$	51.5	\$	70.2		\$	191.0	\$	225.5
Operating expenses reconciliation:															
GAAP Operating expenses	\$	163.0	\$	174.1	\$	183.9	\$	273.7	\$	245.8		\$	598.3	\$	877.5
Stock-based compensation - Research and development expenses <sup>(1)</sup>		(5.6)		(5.1)		(6.1)		(18.9)		(7.1)			(19.4)		(37.2)
Stock-based compensation - Selling, general and administrative expenses <sup>(1)</sup>		(10.2)		(8.9)		(10.0)		(36.7)		(12.2)			(37.2)		(67.9)
Non-GAAP Operating expenses	\$	147.1	\$	160.1	\$	167.8	\$	218.0	\$	226.5		\$	541.7	\$	772.4
Income tax provision															
GAAP Income tax provision (benefit)	\$	16.3	\$	11.4	\$	13.9	\$	(6.0)	\$	(0.3)		\$	77.1	\$	19.1
Income tax effect of stock-based compensation - Research and development <sup>(2)</sup>		1.3		1.1		1.4		4.2		1.6			4.3		8.3
Income tax effect of stock-based compensation - Selling, general and administrative <sup>(2)</sup>		2.3		2.0		2.3		8.2		2.8			8.4		15.3
Non-GAAP Income tax provision	\$	19.8	\$	14.6	\$	17.5	\$	6.4	\$	4.1		\$	89.8	\$	42.6



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

(in millions, except per share amounts)

	_ (	Q4'19		Q4'19 Q1'20		Q2'20		Q3'20		Q4'	20	FY'19	FY'20	
Net Income (loss) reconciliation:											 			
GAAP Net Income (loss)	\$	68.7	\$	48.6	\$	66.8	\$	(32.0)	\$	28.4	\$ 321.0	\$	111.8	
Stock-based compensation - Research and development <sup>(1)</sup>		5.6		5.1		6.1		18.9		7.1	19.4		37.2	
Stock-based compensation - Selling, general and administrative <sup>(1)</sup>		10.2		8.9		10.0		36.7		12.2	37.2		67.9	
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>		(3.6)		(3.2)		(3.6)		(12.4)		<u>(4.3)</u>	 (12.7)		(23.5)	
Non-GAAP Net Income	\$	81.0	\$	59.4	\$	79.4	\$	11.2	\$	43.3	\$ 364.9	\$	193.3	
Net Income (loss) per share, diluted:														
GAAP Net Income (loss) per share, diluted	\$	0.22	\$	0.15	\$	0.21	\$	(0.10)	\$	0.09	\$ 1.02	\$	0.35	
Stock-based compensation - Research and development <sup>(1)</sup>		0.02		0.02		0.02		0.06		0.02	0.06		0.12	
Stock-based compensation - Selling, general and administrative <sup>(1)</sup>		0.03		0.03		0.03		0.12		0.04	0.12		0.21	
Income tax effect of the stock-based compensation adjustments <sup>(2)</sup>		(0.01)		(0.01)		(0.01)		(0.04)	(	0.0 <u>1</u> )	 (0.04)		(0.07)	
Non-GAAP Net Income per share, diluted	\$	0.26	\$	0.19	\$	0.25	\$	0.04	\$	0.14	\$ 1.16	\$	0.61	
Weighted-average shares used to compute GAAP net income (loss) per share, diluted		315.0		315.8		318.1		309.1		319.5	315.0		318.0	
Weighted-average shares used to compute non-GAAP earnings per share, diluted		315.0		315.8		318.1		318.5	:	319.5	315.0		318.0	
<sup>(1)</sup> Non-cash stock-based compensation expense used for GAAP reporting in accordance w <sup>(2)</sup> Income tax effect on the non-cash stock-based compensation expense adjustments	ith AS	C 718												



### **Collaboration Revenues**

#### (in millions)

Partner	Compound	Description		Q4'19		Q1'20		Q2'20	Q3	3'20		Q4'20
Roche (Genentech)	COTELLIC	Profit Share & Royalties on Ex-U.S. sales	\$	2.4	\$	2.7	\$	2.5	\$	3.0	\$	3.2
Partner Royalties	Cabozantinib	Royalties on ex-U.S.		17.0		17.9		<b>16.6</b>	2	20.6		23.3
Milestones:												
Ipsen	Cabozantinib	Amortization of Milestones Triggered prior to Q1'18		0.4		-		0.4		0.5		0.3
Ipsen	Cabozantinib	\$50M M/S 1L RCC Approval		0.2		-		0.1		0.2		0.1
Ipsen	Cabozantinib	\$40M M/S EMA 2L HCC Approval		0.1		-		0.1		0.2		0.1
Ipsen	Cabozantinib	\$20M M/S initiation Phase 3 1L HCC		0.1		-		0.1		0.1		-
Ipsen	Cabozantinib	\$3M MAA approval 1L RCC (Canada)		3.0		-		-		-		-
Ipsen	Cabozantinib	\$2M MAA approval 2L HCC (Canada)		2.0		-		-		-		-
Ipsen	Cabozantinib	\$20M M/S Additional Indication/Initiation Phase 3		-		-		18.8		0.1		-
Takeda	Cabozantinib	\$10M M/S initiation of Phase 3 1L RCC		-		-		-		0.1		-
Takeda	Cabozantinib	\$16M M/S Japan NDA filing 2L RCC <sup>(1)</sup>		0.2		0.1		0.2		1.3		0.3
Takeda	Cabozantinib	\$10M M/S Japan NDA filing 2L HCC		9.1		-		-		0.2		-
Takeda	Cabozantinib	\$26M M/S 1st Commercial Sale in Japan - 2L RCC		-		-		19.1		1.5		0.4
Takeda	Cabozantinib	\$5M M/S 1st Commercial Sale in Japan - 1L RCC as a single agent		-		-		4.6		0.1		-
Takeda	Cabozantinib	\$10M M/S filing MAA 1L RCC		-		-		-		9.2		0.1
Takeda	Cabozantinib	\$15M M/S 1st Commercial Sale 2L HCC		-		-		-		-		14.0
Takeda	Cabozantinib	\$10M M/S Additional Indication/Initiation Phase 3		-		-		-		-		9.3
Takeda	Cabozantinib	\$5M M/S Additional Indication/Initiation Phase 3		-		-		-		-		4.7
		Subtotal Milestones	\$	15.1	\$	0.1	\$	43.5	<b>\$ 1</b>	3.5	\$	29.4
		Milestones License revenues	\$	14.1	\$	-	\$	40.0	\$	9.1	\$	27.2
		Milestones Collaboration services revenues	\$	1.1	\$	0.1	\$	3.5	\$	4.4	\$	2.2
R&D Reimbursements & Of	ther:											
Ipsen	Cabozantinib	R&D reimbursement and Product Supply		9.2		11.1		16.6	1	4.3		10.6
Ipsen	Cabozantinib	\$200M Upfront fee		0.6		-		0.5		0.8		0.4
Takeda	Cabozantinib	R&D reimbursement and Product Supply		1.0		0.8		0.7		9.2		2.4
Takeda	Cabozantinib	\$50M Upfront fee		0.1		0.1		0.1		0.6		0.1
Daiichi Sankyo & royalties	MR CS-3150/MINNEBRO			-		0.2		0.2		0.6		0.4
		Subtotal R&D Reimbursments & Other	\$	10.9	\$	12.2	\$	18.2	\$ 2	25.4	\$	13.9
Total License revenues			\$	33.5	\$	20.9	\$	59.2	\$ 3	3.2	\$	54.0
Total Collaboration servic	es revenues		-	11.9		12.2	-	21.5	- C	9.3		15.7
TOTAL COLLABORATION RE			\$	45.4	Ś		Ś	80.7		52.5	Ś	69.7

<sup>(1)</sup>Milestone amount has been updated in accordance with the Takeda Second Amendment to the Collaboration and License Agreement, executed on May 7, 2019

Adoption of ASU 2018-18 in Q1'20 impacted the presentation of our revenues. Net product revenues and license revenues are recorded in accordance with Topic 606 and presented separately from collaboration services revenues which are recorded in accordance with Topic 808.



# Fourth Quarter and Full Year 2020 Financial Results

Wednesday, February 10, 2021

Nasdaq: EXEL



