3Q 2021 Financial Results and Corporate Update

November 2, 2021





### DECIPHERA | 3Q 2021 FINANCIAL RESULTS AND CORPORATE UPDATE TODAY'S AGENDA

### **OPENING REMARKS**

#### **Steve Hoerter**

President and Chief Executive Officer

### **U.S. QINLOCK COMMERCIAL RESULTS**

#### **Dan Martin**

Senior Vice President and Chief Commercial Officer

### **CLINICAL PROGRAM PROGRESS**

#### Matt Sherman, M.D.

Executive Vice President and Chief Medical Office.

#### FINANCIAL RESULTS FROM

### **Tucker Kelly**

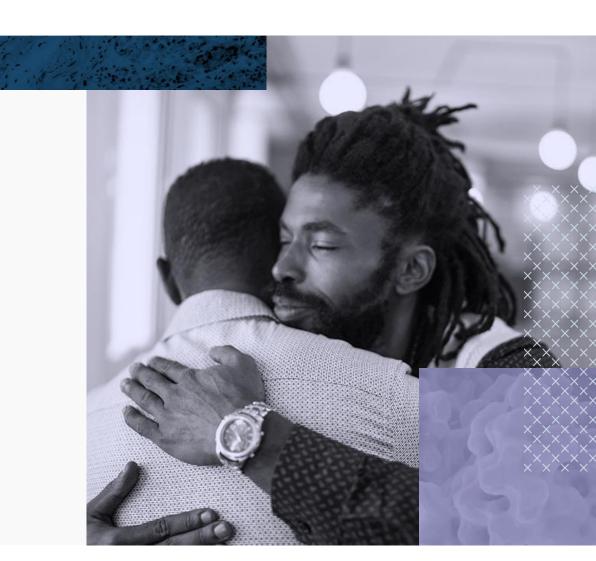
Executive Vice President, Chief Financial Officer and Treasurer

### **CLOSING REMARKS**

#### **Steve Hoerter**

President and Chief Executive Office





#### DECIPHERA | 3Q 2021 FINANCIAL RESULTS AND CORPORATE UPDATE

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# OPENING REMARKS



### **Steve Hoerter**

President and Chief Executive Officer



#### DECIPHERA | 3Q 2021 FINANCIAL RESULTS AND CORPORATE UPDATE

### INNOVATIVE PROGRAMS LEADING TO TRANSFORMATIVE GROWTH

Executing on our mission to discover, develop, and deliver important new medicines to patients for the **treatment of cancer** 



- Established QINLOCK as the clear standard of care in fourth-line GIST
- Phase 3 data in 2<sup>nd</sup> line GIST (INTRIGUE) expected this quarter
- EU approval in 4<sup>th</sup> line GIST expected this quarter

### Positioned to Rapidly Advance Clinical Pipeline<sup>1</sup>

Vimseltinib, our potential best-in-class CSF1R inhibitor, Phase 3 MOTION study initiation expected this quarter **Rebastinib**, our first-in-class TIE2 inhibitor, in combination with paclitaxel Phase 3 study initiation expected in 2022

program, initial data from the Phase 1 dose escalation expected in 2022



Notes: CSF1R=colony-stimulating factor 1 receptor; EU=European Union; GIST=gastrointestinal stromal tumor; TIE2=TEK tyrosine kinase; ULK=unc-51-like autophagy-activating kinase; (1) Represent planned 2021 and 2022 milestones.

# U.S. QINLOCK COMMERCIAL RESULTS



### **Dan Martin**

Senior Vice President and Chief Commercial Officer



# QINLOCK\* | 4<sup>TH</sup> LINE GASTROINTESTINAL STROMAL TUMOR U.S. LAUNCH SUCCESS CONTINUED IN 3Q 2021



U.S. Net Sales in 3Q 2021

\$20.0



Unique Prescribers<sup>1</sup>

~530



Unique Institutions<sup>1</sup>

~500

### **3Q 2021 Highlights**

- Maintained high levels of reach, frequency, share-of-voice, and product awareness<sup>2,3</sup>
- HCP perceptions of QINLOCK remain extremely positive across all product attributes<sup>2</sup>
- Increased launch-to-date prescriber base by ~20% QoQ with the majority of growth coming from the community setting

# **Continued Progress Penetrating the Community Setting in 3Q**

3Q New Prescribers



3Q Total Prescribers



3Q Treated Patients





**Notes:** GIST=gastrointestinal stromal tumor; (1) Data are from May 22, 2020 – September 30, 2021; (2) Deciphera ATU survey, 3Q 2021; (3) Among physicians treating late-line GIST patients.

Community

Academic

# CLINICAL PROGRAM PROGRESS



Matt Sherman, M.D.

Executive Vice President and Chief Medical Officer



# QINLOCK\* | PHASE 3 INTRIGUE STUDY | 2ND LINE GASTROINTESTINAL STROMAL TUMOR TOP-LINE DATA EXPECTED THIS QUARTER





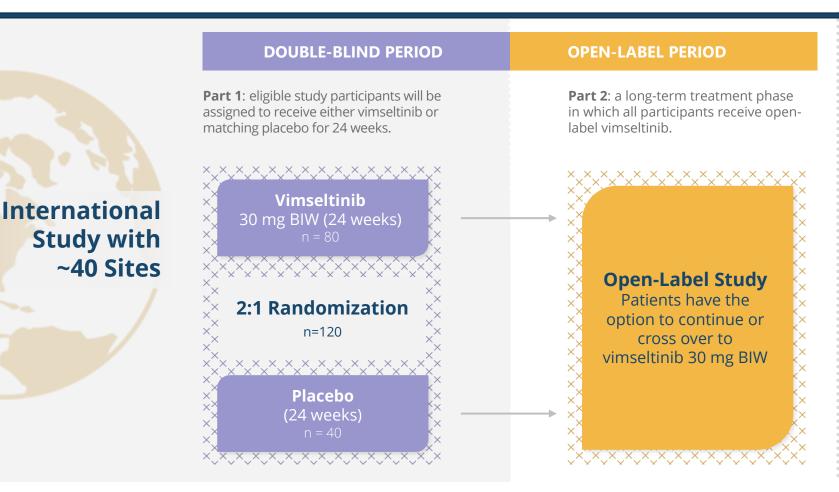




Notes: GIST=gastrointestinal stromal tumor; QD=daily

#### VIMSELTINIB MOTION STUDY | PHASE 3 STUDY OF PATIENTS WITH TGCT

### A MULTICENTER, RANDOMIZED, PLACEBO-CONTROLED, DOUBLE-BLIND STUDY



Phase 3 Motion Study will assess the efficacy and safety of vimseltinib for the treatment of patients with TGCT not amenable to surgical resection Primary Endpoint:

Objective response rate (ORR) at25 weeks

#### **Key Secondary Endpoints:**

- Range of motion (ROM)
- Patient-reported outcomes
- ORR per tumor volume score

STUDY INITIATION IS PLANNED FOR THIS QUARTER

\*\*\*\*\*\*\*\*\*\*\*\*\*\*



Notes: BIW=twice weekly; TGCT=tenosynovial giant cell tumor.

#### VIMSELTINIB | ONGOING PHASE 1/2 STUDY OF PATIENTS WITH TGCT

### ENCOURAGING RESULTS SUPPORT FURTHER DEVELOPMENT

- In patients with TGCT not amenable to surgical resection, vimseltinib demonstrated encouraging preliminary efficacy
- Vimseltinib was generally well-tolerated, and the safety profile remains manageable with longerterm follow-up across all Phase 1 dose cohorts and at the recommended Phase 2 dose in Cohort A
- These results support further evaluation of vimseltinib in the MOTION study, a randomized, placebo-controlled, Phase 3 trial in patients with TGCT not amenable to surgical resection

OBJECTIVE
RESPONSE RATE
47%
Across all dose cohorts of Phase 1
and Phase 2 Cohort A

PHASE 1 PHASE 2 COHORT A 83%

DEEPENING AND
DURABLE RESPONSES
OBSERVED ACROSS ALL
DOSE COHORTS OF
PHASE 1

NO ABNORMALITIES
IN BILIRUBIN LEVELS
REPORTED



# PROMISING RESULTS SUPPORT FURTHER DEVELOPMENT

The updated safety and efficacy of rebastinib at 50 mg BID in combination with paclitaxel shows encouraging results in heavily pretreated patients with PROC, with an acceptable safety profile, supporting further development.

Pivotal Phase 3 study in PROC is anticipated to start in 2022, subject to discussions with health authorities

#### **MEDIAN PFS**

9.1

44% of events

#### **OBJECTIVE RESPONSE RATE<sup>1</sup>**

38%

(confirmed and unconfirmed)

29%

(confirmed)

### MEDIAN DURATION OF TREATMENT

6.5

range 0.5–15.4 months

#### **CLINICAL BENEFIT RATE**

76%

at 16 weeks<sup>2</sup>

#### **CA-125 RESPONSE**

73%

occurred in 19/26 patients

### A MANAGEABLE SAFETY PROFILE

Most AEs reported were Grade <2



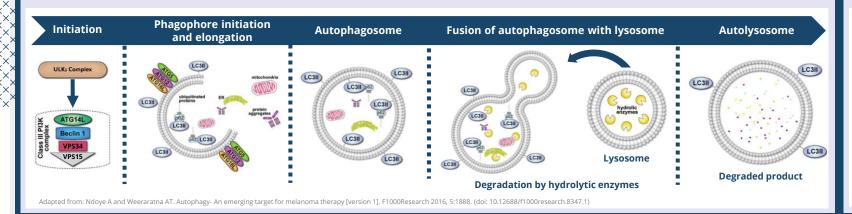
Notes: Data presented at the ESMO Congress 2021; results are reported for patients in the platinum-resistant ovarian cancer expansion cohort with a cutoff date of June 22, 2021; safety population n=38, modified intent-to-treat population n=34; AE=adverse event; BID= twice daily; PFS=progression-free survival; PROC=platinum resistant ovarian cancer; (1) Includes 13 patients with objective response (10 confirmed, 3 to be confirmed at future follow-up), 18 stable disease, and 1 progressive disease; (2) Clinical benefit rate at 16 weeks was defined as overall response of CR, PR, or SD according to RECIST v1.1 at the 16-week response assessments, respectively.

### POTENT AND SELECTIVE ULK INHIBITOR DESIGNED TO INHIBIT AUTOPHAGY

# First-in-class switch-control ULK kinase inhibitor opportunity for cancers caused by RAS/RAF mutations

- Cancers caused by RAS/RAF mutations have high basal levels of autophagy and MAPK pathway inhibitors, as well as other signaling pathway inhibitors, induce autophagy as a survival mechanism
- DCC-3116 observed preclinically to durably and potently inhibit autophagy in RAS/RAF mutant cancer cell lines through the inhibition of ULK kinase
- Combination of DCC-3116 and MAPK pathway inhibitors have been observed to synergize to block RAS/RAF mutant cancers in vivo

Initiated
Phase 1 Study
in 2Q 2021



## Highly potent and selective (IC<sub>50</sub> at 1 mM ATP)

- ULK1 4.7 nM and ULK2 35 nM
- No off-target kinases within 30-fold of ULK1
- 5 kinases within 100-fold of ULK1
- Designed to avoid CNS exposure



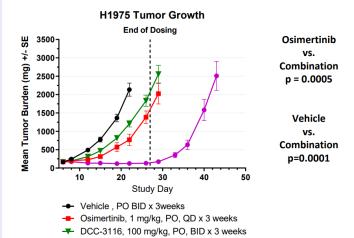
**Notes**: ATP=adenosine triphosphate; CNS=central nervous system; FDA=U.S. Food and Drug Administration;  $IC_{50}$ =half maximal inhibitory concentration; IND=investigational new drug; MAPK=mitogen-activated protein kinase; RAF=rapidly accelerated fibrosarcoma serine/threonine protein kinase; RAS=rat sarcoma gene; ULK=unc-51-like autophagy-activating kinase.

#### DCC-3116 | PRECLINICAL DATA AND THIRD-PARTY RESEARCH

# SCIENTIFIC EVIDENCE BROADENS ROLE OF AUTOPHAGY INHIBITION IN CANCER

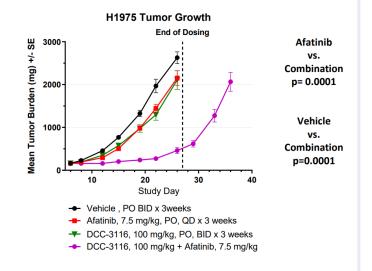
# DCC-3116 SYNERGIZES WITH EGFR INHIBITORS IN NSCLC MODEL

#### **DCC-3116 IN COMBINATION WITH OSIMERTINIB**



DCC-3116, 100 mg/kg + Osimertinib, 1 mg/kg

#### **DCC-3116 IN COMBINATION WITH AFATINIB**



# DCC-3116 decreased tumor burden in combination with osimertinib and afatinib in the H1975 EGFR mutant xenograft model

# GROWING VALIDATION FOR ROLE OF AUTOPHAGY IN CANCER

### **Science** Translational Medicine

RESEARCH ARTICLE | CANCER

ULK1 inhibition promotes oxidative stressinduced differentiation and sensitizes leukemic stem cells to targeted therapy

lanniciello, A., Zarou, M. M., Rattigan, K. M. et al. Sci Transl Med 13, eabd5016 (2021).

### nature cancer

ULK1 inhibition overcomes compromised antigen presentation and restores antitumor immunity in LKB1-mutant lung cancer

Deng, J., Thennavan, A., Dolgalev, I. et al. Nat Cancer 2, 503-514 (2021).



Notes: BID=twice daily; EGFR=epidermal growth factor receptor; LKB1=liver kinase B1; NSCLC=non-small cell lung cancer; PO=by mouth; QD=once daily; ULK=unc-51-like autophagy-activating kinase.

# FINANCIAL RESULTS



### **Tucker Kelly**

Executive Vice President, Chief Financial Officer and Treasurer



# FINANCIAL HIGHLIGHTS

As of September 30, 2021

**Shares Outstanding** 

58.3 MM

(basic)

65.6 MM

(fully-diluted)

**Cash, Cash Equivalents & Marketable Securities** 

\$392 MM

Operating Expenses and CapEx into 1H 2023



# CLOSING REMARKS



### **Steve Hoerter**

President and Chief Executive Officer



# Q&A



# THANK YOU

