UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 11, 2020

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38219	30-1003521
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

200 Smith Street, Waltham, Massachusetts	02451
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (781) 209-6400

(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 203.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events.

On November 11, 2020, Deciphera Pharmaceuticals, Inc. announced the presentation of preliminary results from the ongoing Phase 1/2 study of DCC-3014, a highly selective, oral, investigational switch-control kinase inhibitor of CSF1R, in patients with tenosynovial giant cell tumor. The presentation, titled "Phase 1 Dose-Escalation Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of DCC-3014 in Advanced Solid Tumors and Tenosynovial Giant Cell Tumor (TGCT)", will be presented at the Connective Tissue Oncology Society (CTOS) 2020 Virtual Annual Meeting. A copy of the presentation is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation from November 11, 2020, filed herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 11, 2020

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Name: Steven L. Hoerter
Title: President and Chief Executive Officer

CTOS Annual Meeting, Nov 18–21, 2020

Phase 1 Dose-Escalation Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of DCC-3014 in Advanced Solid Tumors and Tenosynovial Giant Cell Tumor (TGCT) (NCT3069469)

Albiruni Abdul Razak[1], Breelyn A. Wilky[2], Jacqueline Vuky[3], Lara E.Davis[3], Todd Bauer[4], Hans Gelderblom[5], Mary Michenzie[6], Maitreyi Sharma[6], Rodrigo Ruiz-Soto[6], Matthew L. Sherman[6], William D. Tap[7]

[1]Toronto Sarcoma Program, Princess Margaret Cancer Center, Toronto, ON, Canada; [2]Medicine, University of Colorado Cancer Center, Aurora, CO, United States; [3]OHSU Knight Cancer Institute, Portland, OR, United States; [4]Sarah Cannon Research Institute and Tennessee Oncology, Nashville, TN, United States; [5]Medical Oncology, Leiden University Medical Center, Leiden, Netherlands; [6]Deciphera Pharmaceuticals, LLC, Waltham, MA, United States; [7]Medical Oncology, Memorial Sloan Kettering Cancer Center, New York, NY, United States.

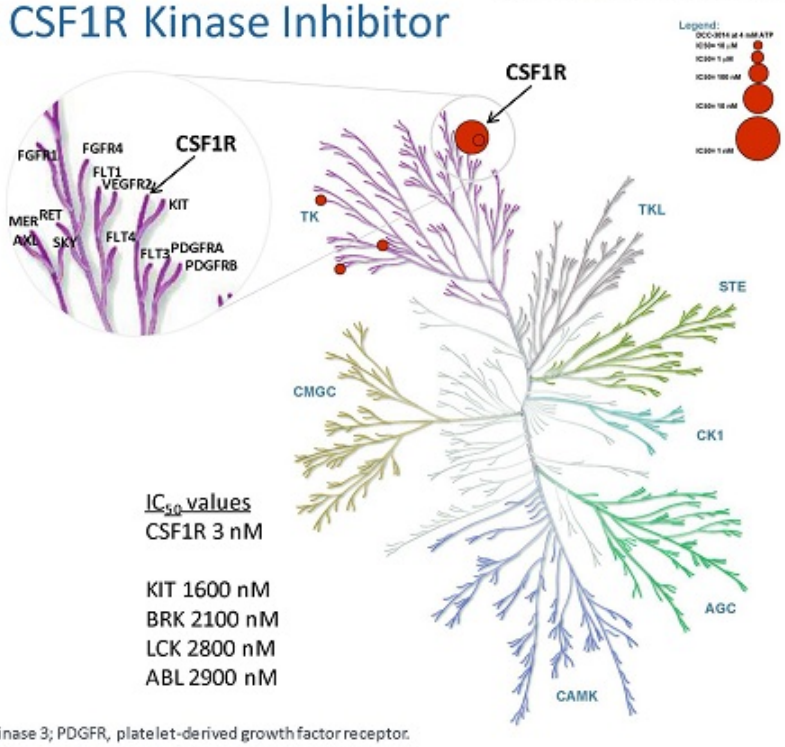
Disclosures

Albiruni R. Abdul Razak

- Honoraria: Boehringer Ingelheim
- Consulting or Advisory Role: Eli Lilly, Merck, Boehringer Ingelheim, Adaptimmune
- Research Funding: CASI Pharmaceuticals, Boehringer Ingelheim, Lilly, Novartis, Deciphera, Karyopharm Therapeutics, Pfizer, Roche/Genentech, Boston Biomedical, Bristol-Myers Squibb, MedImmune, Amgen, GlaxoSmithKline, Blueprint Medicines, Merck, AbbVie, Adaptimmune, Iterion

DCC-3014 – Highly Selective CSF1R Kinase Inhibitor

- DCC-3014 is a highly selective, oral, investigational switch control kinase inhibitor that exhibits nanomolar potency for CSF1R with >100-fold selectivity vs closely related kinases (KIT, PDGFRα, PDGFRβ, and FLT3)[1]
- DCC-3014 inhibits CSF1R signaling in cellular assays, as well as blocks macrophage-mediated tumor cell migration, osteoclast differentiation, and proliferation of a CSF1R-dependent cell line



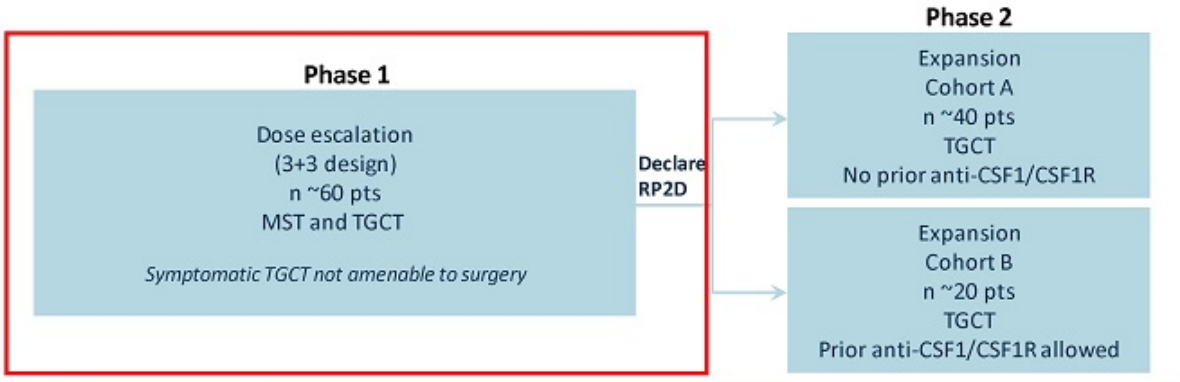
IC_{50} values
CSF1R 3 nM

KIT 1600 nM
BRK 2100 nM
LCK 2800 nM
ABL 2900 nM

CSF1R, colony-stimulating factor 1 receptor; FLT3, fms-like tyrosine kinase 3; PDGFR, platelet-derived growth factor receptor.

1. Smith BD, et al. AACR Annual Meeting; April 16–20, 2016; New Orleans, LA. Abstract 4889.

Study Design



Phase 1 primary objectives

- Assess safety and tolerability of DCC-3014 (including occurrence of DLTs and incidence of TEAEs)
- Characterize the pharmacokinetic profile
- Determine RP2D/MTD

Phase 1 relevant exploratory objectives

- Evaluate preliminary antitumor activity (RECIST v1.1)
  - Read by independent central imaging vendor
- Evaluate pharmacodynamics (CSF1/IL-34 and circulating non-classical monocytes)

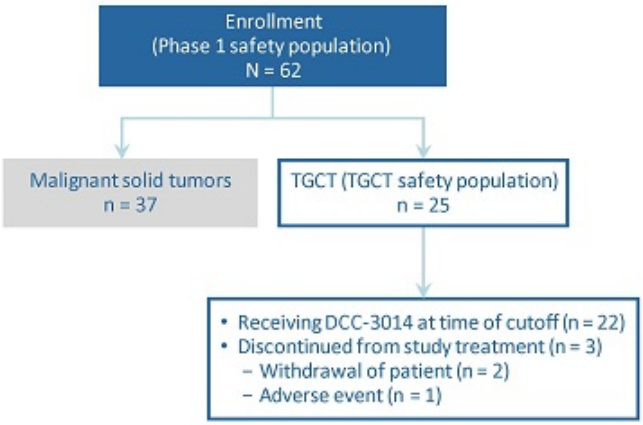
CSF1, colony-stimulating factor 1; CSF1R, colony-stimulating factor 1 receptor; DLT, dose-limiting toxicity; IL, interleukin; MST, malignant solid tumor; pts, patients; MTD, maximum tolerated dose; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; RP2D, recommended phase 2 dose; TEAE, treatment-emergent adverse event; TGCT, tenosynovial giant cell tumor.

(NCT03069469)

Phase 1 Enrollment and Patient Disposition

- Study initially enrolled patients with malignant solid tumors in the first 7 cohorts
- TGCT patients initially enrolled to escalation cohort 5, then TGCT-specific escalation cohorts 8 and 9 were enrolled

	Loading doses	Dose	MST patients, n	TGCT patients, n
Cohort 1	None	10 mg QD	7	
Cohort 2	10 mg QD x 5 days	10 mg BIW	3	
Cohort 3	20 mg QD x 5 days	20 mg QW	4	
Cohort 4	20 mg QD x 5 days	20 mg BIW	4	
Cohort 5	30 mg QD x 5 days	30 mg BIW	6	7
Cohort 6	40 mg QD x 5 days	40 mg BIW	5	
Cohort 7	50 mg QD x 3 days	20 mg QD	8	
Cohort 8	30 mg QD x 3 days	10 mg QD		12
Cohort 9	20 mg QD x 3 days	6 mg QD		6



Data cutoffs: Safety, September 23, 2020; Efficacy, October 5, 2020.
BIW; twice weekly; MST, malignant solid tumor; QD, daily; QW, weekly; TGCT, tenosynovial giant cell tumor.

TGCT Patient Demographics and Prior Therapies

	Total (N = 25)
Age, years, median (min, max)	52 (23, 73)
Gender	
Female	14 (56)
Male	11 (44)
Race	
White	24 (96)
Asian	1 (4)
Disease location	
Knee	16 (64)
Ankle	5 (20)
Hip	2 (8)
Foot	1 (4)
Wrist	1 (4)
Patients with at least one prior surgery	7 (28)
Patients with at least one prior systemic therapy	4 (16)
Tyrosine kinase inhibitor (imatinib)	3 (12)
Anti-CSF1R monoclonal antibody	1 (4)

Data are presented as No. (%) unless otherwise noted.
CSF1R, colony-stimulating factor 1 receptor; TGCT, tenosynovial giant cell tumor.

Common (≥15%) TEAEs, Regardless of Relatedness – TGCT Safety Population

Preferred term, No. (%)	TGCT patients (N = 25)							
	Cohort 5 30 mg BIW[a] (N = 7)		Cohort 8 10 mg QD[b] (N = 12)		Cohort 9 6 mg QD[c] (N = 6)		Total TGCT (N = 25)	
	All grades	Grade 3/4	All grades	Grade 3/4	All grades	Grade 3/4	All grades	Grade 3/4
Blood CPK increased	3 (43)	1 (14)	7 (58)	4 (33)[d]	3 (50)	0	13 (52)	5 (20)
AST increased	4 (57)	1 (14)	6 (50)	2 (17)	1 (17)	0	11 (44)	3 (12)
Periorbital edema	3 (43)	0	7 (58)	0	1 (17)	0	11 (44)	0
Fatigue	3 (43)	0	4 (33)	0	3 (50)	0	10 (40)	0
Lipase increased	1 (14)	0	5 (42)	3 (25)	2 (33)	0	8 (32)	3 (12)
ALT increased	1 (14)	0	5 (42)	0	1 (17)	0	7 (28)	0
Amylase increased	0	0	6 (50)	1 (8)	0	0	6 (24)	1 (4)
Face edema	0	0	5 (42)	0	1 (17)	0	6 (24)	0
Headache	3 (43)	0	3 (25)	0	0	0	6 (24)	0
Pruritis	1 (14)	0	4 (33)	0	1 (17)	0	6 (24)	0
Nausea	2 (29)	0	3 (25)	0	0	0	5 (20)	0
Rash maculo-papular	0	0	4 (33)	0	1 (17)	0	5 (20)	0
Arthralgia	1 (14)	0	2 (17)	0	1 (17)	0	4 (16)	0
Diarrhea	1 (14)	1 (14)	3 (25)	0	0	0	4 (16)	1 (4)
Myalgia	0	0	4 (33)	1 (8)	0	0	4 (16)	1 (4)
Peripheral edema	0	0	3 (25)	0	1 (17)	0	4 (16)	0

- Observed transaminase and pancreatic enzyme elevations are consistent with the mechanism of action of CSF1R inhibitors
  - Asymptomatic, not clinically significant
- All bilirubin levels were within the normal limit
- No related SAEs reported
- 2 DLTs reported
  - 1 patient each in cohort 5 and 8
  - Both patients had asymptomatic grade 3 AST elevation
  - Both patients had grade 1 AST elevation at baseline

[a]After 5-day 30 mg QD loading dose; [b]After 3-day 30 mg QD loading dose; [c]After 3-day 20 mg QD loading dose; [d]Only grade 4 AE reported in TGCT patients is grade 4 CPK increased (cohort 8).

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BIW, twice weekly; CPK, creatine phosphoki nase; DLT, dose-limiting toxicity; Gr, grade; MST, malignant solid tumor; QD, daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TGCT, tenosynovial giant cell tumor.

Dose Modifications Due to Adverse Events

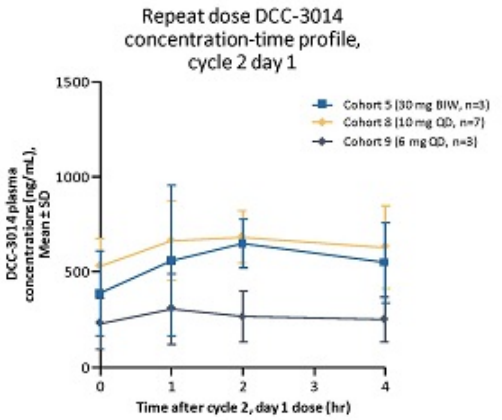
	Cohort 5 30 mg BIW[a] (N = 7)	Cohort 8 10 mg QD[b] (N = 12)	Cohort 9 6 mg QD[c] (N = 6)	Total (N = 25)
Patients with TEAE leading to dose modification, No. (%)	3 (43)	5 (42)	1 (16.7)	9 (36)
Dose interruption	3 (43)	5 (42)	1 (16.7)	9 (36)
Dose reduction	2 (29)	2 (17)	0	4 (16)[d]
Treatment discontinuation	0	1 (8)	0	1 (4)[e]

[a]After 5-day 30-mg QD loading dose; [b]After 3-day 30-mg QD loading dose; [c]After 3-day 20-mg QD loading dose; [d]Grade 3 urticaria, grade 3 diarrhea, grade 1 pyrexia (SAE, not related), grade 2 myalgia, and grade 3 CPK increase; [e]Grade 3 AST increase (DLT).

AST, aspartate aminotransferase; BIW, twice weekly; CPK, creatine phosphokinase; DLT, dose-limiting toxicity; QD, daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

DCC-3014 Pharmacokinetics and Pharmacodynamics

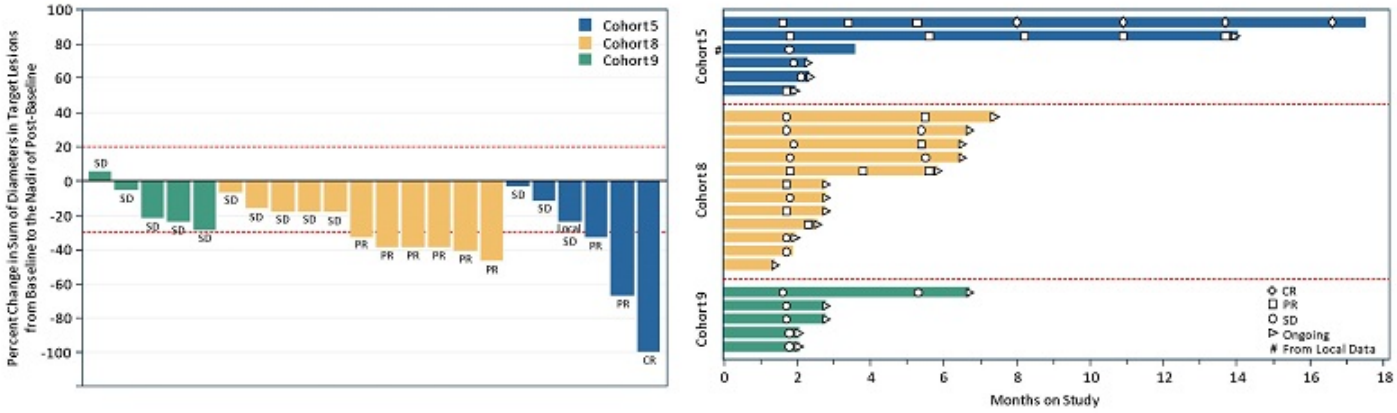
- Steady state DCC-3014 exposure in TGCT patients at cohorts 5, 8, and 9 was characterized
  - Cohorts 5 and 8 had similar PK at cycle 2, day 1
- Across all cohorts, DCC-3014 treatment led to:
  - Increased CSF1 (2.8–41-fold) and IL-34 levels (1.4–13-fold) in plasma
  - Decreased non-classical subtype of monocytes CD14dim/CD16+ (59–87%) in the peripheral blood



CD, cluster of differentiation; CSF1, colony-stimulating factor 1; IL, interleukin; PK, pharmacokinetics; QD, daily; SD, standard deviation; TGCT, tenosynovial giant cell tumor.

Antitumor Activity in TGCT Patients

- Of the 25 TGCT patients enrolled into the study, 22 patients were evaluable for efficacy by RECIST v1.1 at the data cut off
  - 21 patients had central assessment for efficacy
  - 1 patient had local assessment for efficacy but no central assessment performed
  - 3 patients have not yet reached first efficacy assessment timepoint in the study
- 9 (41%) patients across all TGCT cohorts achieved an objective response (1 complete response and 8 partial responses)
- 7 of the 9 (78%) responders had a partial response at their first restaging scan evaluation

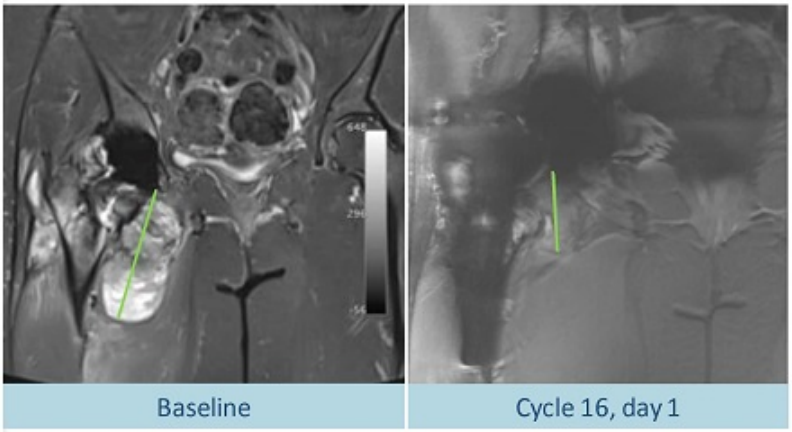


Assessed by independent central review unless otherwise noted (RECIST v1.1). Of the 9 responses, 3 were confirmed and 6 are awaiting confirmation.
Waterfall plot: +20% line is the threshold for disease progression; –30% line is the threshold from baseline to PR.
CR, complete response; PR, partial response; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; SD, stable disease; TGCT, tenosynovial giant cell tumor.

TGCT Case Studies

Case Study 1

- 57-year-old female diagnosed with TGCT (hip) in 2014
- Prior surgeries:
  - Resection (May 2014)
  - Synovectomy (August 2015, August 2016)
  - Resection and total hip replacement (August 2018)
  - Cryoablation (May 2019)
- Baseline tumor burden: 101 mm
- Enrolled July 2019 (cohort 5 – DCC-3014 30 mg twice weekly)
  - Dose reduced to 20 mg twice weekly in cycle 6 due to grade 3 urticaria, re-escalated in cycle 10
- Partial response after 2 cycles (33% decrease from baseline)
- Treatment ongoing in cycle 16 (67% decrease at cycle 16, day 1)
  - Durable, deep response



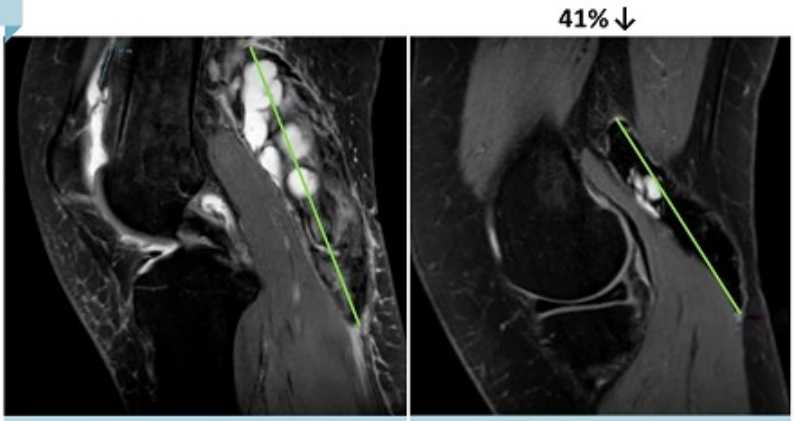
TGCT, tenosynovial giant cell tumor.

Patient provided informed consent for use of these images.

TGCT Case Studies

Case Study 2

- 39-year-old female diagnosed with TGCT (knee) in April 2020
- No prior systemic therapy or surgery
- Baseline tumor burden: 126 mm
- Enrolled in June 2020 (cohort 8 – DCC-3014 10 mg daily)
- Partial response after 2 cycles (41% decrease from baseline)
- Treatment ongoing in cycle 4



Baseline | Cycle 3, day 1

TGCT, tenosynovial giant cell tumor.

Patient provided informed consent for use of these images.

Conclusions

- DCC-3014 is a highly selective, oral, investigational switch control kinase inhibitor of CSF1R and is generally well tolerated in patients with TGCT not amenable to surgery
  - 22 of the 25 TGCT patients remain on the study
- Similar steady state PK profiles were observed between 30 mg twice weekly (cohort 5) and 10 mg daily (cohort 8) dosing regimens; lower exposure was observed in 6 mg daily (cohort 9) dosing regimen
- DCC-3014 treatment resulted in an increase in plasma CSF1/IL-34 and a decrease in non-classical sub-type of monocytes, indicating inhibition of CSF1R
- DCC-3014 showed highly encouraging signs of antitumor activity in TGCT patients (n=22)
  - 9 (41%) patients across all TGCT cohorts achieved an objective response (1 complete response and 8 partial responses)
  - 7 of the 9 (78%) responders had a partial response at their first restaging scan evaluation
  - 2 TGCT patients were on treatment for ≥12 months with responses that deepened over time
- The recommended phase 2 dose for DCC-3014 in TGCT patients was determined to be 30 mg twice weekly (no loading dose)
- These results are encouraging and support further evaluation of DCC-3014 in patients with TGCT not amenable to surgery
  - Study is ongoing and enrolling patients into TGCT expansion cohorts to further evaluate safety and efficacy (NCT03069469)

CSF1, colony-stimulating factor 1; CSF1R, colony-stimulating factor 1 receptor; IL, interleukin; PK, pharmacokinetics; TGCT, tenosynovial giant cell tumor.

Acknowledgements

- The authors would like to thank the patients and their families and caregivers, the investigators, and the investigational site staff of this study

- This study was sponsored by Deciphera Pharmaceuticals, LLC, Waltham, MA, USA

- Editorial assistance for this presentation was provided by Ashfield Healthcare LLC, a UDG company, and was funded by Deciphera Pharmaceuticals, LLC