# **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): October 19, 2018

# **DECIPHERA PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of Incorporation)

> **500 Totten Pond Road** Waltham, MA

001-38219 (Commission ile Number)

30-1003521 (IRS Employer Identification Number)

(Address of registrant's principal executive office)

02451 (Zip code)

(781) 209-6400

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since 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))

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

Emerging growth company  $\boxtimes$ 

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 October 19, 2018, Deciphera Pharmaceuticals, Inc. (the "Company") announced updated preliminary results from its ongoing Phase 1 clinical study of DCC-2618, the company's broad-spectrum KIT and PDGFRα inhibitor, in patients with gastrointestinal stromal tumors ("GIST") at a presentation at the European Society of Medical Oncology 2018 Congress ("ESMO 2018"). The Company provided certain business updates in the materials attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1

Deciphera Pharmaceuticals, Inc. materials dated October 2018.

# INDEX TO EXHIBITS

Exhibit No. Description Deciphera Pharmaceuticals, Inc. materials dated October 2018. 99.1

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: October 19, 2018

# DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Michael D. Taylor

Michael D. Taylor President and Chief Executive Officer

# **Corporate Update**

#### DCC-2618

Ongoing Phase 1 Trial Update

We are studying DCC-2618 in an ongoing Phase 1 trial in patients with advanced malignancies, including gastrointestinal stromal tumors, or GIST. Our ongoing Phase 1 trial is comprised of two parts: a dose escalation portion and a dose expansion portion, as detailed below:

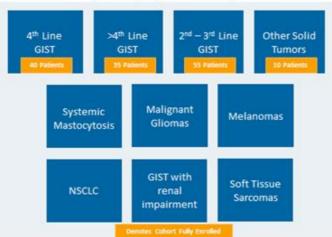
#### Part 1: Dose Escalation

- Key Objectives: MTD, recommended Phase 2 dose, safety, tolerability, pharmacokinetics and anti-tumor activity
- Design: 3+3 design with enrichment of targeted patients
- Dose Levels: 20, 30, 50, 100, 150, and 200 mg BID; and 100, 150 and 250 mg QD
- MTD: not determined



#### Part 2: Dose Expansion





European Society of Medical Oncology (ESMO) 2018 Congress and Additional Interim Results

On October 19, 2018, Deciphera Pharmaceuticals, Inc., or the Company, announced updated preliminary results from its ongoing Phase 1 clinical study of DCC-2618, the Company's broad-spectrum KIT and PDGFRα inhibitor, in patients with GIST at a presentation at the European Society of Medical Oncology 2018 Congress, or ESMO 2018.

The chart below summarizes the demographic profile of the patients for whom data was presented at ESMO 2018:

GIST Patients ≥100 mg /d	n=178	
Age (years), median (range)	61 (27-87)	
GISTSubtype	n (%)	
KIT-driven	168 (94%)	
PDGFRa-driven	9 (5%)	
SDH deficient	1 (1%)	
Line of Therapy	n (%)	
2 <sup>nd</sup> Line	38 (21%)	
3 <sup>rd</sup> Line	29 (16%)	
24 <sup>th</sup> Line <sup>(1)</sup>	111 (62%)	
DCC-2618 Dose	n (%)	
150 mg QD	142 (80%)	
Other (100 mg/d - 400 mg/d)	36 (20%)	

Phase 1 Demographics and Baseline Characteristics of GIST Patients

#### Notes: (1) Mean number of prior regimens for <sup>3</sup>4th line patients was 3.6.

At ESMO 2018, we reported preliminary results with a cutoff date of August 31, 2018 that include investigator-assessed median progression free survival, or mPFS, objective response rates by best response, or ORR, and disease control rates at 3 months, or DCR, as determined by Response Evaluation Criteria in Solid Tumors, or RECIST, version 1.1 across 178 patients receiving DCC-2618 at doses of  $\geq$ 100mg daily.

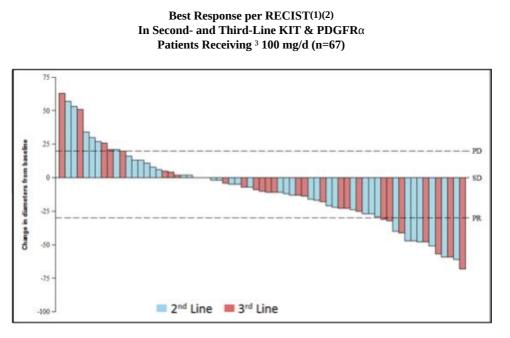
Preliminary results, including those presented at ESMO 2018, are summarized in the below table.

Line of Therapy	<b>GIST Patients (n)</b>	DCR at 3 Months	ORR(1)	Median Progression(5) Free Survival
2nd Line(4, 6 & 7)	38	79%	18%(2)	42 weeks
3rd Line(4, 6 & 7)	29	83%	24%	40 weeks
<sup>3</sup> 4th Line(6 & 7)	111	66%	9%(3)	24 weeks
2nd & 3rd Line(4, 6 & 7)	67	81%	21% (2 & 3)	40 weeks

Notes: (1) Includes nine unconfirmed responses: 2<sup>nd</sup> line (n=1), 3<sup>rd</sup> line (n=3) and <sup>3</sup>4th line (n=5); (2) Does not reflect one PR reported after cutoff date, which would result in an ORR in 2<sup>nd</sup> line of 21% and an ORR in 2<sup>nd</sup> line and 3<sup>rd</sup> line combined of 22%; (3) Excludes five patients due to missing data at the time of data cutoff (n=2), lack of first tumor assessment (n=1), withdrawal of consent prior to first assessment (n=1) and unrelated death at C1D4 prior to first assessment (n=1); (4) 59 of 67 combined 2<sup>nd</sup> line and 3<sup>rd</sup> line patients received 150mg once daily; (5) Censored patients for mPFS were 2<sup>nd</sup> line (58%), 3<sup>rd</sup> line (52%), 4<sup>th</sup> line and 4<sup>th</sup> line plus (35%) and 2<sup>nd</sup> and 3<sup>rd</sup> line (55%); (6) As of the cutoff date, active patients by line of therapy were as follows: 2<sup>nd</sup> line were 61%; 3<sup>rd</sup> line were 59%; 4<sup>th</sup> line and 4<sup>th</sup> line plus were 44% and 2<sup>nd</sup> and 3<sup>rd</sup> line were 60%; and (7) Median Treatment Duration for 2<sup>nd</sup> line is 48 weeks, for 3<sup>rd</sup> line is NR, for 4<sup>th</sup> line and 4<sup>th</sup> line plus is 28 weeks and for 2<sup>nd</sup> and 3<sup>rd</sup> line is 52 weeks. Includes 14 patients who elected for intra-patient dose escalation.

#### Preliminary ORR Data by Best Response with DCC-2816 @ 3 100 mg/d

At ESMO 2018, for the second- and third-line GIST patients in our Phase 1 trial of DCC-2618 who received both a baseline and post-treatment CT scan by the efficacy cutoff date (n = 67), we presented the greatest reduction or smallest increase in tumor size from baseline as measured by CT or MRI scan, or best response, for solid malignancies per RECIST as shown in the following figure.

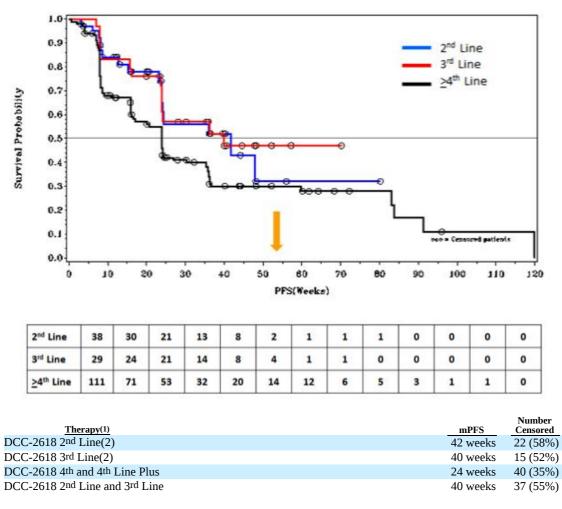


Notes: (1) Based on cutoff date of August 31, 2018; RECIST data per investigator assessment; (2) Includes unconfirmed responses in 2nd line (n=1) and 3rd line (n=3). Does not reflect one PR in 2nd line reported after cutoff date. Includes 14 patients who elected for intra-patient dose escalation.

Preliminary mPFS Data in GIST Patients with DCC-2816 @ 3 100 mg/d

At ESMO 2018, for the second-, third- and fourth- and fourth-line plus GIST patients in our Phase 1 trial of DCC-2618, we presented preliminary mPFS data for patients receiving doses of <sup>3</sup>100mg daily as shown in the following figures.

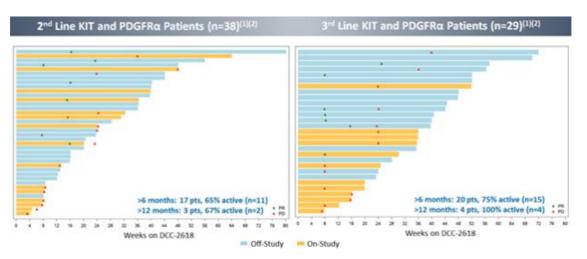
Tumor Control per RECIST(1) KIT & PDGFRα Patients at <sup>3</sup> 100 mg/d (n=178)



Notes: (1) Based on cutoff date of August 31, 2018; RECIST data per investigator assessment; (2) PFS at 52 weeks was 32% for 2<sup>nd</sup> Line and 47% for 3<sup>rd</sup> Line.

#### Duration of Treatment of GIST Patients in Ongoing Phase 1 Trial

The following figure shows the duration of treatment with DCC-2618, as of the cutoff date, for second- and third-line GIST patients in the Phase 1 trial who had received <sup>3</sup> 100 mg of DCC-2618 daily. In the second-line GIST patients, as of the cutoff date, 17 patients received DCC-2618 at doses of <sup>3</sup>100mg daily for more than 6 months with 65% (11 of 17) of these patients remaining on study. In third-line GIST patients, as of the cutoff date, 20 patients received DCC-2618 at doses of <sup>3</sup>100mg daily for more than 6 months with 75% (15 of 20) of these patients remaining on study.



#### Preliminary Data with DCC-2618 at <sup>3</sup> 100 mg Daily Shows Emerging Durability

Notes: (1) Based on cutoff date of August 31, 2018; RECIST data per investigator assessment; (2) Includes unconfirmed responses in 2nd line (n=1) and 3rd line (n=3). Does not reflect one PR in 2nd line reported after cutoff date. Includes 14 patients who elected for intra-patient dose escalation.

In addition to the data presented at ESMO 2018, we also observed the following in the fourth-line and fourth-line-plus GIST patients. As of the cutoff date, of the 46 combined fourth- and fourth-line plus GIST patients that received DCC-2618 at doses of <sup>3</sup>100mg daily for more than 6 months, 74% (34 of 46) of these patients remained on study.

#### Tolerability Results in Phase 1 Trial

DCC-2618 was generally well tolerated at all doses administered and the treatment-emergent adverse events by Grades 1/2 and Grades 3/4 are summarized in the tables below.

For the 178 GIST patients treated at doses above <sup>3</sup>100mg daily, DCC-2618 was generally well tolerated. Among the treatment-emergent adverse events, or TEAEs, reported by investigators (>10%), regardless of relationship to DCC-2618, the most common were: alopecia (50%), myalgia (44%), fatigue (43%), constipation (34%), hand-foot skin reaction (32%), nausea (30%), decreased appetite (28%), weight decreased (24%), abdominal pain (23%), diarrhea (23%) and lipase increase (23%). Clinically asymptomatic lipase elevations were the most frequent Grade 3 TEAE. Among the 178 GIST patients treated at doses of  $\geq$ 100mg daily: 14% (24 patients) experienced dose reductions due to TEAEs and 11% (19 patients) experienced treatment discontinuations due to TEAEs.

# Treatment Emergent Adverse Events in <sup>3</sup> 10% of GIST Patients at <sup>3</sup> 100mg Daily (n = 178)

GIST PATIENTS @ ≥100 MG DAILY						
ADVECT DUCKT	GRADE 1-2	GRADE 3-4	GRADE 1-4 TOTAL			
ADVERSE EVENT	(N=178)	(N=178)	(N=178)			
Alopecia	89 (50%)	0 (0%)	89 (50%)			
Myalgia	79 (44%)	0 (0%)	79 (44%)			
Fatigue	74 (42%)	2 (1%)	76 (43%)			
Constipation	60 (34%)	0 (0%)	60 (34%)			
Hand-Foot Skin Reaction <sup>1</sup>	56 (32%)	1 (1%)	57 (32%)			
Nausea	53 (30%)	0 (0%)	53 (30%)			
Decreased appetite	47 (26%)	2 (1%)	49 (28%)			
Weight decreased	43 (24%)	0 (0%)	43 (24%)			
Abdominal pain	33 (19%)	8 (5%)	41 (23%)			
Diarrhea	38 (21%)	3 (2%)	41 (23%)			
Lipase increased	21 (12%)	20 (11%)	41 (23%)			
Vomiting	32 (18%)	1 (1%)	33 (19%)			
Arthralgia	32 (18%)	0 (0%)	32 (18%)			
Hypertension	22 (12%)	10 (6%)	32 (18%)			
Dry skin	31 (17%)	O (0%)	31 (17%)			
Rash	31 (17%)	0 (0%)	31 (17%)			
Muscle spasms	30 (17%)	0 (0%)	30 (17%)			
Anemia	14 (8%)	13 (7%)	27 (15%)			
Dyspnea	25 (14%)	2 (1%)	27 (15%)			
Cough	26 (15%)	0 (0%)	26 (15%)			
Headache	25 (14%)	O (0%)	25 (14%)			
Dizziness	23 (13%)	0 (0%)	23 (13%)			
Back pain	20 (11%)	2 (1%)	22 (12%)			
Blood bilirubin increased	15 (8%)	6 (3%)	21 (12%)			
Pain in extremity	21 (12%)	0 (0%)	21 (12%)			
Dysgeusia	18 (10%)	0 (0%)	18 (10%)			
Hypomagnesaemia	18 (10%)	0 (0%)	18 (10%)			
Pruritus	18 (10%)	0 (0%)	18 (10%)			

Notes: Data presented at ESMO 2018 based on cutoff as of August 31, 2018. (1) Palmar-plantar erythrodysaesthesia syndrome reported in 19 patients.

For 142 GIST patients treated at 150 mg daily, DCC-2618 was also generally well tolerated. Clinically asymptomatic lipase elevations were the most frequent Grade 3 treatment-emergent adverse event. Among the 142 GIST patients treated at 150 mg daily: 13% (18) patients experienced dose reductions due to TEAEs and 11% (15) experienced treatment discontinuations due to TEAEs.

#### Treatment Emergent Adverse Events in <sup>3</sup> 10% of GIST Patients at 150mg Daily (n = 142)

GIS	T PATIENTS @ 150	) mg QD	
	GRADE	GRADE	TOTAL
ADVERSE EVENT	1/2	3/4	(n=142)
Alopecia	74 (52%)	0 (0%)	74 (52%)
Myalgia	65 (46%)	0 (0%)	65 (46%)
Fatigue	56 (39%)	1 (1%)	57 (40%)
Constipation	50 (35%)	0 (0%)	50 (35%)
Hand-foot skin reaction <sup>(1)</sup>	45 (32%)	1 (1%)	46 (32%)
Nausea	40 (28%)	0 (0%)	40 (28%)
Decreased appetite	34 (24%)	2 (1%)	36 (25%)
Abdominal pain	25 (18%)	5 (4%)	30 (21%)
Diarrhea	27 (19%)	3 (2%)	30 (21%)
Lipase increased	15 (11%)	14 (10%)	29 (20%)
Weight decreased	29 (20%)	0 (0%)	29 (20%)
Rash	28 (20%)	0 (0%)	28 (20%)
Arthralgia	24 (17%	0 (0%)	24 (17%)
Vomiting	24 (17%	0 (0%)	24 (17%)
Dry skin	23 (16%	0 (0%)	23 (16%)
Headache	23 (16%)	0 (0%)	23 (16%)
Muscle spasms	23 (16%)	0 (0%)	23 (16%)
Hypertension	17 (12%)	5 (4%)	22 (16%)
Back pain	18 (13%	2 (1%)	20 (14%)
Pain in extremity	20 (14%)	0 (0%)	20 (14%)
Dizziness	18 (11%)	0 (0%)	18 (13%)
Dyspnoea	16 (11%)	2 (1%)	18 (13%)
Pruritus	18 (13%)	0 (0%)	18 (13%)
Anaemia	11 (8%)	5 (4%	16 (11%)
Blood bilirubin increased	11 (8%)	5 (4%)	16 (11%)
Cough	15 (11%)	0 (0%)	15 (11%)

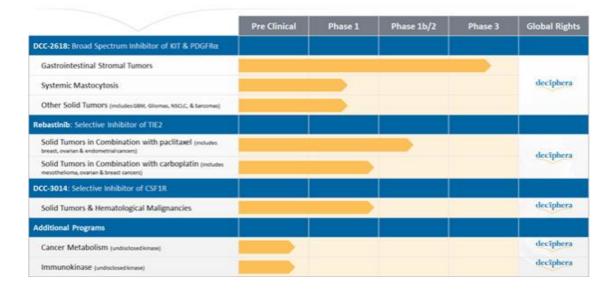
Note: Data presented at ESMO 2018 based on cutoff as of August 31, 2018. (1) Palmar-plantar erythrodysaesthesia syndrome reported in 18 patients.

# Planned Phase 3 Trial INTRIGUE

We expect to initiate our planned randomized (1:1) open label Phase 3 trial, INTRIGUE, comparing treatment with DCC-2618 at 150mg daily to sunitinib at 50mg daily in up to 358 second-line GIST patients, in the fourth quarter of 2018.

# **Our Drug Candidates - Pipeline**

We currently retain global development and commercialization rights to our drug candidates, including the lead programs summarized in the following figure:



### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements, which reflect our current views with respect to, among other things, our clinical programs, operations and financial performance. All statements other than statements of historical facts contained in this document, including statements regarding our strategy, future operations, future clinical programs, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and include, among other things:

- the success, cost and timing of our product development activities and clinical trials, including the timing of our second planned Phase 3 trial for DCC-2618 in GIST;
- our ability to obtain and maintain regulatory approval for DCC-2618 or any of our other current or future drug candidates, and any related restrictions, limitations, and/or warnings in the label of an approved drug candidate;
- our expectations regarding the size of target patient populations for our drug candidates, if approved for commercial use, and any additional drug candidates we may develop;
- our ability to obtain funding for our operations;

- our ability to manufacture sufficient quantities of DCC-2618 to support our planned clinical trials and, if approved, commercialization;
- the commercialization of our drug candidates, if approved;
- our plans to research, develop and commercialize our drug candidates, including the timing of our second planned Phase 3 trial for DCC-2618 in GIST;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our drug candidates;
- future agreements with third parties in connection with the commercialization of DCC-2618, or any of our other current or future drug candidates;
- the size and growth potential of the markets for our drug candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our drug candidates, as well as the reimbursement coverage for our drug candidates;
- regulatory and legal developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our use of the proceeds from our initial public offering and our follow-on public offering.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere in our filings with the SEC. The forward-looking statements contained in this document are made as of the date of this document, and we undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.