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): February 12, 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 Number)**

200 Smith Street Waltham, MA	**02451**
(Address of registrant's principal executive office)	**(Zip code)**

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

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 Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**The 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 2.02. Results of Operations and Financial Condition.

Cash, Cash Equivalents and Short-Term Investments

Deciphera Pharmaceuticals, Inc. ("We," the "Company," or "Deciphera") is currently in the process of finalizing our financial results for the three months and year ended December 31, 2019. Based on preliminary unaudited information available to management as of the date hereof and subject to completion by management of our financial statements as of and for the quarter and the year ended December 31, 2019, we expect to have cash, cash equivalents and short-term investments as of December 31, 2019 of approximately $579.0 million, as compared to $634.6 million at September 30, 2019. The preliminary data has been prepared by, and is the responsibility of, our management. PricewaterhouseCoopers LLP, our independent registered public accounting firm, has not audited, reviewed, compiled, or applied agreed-upon-procedures with respect to such preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto. These results could change as a result of further review. Complete quarterly and annual results will be included in our Annual Report on Form 10-K for the year ended December 31, 2019.

Item 8.01. Other Events.

Business Update

Deciphera is filing information for the purpose of supplementing and updating certain aspects of the description of its business from that described under the heading, "Item 1. Business" in Deciphera's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2019. The updated disclosure is set forth below:

Overview

We are a clinical-stage biopharmaceutical company developing new drugs to improve the lives of cancer patients by addressing key mechanisms of drug resistance that limit the rate and durability of response of many cancer therapies. Our targeted, small molecule drug candidates, designed using our proprietary kinase switch control inhibitor platform, inhibit the activation of kinases, an important family of enzymes, that when mutated or over expressed, are known to be directly involved in the growth and spread of many cancers. We have built a diverse pipeline of orally administered drug candidates that includes three clinical-stage, one preclinical-stage, and one research-stage program. We wholly own all of our drug candidates with the exception of a development and commercialization out-license agreement for our lead drug candidate, ripretinib, in the Greater China region.

In December 2019, we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for ripretinib for the treatment of patients with advanced gastrointestinal stromal tumors, or GIST, who have received prior treatment with imatinib, sunitinib, and regorafenib. Our NDA is based on positive results from our first Phase 3 study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies in the U.S. other than avapritinib, which is approved for GIST patients with PDGRFα exon 18 mutations only (estimated to be approximately six percent of all patients with newly-diagnosed GIST). In August 2019, we announced top-line results from INVICTUS, including that the study achieved its primary endpoint of improved progression free survival, or PFS, compared to placebo as determined by blinded independent radiologic review using modified Response Evaluation Criteria in Solid Tumors, or RECIST, version 1.1. In February 2020, the FDA accepted our NDA for ripretinib for the treatment of patients with advanced GIST, granted priority review and set an action date of August 13, 2020 under the Prescription Drug User Fee Act, or PDUFA.

The NDA is being reviewed under the FDA's Oncology Center of Excellence, or OCE, Real-Time Oncology Review pilot program, or RTOR, which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. In October 2019, the FDA granted Breakthrough Therapy Designation, or BTD, for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. BTD is designed to expedite the development and review of drugs that are intended to

treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). In December 2019, we filed a New Drug Submission, or NDS, with Health Canada, and a market authorisation application, or AUS MAA, with the Therapeutic Goods Administration, or TGA, in Australia, for ripretinib in advanced GIST, under the FDA's Project Orbis pilot program, or Project Orbis. Project Orbis is an initiative of the OCE and, according to the FDA, provides a framework for concurrent submission and review of oncology products among international partners. Both the NDS and the AUS MAA have received priority review. Acceptance into the RTOR and Orbis pilot programs does not guarantee or influence approvability of our NDA, NDS, and AUS MAA for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by the FDA, and the review standards of Health Canada and TGA, and we may not derive any benefit from inclusion in these pilot programs, including, but not limited to, a more efficient review process. These pilot programs are not formal regulatory pathways and may be changed, suspended, or halted at any time.

We are actively engaged in commercial preparations to support the potential U.S. launch of ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib, if approved. We expect to file a marketing authorisation application, or MAA, with the European Medicines Agency, or EMA, in the European Union, or EU, for ripretinib in advanced GIST in the second half of 2020, and we are exploring whether to partner, or build our own, European go-to-market capabilities, to support a potential EU approval. In June 2019, we entered into a License Agreement, or the Zai License Agreement, with an affiliate of Zai Lab (Shanghai) Co., Ltd., or Zai, pursuant to which we granted Zai exclusive rights to develop and commercialize ripretinib, including certain follow-on compounds, or the Licensed Products, in Mainland China, Hong Kong, Macau, and Taiwan, collectively Greater China.

In addition, we are studying ripretinib in our global pivotal Phase 3 study, INTRIGUE, in second-line GIST patients, comparing ripretinib to sunitinb. As of January 6, 2020, we had 106 sites open for enrollment in INTRIGUE in 18 countries. We expect to complete enrollment in INTRIGUE in the second half of 2020.

We also have an ongoing Phase 1 trial studying ripretinib in patients with different stages of GIST following treatment with at least imatinib, as well as in patients with systemic mastocytosis other than indolent systemic mastocytosis, or SM, and other solid tumors driven by KIT or PDGFRα including gliomas, melanoma, non-small cell lung cancer, or NSCLC, germ cell cancer, penile cancer, and soft tissue sarcomas, as well as a cohort for GIST and other solid tumors with renal impairment. We expect to report data from one or more of these expansion cohorts in the second half of 2020.

Beyond ripretinib, we are developing two other clinical-stage drug candidates, DCC-3014 and rebastinib, which target the macrophage tumor microenvironment.

DCC-3014 is an investigational, orally administered, potent, and highly selective inhibitor of CSF1R, a kinase that controls the survival and function of certain immunosuppressive tumor associated macrophages, or TAMs. We are currently studying DCC-3014 in a Phase 1 dose escalation study that includes patients with advanced malignancies as well as patients with a type of tenosynovial giant cell tumors, or TGCT, known as diffuse-type TGCT. The dose escalation Phase 1 study is designed to determine a Phase 2 dose for an expansion study. During 2019, we announced positive, preliminary data from the ongoing dose escalation Phase 1 study with DCC-3014 in patients with advanced malignancies and preliminary data from three initial patients diagnosed with TGCT. To explore the potential of DCC-3014 in this target population, we intend to continue to enroll TGCT patients in the dose escalation study, and, in the second half of 2020, provide a data update on TGCT patients. Subject to favorable results from the dose escalation study, in the second half of 2020 we intend to determine a Phase 2 dose for, and initiate an expansion study with DCC-3014, including in patients with TGCT. We will also continue to evaluate the potential to study DCC-3014 in advanced malignancies in combination with immuno-oncology, or I/O, therapies.

Rebastinib is an investigational, orally administered, potent, and selective inhibitor of TIE2 kinase, which plays an important role in regulating tumor angiogenesis, invasiveness, metastasis, and immunotolerance. We are currently studying rebastinib in two Phase 1b/2 studies in combination with chemotherapy. In October 2018, we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with paclitaxel to assess safety, tolerability, pharmacokinetics, or PK, and efficacy in patients with advanced or metastatic solid tumors. Part 2 of this study is currently ongoing and we expect to present Phase 1b/2 data from this study in the second half of 2020.

In January 2019, we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with carboplatin in patients with advanced or metastatic solid tumors. In January 2020, we selected a Phase 2 dose for, and activated, Part 2 of this Phase 1b/2 study in combination with carboplatin and we expect to present data from this study in the second half of 2020.

In addition to our clinical-stage programs, we are conducting preclinical investigational new drug, or IND, enabling studies, with DCC-3116, a small molecule ULK kinase inhibitor discovered using our novel switch control inhibitor platform. DCC-3116 is designed to inhibit autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK kinase, which has been shown to be the initiating factor that activates autophagy. Subject to favorable IND-enabling studies and FDA acceptance of our IND, currently expected to be filed in second half of 2020, we intend to develop DCC-3116 for the potential treatment of RAS mutant cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

We believe our proprietary kinase switch control inhibitor platform, supported by our experienced management team, enables us to develop advanced, differentiated, kinase inhibitors that may provide significant benefits to cancer patients. We continue to work on potential new drug candidates for undisclosed targets.

Ripretinib: A Broad-spectrum KIT and PDGFRα Inhibitor

We are developing our lead drug candidate ripretinib, an orally administered kinase switch control inhibitor, for the treatment of GIST, SM, and other solid tumors driven by KIT or PDGFRα where significant unmet medical need exists despite currently available therapies. While approved kinase inhibitors control certain initiating and drug resistance-causing mutations in KIT and PDGFRα, the kinases that drive disease progression in most GIST patients, these approved drugs fail to inhibit all known mutations. We designed ripretinib to improve the treatment of GIST patients by inhibiting the full spectrum of the known mutations in KIT and PDGFRα.

GISTs are the most common sarcoma of the gastrointestinal tract and present most often in the stomach or small intestine. The typical patient is over 40 years old. According to the American Cancer Society, in 2019 approximately 4,000 to 6,000 patients were newly diagnosed with GIST in the United States. Disease progression in advanced GIST is often due to secondary mutations in KIT or PDGFRα that cause resistance to first-line treatment. We estimate that annual new treatment-eligible second-line GIST patients in the U.S. are approximately 2,000 with an estimated annual prevalence of treated GIST patients in the second-line of approximately 2,600. We estimate that approximately 70 to 80% of eligible patients from the second-line will be eligible for third-line treatment, and approximately 70 to 80% of eligible patients from the third-line will be eligible for fourth-line treatment. Eligible patients for third- and fourth-line treatment exclude the estimated proportion of patients that die, discontinue treatment, or enter a clinical trial and, therefore, are not eligible for treatment; for later lines of therapy, we expect a similar drop-off rate. These estimates, which are based on our recent analyses of U.S. claims data, are inherently uncertain.

INVICTUS: Completed Phase 3 Study in Fourth-Line and Fourth-Line Plus GIST

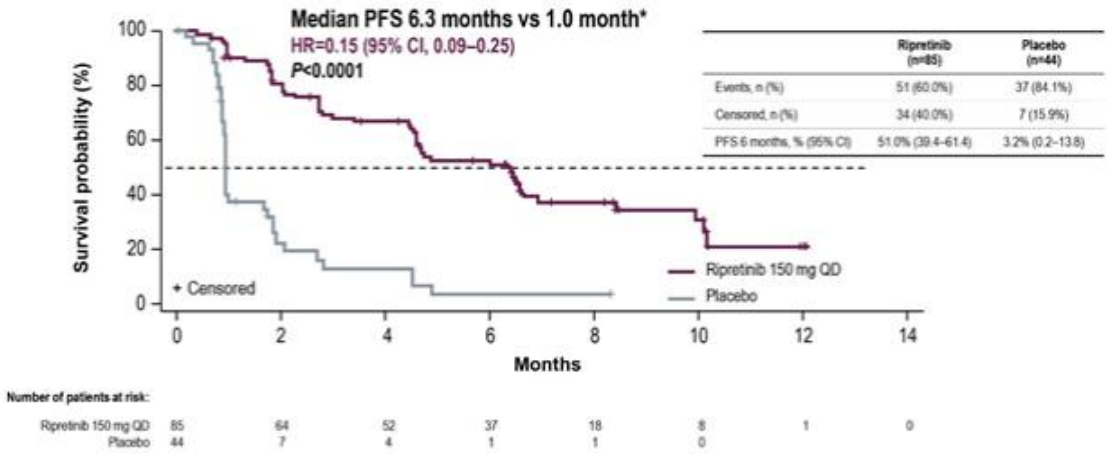
The INVICTUS Phase 3 study was a randomized, double-blind, placebo-controlled, global, multicenter trial to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. We enrolled 129 patients who had a confirmed diagnosis of GIST and had previously received at least three different kinase inhibitors including imatinib, sunitinib, and regorafenib. Patients were treated with ripretinib or placebo, in accordance with their randomization, until they developed disease progression, experienced unacceptable toxicity, or withdrew consent. Placebo patients had the opportunity to cross over to ripretinib treatment upon disease progression with placebo. Patients on ripretinib had the opportunity to remain on their current dose or escalate to 150 mg twice daily, or BID, upon disease progression.

Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily, or QD, in repeated 28-day cycles with best supportive care, or BSC. Patients were evaluated for PFS based upon independent radiologic review of CT scans, as assessed by modified RECIST version 1.1. Tumor response assessments per modified RECIST were conducted every cycle for the first three cycles and then every two cycles thereafter beginning with the fourth cycle. The primary efficacy endpoint was PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST included objective response rate, or ORR, overall survival, or OS, and time to tumor progression.

In 2019, we announced top-line data from INVICTUS, including that the study achieved its primary endpoint of improved PFS compared to placebo.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (Hazard Ratio (HR) of 0.15, 95% Confidence Interval (0.09, 0.25), p-value <0.0001) compared to placebo. This PFS benefit was consistent across all assessed patient subgroups. The following graph shows the estimated PFS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated PFS Probability for Ripretinib and Placebo Arms

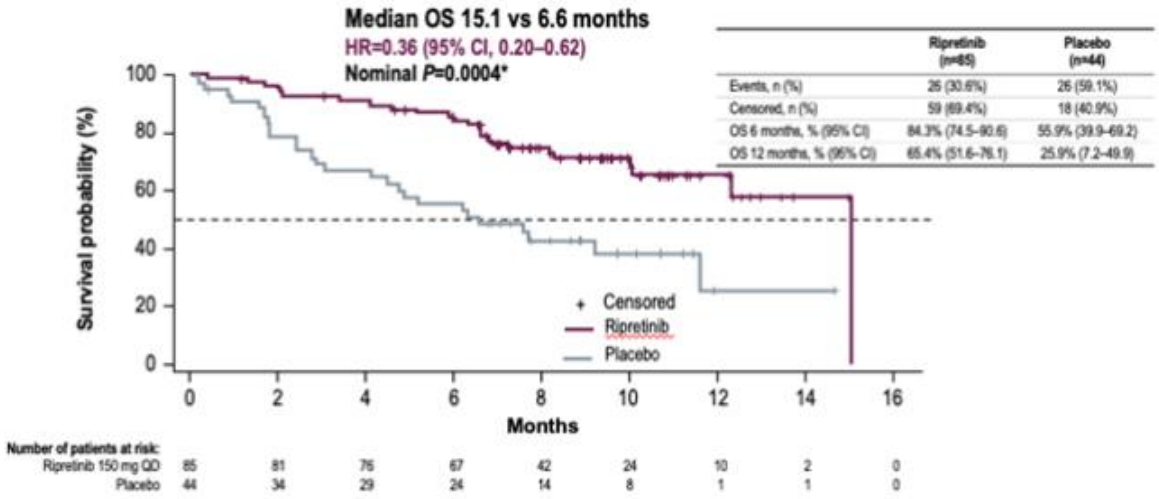


* Double-blind period.

For the key secondary endpoint of ORR, as determined by blinded independent radiologic review using modified RECIST, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Ripretinib also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of OS (median OS 15.1 months with ripretinib compared to 6.6 months with placebo, HR = 0.36, 95% Confidence Interval (0.20, 0.62), nominal p-value=0.0004). According to the pre-specified hierarchical testing procedure of the endpoints, the hypothesis testing of OS cannot be formally conducted unless the test of ORR is statistically significant. Since statistical significance was not achieved for ORR, the hypothesis testing of OS was not formally performed. The OS data for the placebo arm include patients taking placebo who, following progression, were crossed-over to ripretinib treatment. The following graph shows the estimated OS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated OS Probability for Ripretinib and Placebo Arms†



* Due to hierarchal testing procedures of the endpoints, the OS endpoint could not be formally tested because the ORR was not statistically significant.

† Data include all time periods, including dose escalations. Placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Ripretinib was generally well tolerated and the adverse events reported in the INVICTUS study were consistent with data from previously presented Phase 1 study results. Grade 3 or 4 treatment-emergent adverse events, or TEAEs, occurred in 42 patients (49%) on the ripretinib arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6), and hypertension (7%; n=6). Grade 3 or 4 TEAEs in greater than 5% of patients in the placebo arm were anemia (14%; n=6).

The below table lists all TEAEs (and corresponding grade 3 and 4 TEAEs) in greater than 10% of patients in the ripretinib arm compared to the placebo arm in INVICTUS.

INVICTUS: TEAEs in >10% of Patients
(and Corresponding Grade 3 and 4 TEAEs)

Treatment Emergent Adverse Event	Ripretinib any grade (n=85)	Ripretinib grade 3 and 4 (n=85)[1]	Placebo any grade (n=43)[2]	Placebo grade 3 and 4 (n=43)[1,2]
Any TEAE or grade 3/4 TEAE[3]	**84 (98.8%)**	**42 (49.4%)**	**42 (97.7%)**	**19 (44.2%)**
Alopecia	44 (51.8%)	0	2 (4.7%)	0
Fatigue	36 (42.4%)	3 (3.5%)	10 (23.3%)	1 (2.3%)
Nausea	33 (38.8%)	3 (3.5%)	5 (11.6%)	0
Abdominal pain	31 (36.5%)	6 (7.1%)	13 (30.2%)	2 (4.7%)
Constipation	29 (34.1%)	1 (1.2%)	8 (18.6%)	0
Myalgia	27 (31.8%)	1 (1.2%)	5 (11.6%)	0
Diarrhea	24 (28.2%)	1 (1.2%)	6 (14%)	1 (2.3%)
Decreased appetite	23 (27.1%)	1 (1.2%)	9 (20.9%)	1 (2.3%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0	0	0
Vomiting	18 (21.2%)	3 (3.5%)	3 (7%)	0
Headache	16 (18.8%)	0	2 (4.7%)	0
Weight decreased	16 (18.8%)	0	5 (11.6%)	0
Arthralgia	15 (17.6%)	0	2 (4.7%)	0
Blood bilirubin increased	14 (16.5%)	1 (1.2%)	0	0
Edema peripheral	14 (16.5%)	1 (1.2%)	3 (7%)	0

Muscle spasms	13 (15.3%)	0	2 (4.7%)	0
Anemia	12 (14.1%)	8 (9.4%)	8 (18.6%)	6 (14%)
Hypertension	12 (14.1%)	6 (7.1%)	2 (4.7%)	0
Asthenia	11 (12.9%)	1 (1.2%)	6 (14%)	2 (4.7%)
Dry skin	11 (12.9%)	0	3 (7%)	0
Dyspnea	11 (12.9%)	0	0	0
Hypophosphatemia	9 (10.6%)	4 (4.7%)	0	0
Lipase increased	9 (10.6%)	4 (4.7%)	0	0
Pruritus	9 (10.6%)	0	2 (4.7%)	0
Stomatitis	9 (10.6%)	0	0	0

1 Corresponding grade 3/4 TEAEs to TEAEs in >10% of patients receiving ripretinib.
2 44 patients were randomized to placebo, but 1 did not receive treatment.
3 Regardless of causality.

TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

INTRIGUE: Ongoing Phase 3 Study in Second-Line GIST

In December 2018, we initiated a pivotal Phase 3 study, INTRIGUE, to evaluate the efficacy and tolerability of ripretinib compared to sunitinib in second-line GIST patients. We believe that the results from INTRIGUE, if positive, would support an NDA for approval in second-line GIST patients in the United States, and similar applications in Europe and other major markets.

The INTRIGUE Phase 3 study is an interventional, randomized, global, multicenter, open-label study to evaluate the safety, tolerability and efficacy of ripretinib compared to sunitinib in approximately 358 patients with GIST previously treated with imatinib. Patients will be randomized 1:1 to either 150 mg of ripretinib QD or 50 mg of sunitinib QD for four weeks followed by two weeks without sunitinib. The primary efficacy endpoint is PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST include ORR and OS. As of January 6, 2020, we had 106 sites open for enrollment in INTRIGUE. We expect to complete enrollment in INTRIGUE in the second half of 2020. As an event-driven study, the analysis of the primary endpoint for INTRIGUE will occur once a pre-specified number of events, defined as death or disease progression events based on independent radiologic review using modified RECIST, has occurred. We are planning to increase the total number of patients in the study to strengthen the ability to achieve the pre-specified number of events due to a recent trend of a higher than expected number of censored patients. Patient discontinuations that result in a patient being censored instead of counting toward the required number of total events can include discontinuations after local progression that has not been confirmed centrally, withdrawal of consent and a randomized patient that does not ever receive treatment. An increase in the total number of patients would require a protocol amendment and the currently anticipated increase is not expected to change the total number of required events, the statistical powering of the study, or our current guidance of achieving full enrollment in the second half of 2020.

Ongoing Phase 1 Expansion Trial of Ripretinib in GIST and Other Solid Tumors

We have an ongoing Phase 1 trial studying ripretinib in patients with different stages of GIST following treatment with at least one systemic anticancer therapy, such as imatinib, as well as in patients with SM and other solid tumors driven by KIT or PDGFRα including gliomas, melanoma, NSCLC, germ cell cancer, penile cancer, and soft tissue sarcomas, as well as a cohort for GIST and other solid tumors with renal impairment. We completed the dose escalation stage of the Phase 1 trial, focused on evaluating the safety, tolerability, and maximum tolerated dose, or MTD, of ripretinib, and determined a Phase 2 dose. The primary objectives of the expansion stage of the Phase 1 trial are to further evaluate the safety and tolerability of ripretinib and to determine the antitumor activity of ripretinib in all diseases studied in the trial. The secondary objectives are to determine the PK profile of ripretinib and determine allele frequency of KIT and PDGFRα mutations in ctDNA and compare it with mutation allele frequency in GIST tumor tissue at baseline and in response to treatment of ripretinib. The safety endpoints of the expansion phase of the Phase 1 trial include dose reduction or discontinuation of study drug due to toxicity and adverse events. The endpoints for preliminary assessment of antitumor activity include ORR and disease control rate, or DCR, at 12 weeks. Other endpoints include PFS for all solid tumor patients.

The expansion stage may enroll up to 270 patients in 10 cohorts including three GIST cohorts, one for each of second/third-, fourth-, and fourth-line plus GIST, one for GIST or other solid tumor patients with renal impairment, one cohort for SM with other hematologic malignancies, and five cohorts for other KIT and PDGFRα-driven solid tumors, including another solid tumor cohort, and one for each of malignant gliomas, melanoma, NSCLC/germ cell/penile, and soft tissue sarcoma.

The starting dose for ripretinib in the expansion cohorts is the expansion dose of 150 mg QD that was determined during the dose escalation stage of the Phase 1 trial, except for the SM cohort, which is currently using 150 mg BID as the starting dose. Patients who have disease progression by specified indication response criteria in the expansion stage may escalate to the higher daily dose (150 mg BID) of ripretinib after completion of the second cycle. We expect to report data from one or more of these expansion cohorts in the second half of 2020.

AACR-NCI-EORTC Meeting 2019 Data Presentation on Phase 1 Study in GIST Patients at Starting Dose of 150 mg Daily and Additional Related Data

We presented updated preliminary results from our ongoing Phase 1 study of ripretinib in patients with second-line through fourth-line plus GIST at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, or the Triple Meeting 2019, in October 2019, and in related releases. These results included data from 142 GIST patients in the escalation and expansion phases of the study receiving 150 mg QD of ripretinib as the starting dose, which is the dose being administered in our INVICTUS and INTRIGUE registration-enabling studies, as of an August 10, 2019 data cutoff date. The table below includes local, investigator-assessed ORR by best response as determined by modified RECIST, median duration of response, median progression free survival, or mPFS, and mean treatment duration.

Line of Therapy	2nd Line (n=31)	3rd Line (n=28)	[3]4th Line (n=83)
ORR (confirmed responses only)(1)	19% (n=6)	14% (n=4)	7% (n=6)
Median Duration of Response	80 weeks	NE(2)	76 weeks
mPFS	46 weeks(4)	36 weeks(5)	24 weeks(6)
Mean Treatment Duration(3)	56 weeks	58 weeks	45 weeks

Ripretinib was generally well tolerated and the updated adverse events were consistent with previously presented Phase 1 data in patients with GIST. Grade 3 or 4 TEAEs in greater than 5% of patients were increase in lipase level (n=25; 18%), anemia (n=11; 8%), and abdominal pain (n=11; 8%). The most common TEAEs in greater than 10% of patients is shown in the table below.

Phase 1 Study: All Grade TEAEs, Regardless of Relatedness, in >10% of Patients with GIST Treated with Ripretinib 150 mg QD

Treatment Emergent Adverse Events	Grade 1/2, n (%) (n=142)	Grade 3/4, n (%) (n=142)	All grades, n (%) (n=142)
Alopecia	86 (60.6%)	0	86 (60.6%)
Fatigue	74 (52.1%)	4 (2.8%)	78 (54.9%)
Myalgia	68 (47.9%)	0	68 (47.9%)
Nausea	64 (45.1%)	2 (1.4%)	66 (46.5%)
Palmar-plantar erythrodysesthesia syndrome	62 (43.7%)	1 (0.7%)	63 (44.4%)
Constipation	57 (40.1%)	0	57 (40.1%)
Decreased appetite	46 (32.4%)	2 (1.4%)	48 (33.8%)
Diarrhea	44 (31.0%)	3 (2.1%)	47 (33.1%)
Muscle spasms	42 (29.6%)	0	42 (29.6%)
Abdominal pain	28 (19.7%)	11 (7.7%)	39 (27.5%)
Lipase increased	14 (9.9%)	25 (17.6%)	39 (27.5%)
Weight decreased	39 (27.5%)	0	39 (27.5%)
Vomiting	36 (25.4%)	1 (0.7%)	37 (26.1%)
Headache	35 (24.6%)	1 (0.7%)	36 (25.4%)

Arthralgia	32 (22.5%)	0	32 (22.5%)
Hypertension	25 (17.6%)	7 (4.9%)	32 (22.5%)
Dry skin	31 (21.8%)	0	31 (21.8%)
Anemia	19 (13.4%)	11 (7.7%)	30 (21.1%)
Back pain	27 (19.0%)	2 (1.4%)	29 (20.4%)
Dyspnea	25 (17.6%)	3 (2.1%)	28 (19.7%)
Cough	25 (17.6%)	0	25 (17.6%)
Dizziness	25 (17.6%)	0	25 (17.6%)
Rash	23 (16.2%)	0	23 (16.2%)
Actinic keratosis	22 (15.5%)	0	22 (15.5%)
Hypophosphatemia	15 (10.6%)	7 (4.9%)	22 (15.5%)
Seborrheic keratosis	22 (15.5%)	0	22 (15.5%)
Hypokalemia	15 (10.6%)	4 (2.8%)	19 (13.4%)
Rash maculo-papular	19 (13.4%)	0	19 (13.4%)
Blood bilirubin increased	14 (9.9%)	4 (2.8%)	18 (12.7%)
Pain in extremity	17 (12.0%)	1 (0.7%)	18 (12.7%)
Insomnia	17 (12.0%)	0	17 (12.0%)
Pruritus	17 (12.0%)	0	17 (12.0%)
Blood creatine phosphokinase increased	13 (9.2%)	3 (2.1%)	16 (11.3%)
Melanocytic nevus	16 (11.3%)	0	16 (11.3%)
Skin papilloma	16 (11.3%)	0	16 (11.3%)
Stomatitis	16 (11.3%)	0	16 (11.3%)
Urinary tract infection	14 (9.9%)	2 (1.4%)	16 (11.3%)
Peripheral sensory neuropathy	15 (10.6%)	0	15 (10.6%)

The Phase 1 data described above are based on investigator assessment of tumor response in a single arm study with a limited number of patients and may not be predictive of, or consistent with, the results of later trials.

DCC-3014: A Potent and Highly Selective Inhibitor of CSF1R

DCC-3014 is an investigational, orally administered, potent, and highly selective inhibitor of CSF1R, also known as FMS. CSF1R is a kinase that controls the survival and function of TAMs. DCC-3014 was designed to selectively bind to the CSF1R switch pocket. It has greater than 100-fold selectivity for CSF1R over the closely related kinases FLT3, KIT, PDGFRα, PDGFRß, and VEGFR2 and has an even greater selectivity for CSF1R over approximately 300 other human kinases that we tested.

We are currently studying DCC-3014 in a Phase 1 dose escalation study that includes patients with advanced malignancies as well as patients with TGCT. The Phase 1 dose escalation study is designed to determine a Phase 2 dose for an expansion study. During 2019, we announced positive, preliminary data from the ongoing Phase 1 dose escalation study with DCC-3014 in patients with advanced malignancies and preliminary data from three initial patients diagnosed with TGCT. To explore the potential of DCC-3014 in this target population, we intend to continue to enroll TGCT patients in the dose escalation study, and, in the second half of 2020, provide a data update on TGCT patients. Subject to favorable results from the dose escalation study, in the second half of 2020 we intend to determine a Phase 2 dose for, and initiate an expansion study, including in patients with TGCT. We will also continue to evaluate the potential to study DCC-3014 in advanced malignancies in combination with I/O therapies.

Market Opportunity in Tenosynovial Giant Cell Tumor (TGCT)

TGCTs are a group of benign tumors that involve the synovium, bursae and/or tendon sheath. Although benign, these tumors can grow and cause damage to surrounding tissues and structures inducing pain, swelling, and limitation of movement of the joint. Surgery is the main treatment option; however, these tumors tend to recur. If untreated, or if the tumor continually recurs, damage and degeneration may occur in the affected joint and surrounding tissues, which may cause significant disability. A genetic mutation in certain cells within the tumor causes overproduction of CSF-1, the ligand for the CSF1R receptor, which attracts macrophages and certain other cells that become the bulk of these tumors and cause the associated inflammatory changes.

TGCTs are divided into types based on where they are and how quickly they grow. Localized TGCT grows slowly and starts in smaller joints like the fingers, toes, knee, wrist, and ankle. In 2017, annual incidence of new localized TGCT cases in the U.S. is estimated to be approximately 13,000. Diffuse TGCT grows quickly and most commonly affects the knee, as well as the hip, ankle, elbow, and shoulder. In 2017, annual incidence of new diffuse TGCT cases in the U.S. is estimated to be approximately 1,300. The current standard of care for TGCT is surgical resection, with high recurrence rates for diffuse-TGCT following complete resection.

CSF1R inhibition has demonstrated clinical benefit in diffuse TGCT patients and we believe that despite an approved treatment for diffuse TGCT patients in the U.S., there remains an unmet medical need for this population. In a randomized Phase 3 trial, pexidartinib, a CSF1R inhibitor approved by the FDA in August 2019 for the treatment of symptomatic TGCT, demonstrated the proportion of patients who achieved ORR was higher for pexidartinib, at 38%, versus placebo, at 0%, at week 25 by RECIST, version 1.1. The FDA approval includes a Risk Evaluation and Mitigation Strategy, or REMS, for pexidartinib, including intensive monitoring, due to off-target hepatotoxicity concerns.

Ongoing Phase 1 Dose Escalation Study and Proposed Phase 2 Expansion Study of DCC-3014, including in Patients with Diffuse-Type TGCT

The Phase 1 dose escalation study is a single arm study of DCC-3014 that is designed to evaluate the safety, PK, and pharmacodynamics, or PD, and antitumor activity of multiple doses of DCC-3014 in up to 55 patients with advanced malignancies, including TGCT. The ongoing dose escalation study will determine the Phase 2 dose and the MTD using a 3+3 dose escalation design with a minimum of three patients enrolled at each dose level cohort, starting at a dose of 10 mg once daily. Loading doses administered in the second level cohort and subsequent cohorts were based on PK profiles observed in the first cohort. Subject to favorable results from the dose escalation study, we intend in the second half of 2020 to select a Phase 2 dose and initiate a Phase 2 expansion study. The Phase 2 study will be designed to evaluate the safety, tolerability, preliminary antitumor activity, PK, and PD of DCC-3014 in various cohorts including diffuse-type TGCT.

In October 2019, at the Triple Meeting 2019, we announced positive, preliminary, updated top-line data from the ongoing dose escalation Phase 1 study with DCC-3014 in patients with advanced malignancies. We also announced preliminary initial data from three diffuse-type TGCT patients enrolled in the dose escalation study in November 2019 at the Connective Tissue Oncology Society 2019 Annual Meeting, or CTOS 2019. Preliminary results from the ongoing dose escalation Phase 1 study, including the three initial patients with TGCT, are summarized below.

Safety, PK, and PD data were analyzed as of September 10, 2019, with additional anti-tumor activity data reported as of November 8, 2019. Tumor reductions from baseline were determined by investigator assessment by modified RECIST. As of the data cut-off date of September 10, 2019, increasing doses of DCC-3014 were assessed in seven dose cohorts across 39 patients with advanced solid tumor tumors, including three patients with diffuse-type TGCT. This included one dose cohort that received 10 mg QD and six dose cohorts that received a three to five day loading dose regimen at doses of up to 50 mg followed by a schedule of daily, once-weekly or twice-weekly, maintenance dosing with DCC-3014.

DCC-3014 was generally well-tolerated, and among TEAEs occurring in greater than or equal to 10% of patients, regardless of relatedness, most events were grade 1 or 2. Grade 3 or 4 related TEAEs occurred in four patients, which were grade 3 aspartate aminotransferase, or AST, increase, grade 4 lipase increased, grade 3 amylase increased, and grade 3 colitis; no grade 3 or 4 TEAEs occurred in the diffuse-type TGCT patients. Serious adverse events, or SAEs, were reported in 17 malignant solid tumor patients, none of which were related to DCC-3014 and there were no SAEs reported in diffuse-type TGCT patients. The most common TEAEs in greater than 10% of patients is shown in the table below.

Phase 1 Study of DCC-3014: Common (≥10%)
TEAEs Regardless of Relatedness

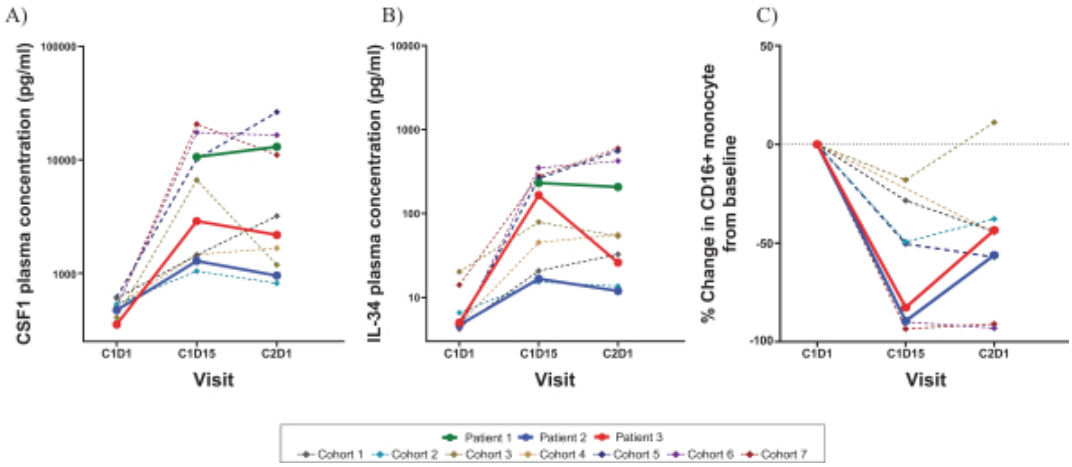
Treatment Related Adverse Events	Advanced solid tumor total n = 36		Diffuse-type TGCT n = 3		Total (All patients) n = 39	
	All	*≥G3*	*All*	*≥G3*	*All*	*≥G3*
Constipation	13 (36.1%)	0	1 (33.3%)	0	14 (35.9%)	0
Vomiting	12 (33.3%)	2 (5.6%)	1 (33.3%)	0	13 (33.3%)	2 (5.1%)
Diarrhea	10 (27.8%)	0	1 (33.3%)	0	11 (28.2%)	0
Nausea	10 (27.8%)	0	1 (33.3%)	0	11 (28.2%)	0
Fatigue	8 (22.2%)	2 (5.6%)	2 (66.7%)	0	10 (25.6%)	2 (5.1%)
Decreased appetite	9 (25%)	1 (2.8%)	0	0	9 (23.1%)	1 (2.6%)
Dyspnea	8 (22.2%)	0	1 (33.3%)	0	9 (23.1%)	0
Abdominal pain	7 (19.4%)	3 (8.3%)	1 (33.3%)	0	8 (20.5%)	3 (7.7%)
AST increased	5 (13.9%)	1 (2.8%)[a]	3 (100%)	0	8 (20.5%)	1 (2.6%)
Dehydration	7 (19.4%)	0	0	0	7 (17.9%)	0
Pyrexia	6 (16.7%)	0	1 (33.3%)	0	7 (17.9%)	0
Arthralgia	5 (13.9%)	1 (2.8%)	1 (33.3%)	0	6 (15.4%)	1 (2.6%)
Back pain	5 (13.9%)	0	1 (33.3%)	0	6 (15.4%)	0
Blood CPK increase	4 (11.1%)	0	2 (66.7%)	0	6 (15.4%)	0
Anemia	5 (13.9%)	1 (2.8%)	0	0	5 (12.8%)	1 (2.6%)
Asthenia	5 (13.9%)	0	0	0	5 (12.8%)	0
Cough	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Headache	3 (8.3%)	1 (2.8%)	2 (66.7%)	0	5 (12.8%)	1 (2.6%)
Pain in extremity	5 (13.9%)	0	0	0	5 (12.8%)	0
Periorbital edema	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Urinary tract infection	4 (11.1%)	0	1 (33.3%)	0	5 (12.8%)	0
Abdominal distension	4 (11.1%)	0	0	0	4 (10.3%)	0
Depression	4 (11.1%)	0	0	0	4 (10.3%)	0
Dyspepsia	4 (11.1%)	0	0	0	4 (10.3%)	0
Hypokalemia	4 (11.1%)	1 (2.8%)	0	0	4 (10.3%)	1 (2.6%)
Insomnia	4 (11.1%)	0	0	0	4 (10.3%)	0
Edema peripheral	4 (11.1%)	0	0	0	4 (10.3%)	0
Pain	3 (8.3%)	2 (5.6%)	1 (33.3%)	0	4 (10.3%)	2 (5.1%)

Key:

[a] Grade 2 by the central laboratory assessment.
AST, aspartate aminotransferase; CPK, creatine phosphokinase; G, grade.

Data from the Phase 1 trial also demonstrated approximately dose-proportional exposure for DCC-3014 and exposure was generally consistent between diffuse-type TGCT and solid tumor patients. As depicted in the graphs below, DCC-3014 treatment in this study demonstrated on-target PD inhibition of CSF1R by causing a dose-related rise in plasma CSF1 and IL-34 and a reduction of CD16+ monocytes in peripheral blood as well as decreases in CD163+ macrophages in tumor.

Phase 1 Study in DCC-3014: Pharmacodynamic Changes in Levels of Circulating A) CSF1 and B) IL-34 in Plasma and C) Changes in Levels of Whole Blood CD16+ Monocytes

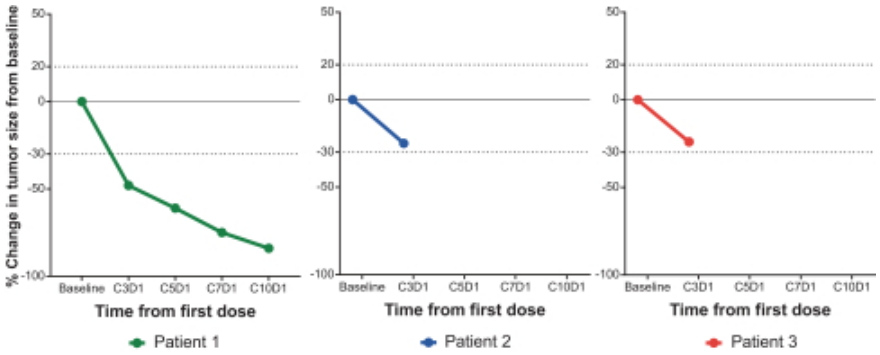


Key:

A and B: Levels of CSF1 and IL-34 in plasma were determined by standard ELISA. Plasma samples were collected from patients on Cycle 1 Day 1, Cycle 1 Day 15, and Cycle 2 Day 1. C: Levels of CD16+ monocytes were assessed by flow cytometry. Whole blood samples were collected from patients on Cycle 1 Day 1, Cycle 1 Day 15, and Cycle 2 Day 1.
C, cycle; CSF1, colony stimulating factor 1; D, day; IL-34, interleukin 34.

All three patients with diffuse-type TGCT treated as of the data analyses dates showed preliminary anti-tumor activity, as depicted in the graph below. As of their first tumor assessment at Cycle 3 Day 1, tumor reductions from baseline of 48%, 25% and 24%, respectively, were observed. One patient had a confirmed partial response, which had been sustained for nine months and was ongoing as of the most recent investigator report (as of the November 2019 analyses date), with a tumor reduction from baseline of 84% as of Cycle 10 Day 1. Symptomatic improvements in mobility and reduced pain, as reported by the investigator, were observed. These patients were enrolled in cohort 5, 30 mg loading dose daily for five days followed by a maintenance dose of 30 mg twice a week. Two patients remained on study as of the November 2019 data analyses date. One patient discontinued in Cycle 4 due to relocation outside of the U.S.

Phase 1 Study of DCC-3014: Three Initial Patients with Diffuse-Type TGCT
Changes from Baseline in Tumor Size Assessed per RECIST, version 1.1



Key:

—Dashed lines denote 30% decrease and 20% increase in tumor size threshold for partial response and progressive disease, respectively, per RECIST version 1.1.
—C, cycle; D, day; RECIST, response evaluation criteria in solid tumors.

The Phase 1 data described above are based on investigator assessment of tumor response and symptomatic improvements for TGCT patients were based on descriptive notes obtained from investigators. This data set is in a very small number of patients, including without limitation, only three diffuse-type TGCT patients, and may not be predictive of, or consistent with, the complete, additional or final results of this study or later studies.

Rebastinib: A Potent and Selective TIE2 Inhibitor

Rebastinib is an investigational, orally administered, potent, and selective inhibitor of the TIE2 immunokinase, the receptor for angiopoietins, an important family of vascular growth factors. Rebastinib binds potently into the switch pocket of TIE2, stabilizing the inhibitory switch and displacing the activation switch to block TIE2 signaling. TIE2 has an important role in regulating tumor angiogenesis, invasiveness, metastasis, and immunotolerance in a manner analogous to CSF1R. Whereas CSF1R is expressed on TAMs in certain cancers, there is a different and distinct population of pro-tumoral M2 macrophages in which TIE2 is active, known as TIE2 expressing macrophages, or TEMs.

Ongoing Phase 1b/2 Studies of Rebastinib in Combination with Chemotherapy

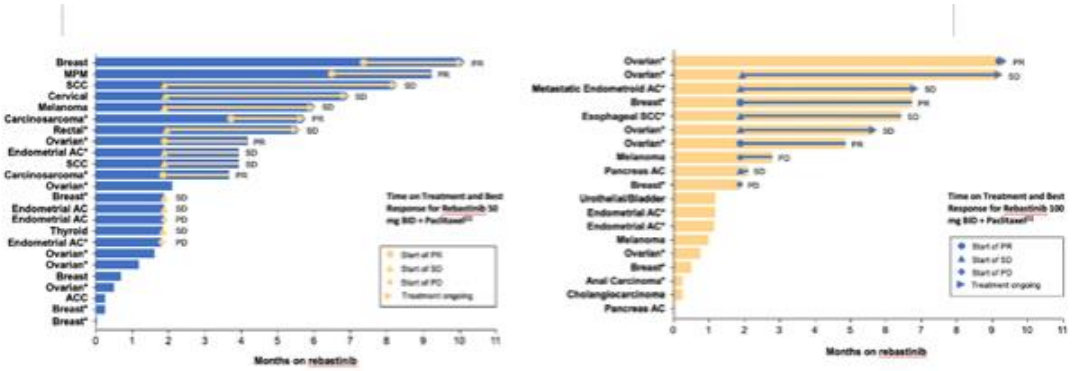
Rebastinib is currently in clinical development for the treatment of multiple solid tumors in combination with chemotherapy in two Phase 1b/2 studies.

In October 2018, we announced that we initiated an open-label, multicenter, two-part Phase 1b/2 study of rebastinib in combination with paclitaxel to assess safety, tolerability, PK, and efficacy in patients with advanced or metastatic solid tumors. Part 1 of this study was designed to evaluate the safety, tolerability, and PK of 50 mg and 100 mg rebastinib BID when administered in combination with paclitaxel, and to determine the Phase 2 dose of rebastinib in combination with paclitaxel, in patients with advanced or metastatic solid tumors that are refractory to standard therapies. In Part 2 of this study, the safety, tolerability, and efficacy of the Phase 2 dose of rebastinib in combination with weekly paclitaxel is being assessed across multiple cohorts, including: breast, ovarian, and endometrial cancers. This study enrolled 43 evaluable patients in Part 1 and will enroll up to 132 evaluable patients in Part 2. At the Triple Meeting 2019, we presented preliminary data from 43 patients from Part 1 of the study, including 24 patients from the rebastinib 50 mg oral BID with paclitaxel 80 mg/m^2 IV cohort and 19 patients from the rebastinib 100 mg oral BID with paclitaxel 80 mg/m^2 IV cohort.

Rebastinib in combination with paclitaxel was generally well-tolerated, with similar frequency of TEAEs between the two dose cohorts, and most TEAEs were consistent with the first-in-human study of rebastinib, or known to be associated with treatment with paclitaxel. One patient experienced a rebastinib-related SAE (grade 2 muscular weakness), and four patients had an SAE related to paclitaxel and rebastinib (five events including grade 3 pneumonia (n=2), grade 3 nausea (n=1), grade 3 vomiting (n=1), and grade 2 myocardial ischemia (n=1)). Based on the observed frequency of muscular weakness in preliminary data from the ongoing Part 2 portion of the study with the 100 mg BID dose, the Phase 2 dose was changed from 100 mg BID to 50 mg BID.

Preliminary results from Part 1 included encouraging early signals of anti-tumor activity observed in both dose cohorts, with objective responses seen across a heavily pre-treated patient population, including patients with prior exposure to paclitaxel. Objective responses were seen in eight patients including ovarian (3), breast (2), carcinosarcoma (2), and peritoneal mesothelioma (1), seven of whom had prior therapy with paclitaxel or docetaxel. A best response of partial response was observed in 5 of 24 patients in the 50 mg BID dose cohort and 3 of 19 patients in the 100 mg BID dose. The charts below illustrate the time on treatment and best response in both dose cohorts for Part 1 of the study.

Phase 1b/2 Study of Rebastinib in Combination with Paclitaxel: Part 1:
Time on Treatment and Best Response for Rebastinib 50 and 100 mg BID + Paclitaxel



Notes: Data presented at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2019; AC=adenocarcinoma; ACC=adrenocortical carcinoma; MPM=malignant peritoneal mesothelioma; PD=progressive disease; PR=partial response; SCC=squamous cell carcinoma; SD=stable disease; (1) Tumor responses were evaluated by the investigator according to Response Evaluation Criteria in Solid Tumors 1.1 criteria; as per study protocol, includes confirmed and unconfirmed responses; *prior paclitaxel therapy; †patient did not receive prior paclitaxel, but did receive prior docetaxel.

Exposure to rebastinib in this study was dose-proportional at the 50 mg BID and 100 mg BID doses when administered in combination with paclitaxel. Mean circulating angiopoietin-2 levels increased with exposure to higher doses of rebastinib in combination with paclitaxel.

Part 2 of the study is ongoing. We expect to report Phase 1b/2 data with rebastinib in combination with paclitaxel in the second half of 2020.

In January 2019, we announced that we initiated an open-label, multicenter, Phase 1b/2 study of rebastinib in combination with carboplatin in patients with advanced or metastatic solid tumors. Part 1 (3+3 dose escalation) of this two-part study is designed to evaluate the safety, tolerability, and PK of 50 mg and 100 mg rebastinib BID when administered in combination with carboplatin, and to determine the Phase 2 dose of rebastinib in combination with carboplatin, in patients with advanced or metastatic solid tumors that are refractory to standard therapies. In Part 2, the safety, tolerability, and efficacy of the Phase 2 dose of rebastinib in combination with carboplatin administered once every three weeks will be assessed across multiple disease cohorts, including: breast cancer, ovarian cancer, and mesothelioma. This study is expected to enroll up to 117 patients in total, with approximately 18 patients in Part 1 and up to 99 patients in Part 2. We have completed Part 1, selected a Phase 2 dose of 100 mg BID of rebastinib and activated Part 2 of the Phase 1b/2 study of rebastinib in combination with carboplatin. We expect to report Phase 1b/2 data with rebastinib in combination with carboplatin in the second half of 2020.

Employees

We have operated by leveraging skilled experts, consultants, contract research organizations, and contractors to manage our clinical operations, under the leadership and direction of our management. We will expand our infrastructure to manage our operations, including commercial, with additional full-time employees.

As of January 31, 2020, we had 249 full-time employees and 3 part-time employees, 76 of whom hold Ph.D. or M.D. degrees. Of our full-time employees, 36 were engaged in research and development activities and 56 were engaged in general and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding our expectations regarding our goal of bringing ripretinib to patients with advanced GIST, the potential for ripretinib to serve as an important new treatment option for people with advanced GIST, working with the FDA through its review of our NDA application via the FDA's Real-Time Oncology Review pilot program, working with the FDA, Health Canada and the Therapeutic Goods Administration on our Canadian and Australian regulatory approval filings under the Project Orbis pilot program, and the possible benefits of those pilot programs and breakthrough therapy designation, receipt of priority review, preparing for the potential launch of ripretinib in the United States, if approved, and corporate guidance for 2020, including related to our expectations and timing for an MAA submission to the EMA for ripretinib in advanced GIST patients, presentation of additional Phase 1 ripretinib expansion data, completion of enrollment in the INTRIGUE Phase 3 study, the potential to increase enrollment in INTRIGUE, selection of a Phase 2 dose for DCC-3014 and opening an expansion study in such trial in various cohorts including diffuse-type TGCT, the timing of and our expectations regarding our product candidates, including data for DCC-3014 from TGCT patients, data updates for rebastinib, submitting an IND for DCC-3116 and our cash position at December 31, 2019. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this Form 8-K are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Form 8-K, including, without limitation, risks and uncertainties related to the delay of any current or planned clinical studies or the development of our product candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and clinical results for our product candidates, which may not support further development of such product candidates, the possibility that

results experienced in early, preliminary, top-line or initial data may not be indicative of the results experienced in final data, our ability to work with the FDA under its RTOR pilot program and our ability to work with the FDA, Health Canada and the TGA under the Project Orbis pilot program and timely respond to information requests or requirements in connection with our recently-filed NDAs and marketing approval applications in Canada and Australia for ripretinib in advanced GIST, that acceptance into the RTOR and Project Orbis pilot programs does not guarantee or influence approvability of our NDAs for ripretinib in advanced GIST, which are subject to the standard benefit-risk evaluation by FDA, and the review standards of Health Canada and the TGA, and that we may not derive any benefit from inclusion in the RTOR or Orbis pilot programs, including, but not limited to, a more efficient review process compared to investigational drugs evaluated without these pilot programs or under standard FDA, Health Canada or TGA procedures, the fact that these pilot programs are being tested by FDA, are not formal regulatory pathways with regulatory process, regulations or procedures, and may be changed, suspended or halted at any time, including, without limitation, because FDA decides not to continue these pilots, or because FDA determines that our application no longer meets its criteria for inclusion in one or both of these pilot programs, the fact that receipt of a breakthrough therapy designation for a product candidate, such as ripretinib, may not result in us receiving any of the benefits of such designation such as a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, the fact such designation does not assure ultimate approval by FDA and is subject to the risk FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened, the fact that any priority review received may not result in any more efficient review or other benefits, our ability to manage and our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, actions of regulatory agencies, our ability to plan for potential commercialization of our product candidates, such as ripretinib, and if approved execute on our marketing plans, the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain regulatory approval, if at all, and make our investigational drugs, including ripretinib, available to patients, and, once commercial, to derive revenue from product sales, and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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: February 12, 2020

DECIPHERA PHARMACEUTICALS, INC.

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