# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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

Date of Report (Date of Earliest Event Reported): September 10, 2022

# Deciphera Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

	Delaware (State or other jurisdiction of incorporation)	001-38219 (Commission File Number)	30-1003521 (IRS Employer Identification No.)			
200 Smith Street, Waltham, Massachusett (Address of principal executive offices)		tts	02451 (Zip code)			
	Registrant's telep	phone number, including area code: (781)	209-6400			
	(Former n	name or former address, if changed from last report	(;)			
	ck the appropriate box below if the Form 8-K filing is awing provisions:	intended to simultaneously satisfy the filing	s obligation of the registrant under any of the			
	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))					
Secu	urities registered pursuant to Section 12(b) of the Exchange	ange Act:				
	Title of each class	Trading Symbol	Name of exchange on which registered			
	Common Stock, \$0.01 Par Value	<b>DCPH</b>	Nasdaq Global Select Market			
	cate by check mark whether the registrant is an emergi ster) or Rule 12b-2 of the Securities Exchange Act of 1		of the Securities Act of 1933 (§230.405 of this			
Eme	rging 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 7.01 Regulation FD Disclosure.

On September 10, 2022, Deciphera Pharmaceuticals, Inc. (the "Company") issued a press release announcing the presentation of initial clinical study results from the ongoing single agent dose escalation portion of the Company's Phase 1 study of DCC-3116, the Company's investigational inhibitor of ULK1/2, in patients with advanced or metastatic tumors with a mutant RAS or RAF gene, as an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the DCC-3116 presentation at the ESMO Congress 2022 is posted on the Investors and News portion of the Company's website (www.deciphera.com) under "Events and Presentations".

On September 11, 2022, the Company issued a press release announcing the presentation of new clinical study results from the Phase 1 and Phase 2 portions of the Company's ongoing study of vimseltinib, the Company's investigational inhibitor of CSF1R, in patients with tenosynovial giant cell tumor not amenable to surgery, as two separate posters at the ESMO Congress 2022. A copy of the press release is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. Copies of the Phase 1 and Phase 2 posters from the ESMO Congress 2022 are posted on the Investors and News portion of the Company's website (www.deciphera.com) under "Events and Presentations".

The information in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

# Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

- 99.1 Press Release issued by Deciphera Pharmaceuticals, Inc. on September 10, 2022
- 99.2 Press Release issued by Deciphera Pharmaceuticals, Inc. on September 11, 2022
- 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: September 12, 2022

# DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Jeffrey M. Held
Name: Jeffrey M. Held
Title: General Counsel



# Deciphera Pharmaceuticals, Inc. Presents Initial Phase 1 Single Agent Dose Escalation Data for First-in- Class ULK Inhibitor of Autophagy, DCC-3116, at the European Society for Medical Oncology (ESMO) Congress 2022

- DCC-3116 Was Well-tolerated with No Dose Limiting Toxicities or Treatment-Related Serious Adverse Events Observed -
- Pharmacokinetic and Pharmacodynamic Data Across all Doses Levels Demonstrated Exposure and ULK 1/2 Inhibition Associated with Anti-cancer
   Efficacy in Preclinical Studies –
- Selection of Starting Dose and Initiation of Combination Dose Escalation Cohorts with MEK and KRASG12C Inhibitors Expected in Fourth Quarter
   2022
  - Company to Host Virtual Investor Event Sunday, September 11 at 7:30 AM ET/1:30 PM CEST -

WALTHAM, Mass. – September 10, 2022 – Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced positive initial data from the single agent dose escalation portion of the Phase 1 study of DCC-3116, the Company's first-in-class, potent, and selective small molecule switch-control kinase inhibitor of ULK1/2, in patients with advanced or metastatic tumors with a mutant RAS or RAF gene. Results from the study were presented in an oral presentation as a Proffered Paper titled "Initial monotherapy results of a phase 1 first-in-human study of ULK1/2 inhibitor DCC-3116 alone and in combination with MAPK pathway inhibition" at the ESMO Congress 2022.

"We are excited to report first-in-human DCC-3116 clinical data demonstrating a favorable tolerability profile and pharmacokinetics, and strong target inhibition across all dose levels tested," said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. "As the first ULK1/2 inhibitor to enter clinical development, these positive initial results represent a significant milestone as we prepare to initiate combination dose escalation later this year. With a novel mechanism of action and strong preclinical data demonstrating compelling anti-tumor activity in combination with a broad array of RTK, RAS, and other MAP kinase pathway inhibitors, we believe DCC-3116 has the potential to open a new frontier in the treatment of cancer."

Anthony Tolcher, M.D., FRCPC, Co-Founder and Director of Clinical Research, NEXT Oncology said, "The initial DCC-3116 monotherapy results reported today are very encouraging and strongly support the advancement of DCC-3116 into the combination setting. The preliminary data show DCC-3116 to be a very well-tolerated agent that has demonstrated strong target inhibition of ULK 1/2 from even the lowest tested dose. I look forward to the selection of the combination starting dose and advancing the program into the first combination studies with MEK and KRASG12C inhibitors."

#### **Summary of Data and Findings**

As of June 9, 2022, 18 patients with locally advanced or metastatic cancer with a RAF or RAS mutation were enrolled across four cohorts dosed with DCC-3116 twice daily (BID): 50 mg BID (n=3); 100 mg BID



(n=4); 200 mg BID (n=7); and 300 mg BID (n=4). The median number of prior anti-cancer regimens was three (range 1-10). The most common cancer types were colorectal (56%) and pancreatic (28%) and patients had KRAS (83%) and BRAF (17%) mutations.

The results of the primary objectives of safety and tolerability as well as the additional objectives of pharmacokinetics, pharmacodynamics, and antitumor activity are summarized below:

Safety and Tolerability:

- Treatment with DCC-3116 was well tolerated and most treatment-emergent adverse events (TEAEs) were Grade 1/2; the most common (≥15%) TEAEs regardless of relatedness reported (all grades) were: fatigue (39%), dehydration (22%), alanine transaminase (ALT) increases (17%), anemia (17%), aspartate transaminase (AST) increases (17%), decreased appetite (17%), hyponatremia (17%), nausea (17%), and vomiting (17%).
- No dose-limiting toxicities or treatment-related serious adverse events were observed with DCC- 3116; two asymptomatic, reversible Grade 3 alanine transaminase increases that led to dose interruption and reduction were reported as treatment-related.

Pharmacokinetics, Pharmacodynamics and Anti-Tumor Activity:

- DCC-3116 exposure appeared to increase dose-proportionally across the four dose levels tested from 50 mg BID to 300 mg BID; at all
  doses levels, the area under the curve (AUC) of DCC-3116 was at or above the AUC of the lowest tested dose that was effective in
  preclinical studies.
- DCC-3116 demonstrated target inhibition with significant decreases in phosphorylation of ATG14, a direct ULK1/2 substrate, in peripheral blood mononuclear cells; at all dose levels, reductions in phosphorylated ATG14 were observed that were associated with anti-tumor activity in preclinical studies combining DCC-3116 and a MEK inhibitor as measured by reductions in phosphorylated ATG13 in tumors.
- Fourteen patients were evaluable for response per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 as of the cutoff date; best overall response was stable disease and the disease control rate at week 16 was 29%.

Dose cohorts 100 to 300 mg BID are being expanded to further characterize the safety, pharmacokinetics, and pharmacodynamics of DCC-3116. In the fourth quarter of 2022, we expect to select the starting dose of DCC-3116 for, and initiate, dose escalation cohorts in combination with MEK and KRASG12C inhibitors.

#### Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss data presentations from the Company's DCC-3116 and vimseltinib clinical programs at the ESMO Congress 2022 on Sunday, September 11, 2022, at 7:30 AM ET/ 1:30 PM CEST. The event may be accessed by registering at https://deciphera-pharmaceuticals.open-exchange.net/registration. A webcast of the event will be available in the "Events and Presentations" page in the "Investors" section of the Company's website at https://investors.deciphera.com/events-presentations. The archived webcast will be available on the Company's website within 24 hours after the event and will be available for 30 days following the event.

**About DCC-3116** 



DCC-3116 is an investigational, orally administered, potent, and highly selective switch-control inhibitor designed to inhibit cancer autophagy, a key tumor survival mechanism in cancer cells, by inhibiting the ULK1/2 kinases, which have been shown to be the enzymes responsible for initiating autophagy. DCC-3116 is currently being studied in a Phase 1/2, multicenter, open-label, first-in-human study as a single agent and in combination with RAS/MAPK pathway inhibitors in patients with advanced or metastatic solid tumors with a RAS/MAPK pathway mutation (NCT04892017).

#### **About Deciphera Pharmaceuticals**

Deciphera is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, QINLOCK® is Deciphera's switch control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@Deciphera).

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations and timing regarding the potential for DCC-3116 to be a first-in-class treatment that opens a new frontier in the treatment of cancer, and the selection of a starting dose for DCC-3116 for and the initiation of combination dose escalation cohorts with MEK and KRAS G12C inhibitors in the Phase 1 study of DCC-3116. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forwardlooking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release 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 press release, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, comments, feedback and actions of regulatory agencies, our ability to commercialize OINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, the inherent uncertainty in estimates of patient populations, 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 and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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.



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# Deciphera Pharmaceuticals, Inc. Presents Updated Phase 1/2 Data for Vimseltinib in TGCT at the European Society for Medical Oncology (ESMO) Congress 2022

- Updated Results for Vimseltinib Showed Objective Response Rate of 69% in Phase 1, 53% in Phase 2 Cohort A, and 46% in Phase 2 Cohort B;
   Demonstrated a Clinical Benefit Rate of 100% Across All Phase 1/2 Patients
  - Preliminary Patient-Reported Outcome Data in Phase 2 Demonstrate Clinically Meaningful Improvements in Pain and Stiffness -
    - Updated Safety and Efficacy Data Support Ongoing Phase 3 MOTION Study -
    - Company to Host Virtual Investor Event Sunday, September 11 at 7:30 AM ET/ 1:30 PM CEST -

WALTHAM, Mass. – September 11, 2022 – Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced updated results from the ongoing Phase 1/2 study of vimseltinib, an orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R, for the treatment of patients with tenosynovial giant cell tumor (TGCT) not amenable to surgery. Results from the Phase 1 and Phase 2 portions of the study are being presented as separate posters, titled "Efficacy and safety of vimseltinib in tenosynovial giant cell tumour (TGCT): Phase 2 expansion" and "Safety and efficacy of vimseltinib in tenosynovial giant cell tumour (TGCT): Long-term phase 1 update" at the ESMO Congress 2022 on September 11 and September 12, respectively.

"The updated data presented at ESMO underscore the best-in-class potential of vimseltinib for patients with TGCT. Additionally, preliminary patient-reported outcome results found a clinically meaningful symptomatic benefit at week 25 compared with baseline for both pain and stiffness, highlighting the important impact that vimseltinib can have on a patient's quality of life," said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. "These results support vimseltinib's evaluation in the Phase 3 MOTION study, a two-part, randomized, double-blind, placebo-controlled study, which is currently enrolling patients. We believe vimseltinib has the potential to become a best-in-class therapy for TGCT patients who are not amenable to surgery."

Jean-Yves Blay, M.D., Ph.D., General Director of the Centre Léon Bérard Lyon said, "There remains a substantial unmet medical need for a highly effective and well-tolerated drug for patients with TGCT whose disease is not amenable to surgery. These updated Phase 1/2 data demonstrate not only the strong clinical activity of vimseltinib, but also the favorable safety and tolerability profile that is essential for TGCT patients. Vimseltinib has the potential to address this unmet need and offer a new option for patients around the world."

# Summary of Data and Findings from Phase 1/2 Studies

Results from the Phase 2 portion of the study are being presented today in a poster presentation, summarized below. Updated results from the Phase 1 study are being presented in a poster presentation



tomorrow, Monday, September 12. The Phase 1 data summarized below are based on the previously released abstract with a data cutoff date of February 18, 2022. The Phase 1 poster presentation remains under embargo until tomorrow and will include updated data based on a May 6, 2022 data cutoff date.

## Safety and Efficacy of Vimseltinib in Tenosynovial Giant Cell Tumour (TGCT): Long-term Phase 1 Update

The Phase 1/2 study of vimseltinib is an open-label, multicenter study evaluating the safety, efficacy, pharmacokinetics, and pharmacodynamics of vimseltinib in patients with solid tumors and TGCT. The data presented from the Phase 1 update include long-term safety and efficacy for patients with TGCT from the dose escalation portion of the study.

#### Dose Cohorts and Demographics

- As of the February 18, 2022 cutoff date, 32 patients were enrolled in three dose cohorts:
  - Phase 1 Cohort 5 (n=8): 30 mg loading dose daily for five days followed by a maintenance dose of 30 mg twice a week.
  - Phase 1 Cohort 8 (n=12): 30 mg loading dose daily for three days followed by a maintenance dose of 10 mg daily.
  - Phase 1 Cohort 9 (n=12): 20 mg loading dose daily for three days followed by a maintenance dose of 6 mg daily.
- 32 patients were evaluable for efficacy by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 at the data cutoff; response data is based on independent radiological review (IRR) except for one patient that did not have an IRR.

#### Antitumor Activity and Treatment Duration

- Clinical Benefit Rate: 100% of patients demonstrated clinical benefit, defined as patients with complete response, partial response, or stable disease, without disease progression.
- Objective Response Rate: 69% ORR (CR=1, PR=21).
  - Most responses were achieved within six months.
- Treatment Duration: The median duration of treatment was 16.4 months with 59% of patients remaining on treatment as of the data cutoff date in February 2022.

#### Safety and Tolerability

- Treatment with vimseltinib was generally well-tolerated in patients with TGCT and consistent with previously disclosed data.
- Grade 3 or 4 treatment-emergent adverse events (TEAEs) (>5%) included increases in creatine phosphokinase, aspartate aminotransferase, lipase, amylase, and hypertension.
- Observed transaminase, lipase, amylase, and creatine phosphokinase enzyme elevations were mostly low grade, asymptomatic, and consistent with mechanism of action of CSF1R inhibitors.
- No postbaseline bilirubin elevations observed.
- There were no new treatment-related serious adverse events since the June 7, 2021 data cutoff date.

Safety and Efficacy of Vimseltinib in Tenosynovial Giant Cell Tumour (TGCT): Phase 2 Expansion



The data presented from the Phase 2 expansion portion of the ongoing Phase 1/2 study includes safety, efficacy, and preliminary patient-reported outcome data in patients with TGCT treated with vimseltinib at the recommended Phase 2 dose (RP2D; 30 mg twice weekly) enrolled in two cohorts. Cohort A includes TGCT patients with no prior anti-CSF1/CSF1R (previous therapy with imatinib or nilotinib is allowed) and Cohort B includes patients with prior anti-CSF1/CSF1R (previous therapy with only imatinib or nilotinib are not eligible).

#### Dose Cohorts and Demographics

- As of the May 6, 2022 cutoff date, 58 TGCT patients treated with vimseltinib were included in the safety population, including 46 patients enrolled in Cohort A and 12 patients enrolled in Cohort B.
- 56 patients were evaluable for efficacy by RECIST version 1.1 at the data cutoff in the Phase 2 across both cohorts; response data is based on independent radiological review.

#### Antitumor Activity, Treatment Duration, and Preliminary Patient-Reported Outcomes

- Clinical Benefit Rate: 100% of patients demonstrated clinical benefit, defined as patients with complete response, partial response, or stable disease, without disease progression.
- Objective Response Rate: 53% ORR (PR=24) in Cohort A and 46% ORR (CR=1, PR=4) in Cohort B.
  - In Cohort B, responses were observed in patients who had not achieved a response to prior anti-CSF1/CSF1R therapy.
  - Median duration of response was not reached in both cohorts.
  - 75% of responses and 80% of responses were achieved within six months in Cohorts A and B, respectively.
  - ORR at 25 weeks was 38% (PR=17) in Cohort A.
- Treatment Duration: The median duration of treatment was 9.8 months in Cohort A and 5.9 months in Cohort B. As of the data cutoff date, 61% of patients remained on treatment in Cohort A and 67% of patients remained on treatment in Cohort B.
- Preliminary Patient-reported Outcomes: Initial data demonstrate that patients achieved clinically meaningful symptomatic benefit as of week 25 by two measures of patient-reported outcomes.
  - Brief Pain Inventory (BPI): 48% (Cohort A) and 56% (Cohort B) of patients had a BPI worse pain response at week 25.
  - Worse Stiffness Numeric Rating Scale: Patients showed progressive improvements in stiffness from baseline to week 25, with mean changes from baseline of -2.0 (Cohort A) and -2.7 (Cohort B). Improvement observed is considered clinically meaningful change with a threshold for meaningful change is estimated to be 1.

#### Safety and Tolerability

- Treatment with vimseltinib was generally well-tolerated in patients with TGCT at the recommended Phase 2 dose of 30 mg twice weekly.
- Most non-laboratory TEAEs were Grade 2 or lower.
- The only Grade 3/4 TEAE observed in >5% of patients was elevated creatine phosphokinase.

## **Phase 3 MOTION Study**



The pivotal Phase 3 MOTION study of vimseltinib for the treatment of TGCT is ongoing. MOTION is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with TGCT who are not amenable to surgery. The primary endpoint of the study is objective response rate at week 25 as measured by RECIST version 1.1 by blinded independent radiologic review. https://www.clinicaltrials.gov/ct2/show/NCT05059262

#### **Conference Call and Webcast**

Deciphera will host a conference call and webcast to discuss data presentations from the Company's DCC-3116 and vimseltinib clinical programs at the ESMO Congress 2022 on Sunday, September 11, 2022, at 7:30 AM ET/ 1:30 PM CEST. The event may be accessed by registering at https://deciphera-pharmaceuticals.open-exchange.net/registration. A webcast of the event will be available in the "Events and Presentations" page in the "Investors" section of the Company's website at https://investors.deciphera.com/events-presentations. The archived webcast will be available on the Company's website within 24 hours after the event and will be available for 30 days following the event.

#### **About Vimseltinib**

Vimseltinib is an investigational, orally administered, potent and highly selective switch-control kinase inhibitor of CSF1R. It was discovered using Deciphera's proprietary drug discovery platform and was designed to selectively bind to the CSF1R switch pocket. Vimseltinib has demonstrated encouraging preliminary efficacy and safety data in patients with TGCT and is currently being evaluated in a Phase 1/2 clinical study. The Phase 3 MOTION study, a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with symptomatic TGCT who are not amenable to surgery, is currently enrolling.

#### **About Deciphera Pharmaceuticals**

Deciphera is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, QINLOCK® is Deciphera's switch control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@Deciphera).

#### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations and timing regarding the best-in-class potential of vimseltinib in TGCT patients not amenable to surgery, enrollment in the pivotal Phase 3 MOTION study of vimseltinib in TGCT patients, and presenting updated vimseltinib data from our Phase 1/2 study in TGCT patients at ESMO 2022. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "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 press release 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 press release, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, comments, feedback and actions of regulatory agencies, our ability to commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, the inherent uncertainty in estimates of patient populations, 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 and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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.

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