
**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 13, 2023

Aravive, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36361
(Commission
File Number)

26-4106690
(IRS Employer
Identification No.)

River Oaks Tower
3730 Kirby Drive, Suite 1200
Houston, Texas 77098
(Address of principal executive offices)

(936) 355-1910
(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 (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- 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(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ARAV	Nasdaq Global Select Market

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

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

On February 13, 2022, Aravive, Inc. (the “Company”) issued a press release announcing the presentation of updated results from its ongoing Phase 1b/2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place February 16-18, 2023 in San Francisco and virtually.

As of January 17, 2023, safety, pharmacokinetics (PK), and pharmacodynamics (PD), and clinical activity of 15 mg/kg and 20 mg/kg batiraxcept in combination with 60 mg cabozantinib were evaluated in 26 patients with 2L+ ccRCC. A summary of the results highlighted from the poster presentation include (as of January 17, 2023, the cut-off date):

- Batiraxcept in combination with 60 mg cabozantinib has a manageable safety profile in previously treated ccRCC; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- No dose limiting toxicities were observed at either dose of batiraxcept.
- A minimally efficacious concentration (MEC) of batiraxcept was determined to be > 12.2 mg/L, of which 19/26 patients achieved during Cycle 1, with no difference between 15 mg/kg and 20 mg/kg dose cohorts.
- 85% of patients (22/26) had a reduction in target lesions at the 8-week response assessment.
- 58% (15/26) of total population achieved a better response on batiraxcept plus cabozantinib than they did on prior therapy.
- Best overall response of partial response was observed in 42% (11/26) of the overall population, 57% (8/14) of the prior VEGF-TKI-treated group and 55% (11/20) of the biomarker high (sAXL/GAS6) group.
- 9-month progression free survival (PFS) rate was 65% in the overall population, 69% in the biomarker high group (n=20) and 75% in the prior VEGF-TKI, biomarker high group (n=11).
- Safety, PK/PD, and clinical activity results support a recommended Phase 2 dose of 15 mg/kg.

A copy of the poster titled “A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell (ccRCC) carcinoma” is filed as an exhibit to this Current Report on Form 8-K.

The information in this Item 7.01 and in the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release furnished as Exhibit 99.1 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are “forward-looking” rather than historical.

Item 8.01. Other Events.

The Company presented updated Phase 1b/2 ccRCC data at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place February 16-18, 2023 in San Francisco and virtually.

As of January 17, 2023, safety, pharmacokinetics (PK), and pharmacodynamics (PD), and clinical activity of 15 mg/kg and 20 mg/kg batiraxcept in combination with 60 mg cabozantinib were evaluated in 26 patients with 2L+ ccRCC. A summary of the results highlighted from the poster presentation include (as of January 17, 2023, the cut-off date):

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 - Safety, PK/PD, and clinical activity results support a recommended Phase 2 dose of 15 mg/kg.
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Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release of Aravive, Inc.
99.2	Poster titled “A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell (ccRCC) carcinoma”
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Date: February 13, 2023

ARAVIVE, INC.
(Registrant)

By: /s/ Gail McIntyre
Name: Gail McIntyre
Title: Chief Executive Officer



Aravive to Present Positive Updated Data from Phase 1b Trial of Batiraxcept in Combination with Cabozantinib for Treatment of Clear Cell Renal Cell Carcinoma at the 2023 ASCO Genitourinary (GU) Cancers Symposium

HOUSTON, TX, February 13, 2023 (GLOBE NEWSWIRE) - Aravive, Inc. (Nasdaq: ARAV, "the Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced the presentation of updated results from its ongoing Phase 1b/2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place February 16-18, 2023 in San Francisco and virtually. The poster presentation will highlight updated results from the Phase 1b portion of the trial in 26 patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of immuno-oncology (IO)- and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies.

"We are pleased at the opportunity to present updated results from our Phase 1b trial of batiraxcept in ccRCC patients at this year's ASCO GU meeting," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "Batiraxcept in combination with cabozantinib in ccRCC patients who have already received IO and VEGF-TKI treatment continues to yield highly encouraging results. Treatment is ongoing in the Phase 1b portion of the trial, and Phase 2 enrollment has been completed. We look forward to providing additional updates on this program throughout 2023."

"We continue to be encouraged by the safety and clinical activity observed in the Phase 1b trial of batiraxcept in patients with ccRCC," said Neil J. Shah, MBBS, Medical Oncologist, Memorial Sloan Kettering Cancer Center. "In addition to promising overall response rate and progression free survival data, baseline biomarker analysis may play a critical role in predicting response and will be further assessed throughout the Phase 2 and 3 trials. Importantly, the updated data continue to indicate the significant potential impact that dual AXL and VEGF inhibition by batiraxcept plus cabozantinib may have in patients who have failed prior VEGF-TKI treatments. Taken together, these findings remain promising and suggest that batiraxcept may serve as a much-needed treatment option for ccRCC patients on their second or later line of therapy."

Poster Presentation Details:

Title:	A phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC)
Abstract Number:	666
Presenter:	Neil Shah, MBBS
Session:	Poster Session C: Renal Cell Cancer; Adrenal, Penile, Urethral and Testicular Cancers
Date/Time:	Saturday, February 18, 2023; 7:00 AM – 8:00 AM; 12:30 PM – 2:00 PM PST
Location:	Level 1 West Hall, Moscone West, San Francisco, CA and Virtual

As of January 17, 2023, safety, pharmacokinetics (PK), and pharmacodynamics (PD), and clinical activity of 15 mg/kg and 20 mg/kg batiraxcept in combination with 60 mg cabozantinib were evaluated in 26 patients with 2L+ ccRCC. Results highlighted in the poster include:

- Batiraxcept in combination with 60 mg cabozantinib has a manageable safety profile in previously treated ccRCC; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
 - No dose limiting toxicities were observed at either dose of batiraxcept.
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- 58% (15/26) of total population achieved a better response on batiraxcept plus cabozantinib than they did on prior therapy.
- Best overall response of partial response was observed in 42% (11/26) of the overall population, 57% (8/14) of the prior VEGF-TKI-treated group and 55% (11/20) of the biomarker high (sAXL/GAS6) group.
- 9-month progression free survival (PFS) rate was 65% in the overall population, 69% in the biomarker high group (n=20) and 75% in the prior VEGF-TKI, biomarker high group (n=11).
- Safety, PK/PD, and clinical activity results support a recommended Phase 2 dose of 15 mg/kg.

Batiraxcept was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy, including both IO-based and VEGF-TKI-based therapies (either in combination or sequentially). Fast Track Designation was based on data submitted to the agency from 26 patients treated with 15 mg/kg or 20 mg/kg batiraxcept plus 60 mg cabozantinib in the Phase 1b ccRCC study as of September 26, 2022. Results showed no dose limiting toxicities at either dose of batiraxcept. In addition, data demonstrated clinical activity of batiraxcept plus cabozantinib in patients with metastatic ccRCC, with an objective response rate (ORR) of 57% and median PFS of 11.4 months in this population (n=14/26).

About Aravive

Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. Our lead product candidate, batiraxcept (formerly AVB-500), is an ultra-high affinity decoy protein that binds to GAS6, the sole ligand that activates AXL, thereby inhibiting metastasis and tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. FDA and Orphan Drug Designation by the European Commission in platinum-resistant recurrent ovarian cancer. Batiraxcept is in an active registrational Phase 3 trial in platinum resistant ovarian cancer (NCT04729608), a Phase 1b/2 trial in clear cell renal cell carcinoma (NCT04300140), and a Phase 1b/2 trial in pancreatic adenocarcinoma (NCT04983407). The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Additional information at www.aravive.com.

Forward Looking Statements

This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions and includes statements regarding being encouraged by the safety and clinical activity observed in the Phase 1b trial of batiraxcept in patients with ccRCC, the baseline biomarker analysis playing a critical role in predicting response and being further assessed throughout the Phase 2 and 3 trials, the significant potential impact that dual AXL and VEGF inhibition by batiraxcept plus cabozantinib may have in patients who have failed prior VEGF-TKI treatments, the suggestion that batiraxcept may serve as a much-needed treatment option for ccRCC patients on their second or later line of therapy providing additional updates to the program throughout 2023. Forward-looking statements are based on current beliefs and assumptions, are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those contained in any forward-looking statement as a result of various factors, including, but not limited to, risks and uncertainties related to the potential of batiraxcept as a treatment for advanced or metastatic clear cell renal cell carcinoma (ccRCC), the ability of the baseline biomarker analysis playing a role in predicting response, the ability to provide data when anticipated; the Company's dependence upon batiraxcept; batiraxcept's ability to have favorable results in clinical trials; the clinical trials of batiraxcept having results that are as favorable as those of preclinical and clinical trials; the ability to receive regulatory approval, potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients especially in light of the COVID-19 pandemic; the risk that batiraxcept may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that the Company may encounter difficulties in manufacturing batiraxcept; if batiraxcept is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing the Company's intellectual property rights; and the Company's reliance on its licensor of intellectual property and financing needs. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, the Company's Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, respectively, recent Current Reports on Form 8-K and subsequent filings with the SEC. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Relations Contact:

Corey Davis, Ph.D.

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A Phase 1b/2 Study Of Batimastat (AVB-56-500) In Combination With Cabozantinib In Patients With Advanced Or Metastatic Clear Cell Renal Cell Carcinoma (ccRCC) Who Have Received Front-Line Treatment (NCT04300140)

Nell J. Shah¹, Matthew T. Campbell², Shifeng S. Mao³, Moshe C. Orntov⁴, Naomi B. Haap⁵, Xin Gao⁶, Hans J. Hammer⁷, Hideohatahi Keshava Prasad⁸, Hongtao Yao⁹, Vanessa Esquivel¹⁰, Gill Mirzayati¹¹, Robert B. Geller¹², Brian Rini¹³, Martin Voss¹⁴, Katy Beckermann¹⁵
¹Memorial Sloan-Kettering Cancer Center, New York, NY; ²The University of Texas MD Anderson Cancer Center, Houston, TX; ³Mayo Clinic Cancer Center, Pittsburgh, PA; ⁴Osaka Cancer Institute, Osaka, Japan; ⁵University of Colorado Cancer Center, Aurora, CO; ⁶University of Michigan Cancer Center, Ann Arbor, MI; ⁷University of Texas Health Science Center at Houston, Houston, TX; ⁸University of Colorado Cancer Center, Aurora, CO; ⁹University of Colorado Cancer Center, Aurora, CO; ¹⁰University of Colorado Cancer Center, Aurora, CO; ¹¹University of Colorado Cancer Center, Aurora, CO; ¹²University of Colorado Cancer Center, Aurora, CO; ¹³University of Colorado Cancer Center, Aurora, CO; ¹⁴University of Colorado Cancer Center, Aurora, CO; ¹⁵University of Colorado Cancer Center, Aurora, CO

BACKGROUND

- AVB-56 is targeted by hypoxanthine phosphoribosyl transferase 1 signaling in some Hsp90 family (Hsp90) deficient tumor cells and plays a critical role in the metastatic phenotype.
- Batimastat is a recombinant fusion protein containing an extracellular region of human AXL combined with the human immunoglobulin G1 heavy chain (Fc), demonstrating highly potent and specific AXL inhibition.

PHASE 1b STUDY DESIGN

Batimastat at doses of 15 and 20 mg/kg IV, in combination with cabozantinib 60 mg daily was evaluated using a 3+3 dose escalation design in patients with advanced, second line (2L) ccRCC as supported by the safety profile and pharmacokinetic (PK) modeling (1).

Phase 1b Study Objectives

- Primary safety, tolerability and identification of the recommended phase 2 dose (RP2D)
- Secondary assessment of anticancer activity
- Exploratory biomarker defined as baseline serum soluble IGF1 (sIGF1) used to evaluate the correlation with ORR retrospectively.

Phase 1b Key Eligibility criteria

- Advanced or metastatic ccRCC
- Progression on or after at least one prior line of therapy
- Prior cabozantinib is excluded

Batimastat, IV, every 2 weeks
 15 mg/kg, N=18
 20 mg/kg, N=10

Cabozantinib, 60 mg, oral, daily

Table 1. Patient Characteristics

	All Patients N = 28 (N)	15 mg/kg N = 18 (N)	20 mg/kg N = 10 (N)
Median age in years (range)	68 (40-82)	65 (40-78)	69 (42-81)
Sex (Male)	22 (79)	13 (72)	9 (90)
Race (Caucasian, Chinese)	24 (86), 3 (11)	14 (78), 2 (11)	10 (100)
Ethnicity (Hispanic, Not Hispanic)	1 (4), 24 (90)	1 (6), 14 (78)	0 (0), 10 (100)
ECOG (0-1)	13 (50), 15 (50)	10 (56), 5 (28)	3 (30), 7 (70)
1, 2, 3 or 4 lines of prior therapy	17 (61), 1 (4), 1 (4)	11 (61), 2 (11)	7 (70), 2 (20)
Metastatic: Testicular, Intermediate, Poor	5 (18), 36 (128), 9 (28)	3 (17), 21 (116), 2 (20), 5 (50)	2 (20), 5 (50)
Prior VEGF-TKI	14 (54)	9 (50)	5 (50)
Protein D	26 (93)	16 (90)	10 (100)
Protein A/B, Protein C	14 (54)	9 (50)	5 (50)
Protein D, Protein A/B, Protein C	2 (8)	2 (11)	0 (0)
Protein A/B, Protein C	8 (29)	5 (28)	3 (30)



Table 3. Best Overall Response by Biomarker Status

Best Overall Response by Biomarker Status	15 mg/kg (N=18)	20 mg/kg (N=10)
Partial Response	11 (61%)	8 (80%)
Stable Disease	3 (17%)	4 (40%)
Progressive Disease	4 (22%)	3 (30%)
Not Evaluable	1 (6%)	1 (10%)

Table 4. Clinical Activity by Biomarker Status

Best Overall Response Assessed by Investigator per RECIST	All Patients* N = 25 (N)
PR in Biomarker Low (N=10/18)	0 (0%)
PR in Biomarker High (N=15/10)	13 (87%)
3-Month Progression-Free Survival Overall	65
PR in Biomarker High Subgroup (N=10)	68
PR in Biomarker Low Subgroup (N=12)	75

PHASE 1b STUDY RESULTS

All of 17 January 2023, Phase 1b completed enrollment with 26 patients with a median follow-up of 13.5 months (range 3.2 - 20.7 months).

- Cabozantinib dose reductions occurred in 46.2% (12/26) of patients overall; median cabozantinib dose intensity was 45.2 mg/kg, range 13.5 - 68 mg/kg.
- Clinical results by biomarker status were determined as a threshold value (> 2.1) that differentiated ORR (Table 3).
- Batimastat Q2W demonstrated clear PK/PD (Q2W) and exposure-response (PR) relationship.
- 80 post-dose serum Q2W levels were suppressed below the level of quantification in 25/26 patients (1 patient had no post-dose result).
- A minimally efficacious concentration (MEC) of batimastat was determined to be > 21.2 ng/L; 26/26 patients achieved Cycle 1 Day 25 (q2w) difference between 15 and 20 mg/kg.

SAFETY DATA

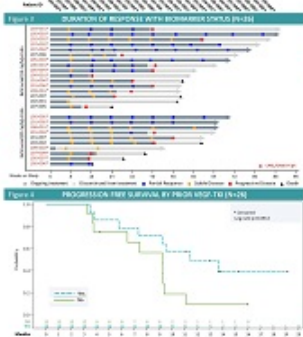
Safety profile between 15 mg/kg and 20 mg/kg dose levels is consistent with prior studies.

Table 2. Batimastat-Related Adverse Events Assessed by Investigator

	All Patients N = 28 (N)	15 mg/kg N = 18 (N)	20 mg/kg N = 10 (N)
All Grade Related AE	28 (100)	18 (100)	10 (100)
Grade 3 or 4 Related AE	5 (18)	2 (11)	3 (30)
All Grade Related SAE	2 (8)	0	2 (20)

Table 3. Related Adverse Events (% N)

Adverse Event	15 mg/kg (N=18)	20 mg/kg (N=10)
Diarrhea	10 (56%)	5 (50%)
Constipation	1 (6%)	1 (10%)
Abdominal pain	1 (6%)	1 (10%)
Headache	1 (6%)	1 (10%)
Nausea	1 (6%)	1 (10%)
Stomatitis	1 (6%)	1 (10%)
Proteinuria	1 (6%)	1 (10%)
Protein A/B, Protein C	1 (6%)	1 (10%)
Protein D	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E, Protein F	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E, Protein F, Protein G	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E, Protein F, Protein G, Protein H	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E, Protein F, Protein G, Protein H, Protein I	1 (6%)	1 (10%)
Protein A/B, Protein C, Protein D, Protein E, Protein F, Protein G, Protein H, Protein I, Protein J	1 (6%)	1 (10%)



CONCLUSIONS

- A RP2D of batimastat 15 mg/kg with cabozantinib 60 mg maintains an acceptable safety profile and encouraging efficacy in previously treated ccRCC patients. Adverse event rates were manageable, and no patients required batimastat discontinuation.
- The addition of batimastat to cabozantinib has a greater impact on patients previously treated with 1D and VEGF-TKI treatments which will be the target population in Phase 3.
- A baseline biomarker appears to have significant predictive value of response (PR of 55% vs 0%). Further analysis with the biomarker will be assessed in Phase 3 and Phase 3-2.

REFERENCES

- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Lancet Oncol*. 2023;24(1):1-11. doi:10.1016/S1473-3099(22)00111-1
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *J Clin Oncol*. 2023;41(1):1-11. doi:10.1200/JCO.2022.41.1.1
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Ann Oncol*. 2023;34(1):1-11. doi:10.1093/annonc/mdac345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Br J Cancer*. 2023;128(1):1-11. doi:10.1093/bjca/kzab345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *PLoS One*. 2023;18(1):1-11. doi:10.1371/journal.pone.0241345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H, Prasad K, Yao H, Esquivel V, Mirzayati G, Geller R, Rini B, Voss M, Beckermann K. Batimastat (AVB-56-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): a phase 1b/2 study. *Front Oncol*. 2023;13(1):1-11. doi:10.3389/fonc.2023.1081345
- Shah NJ, Campbell MT, Mao SS, Orntov M, Haap N, Gao X, Hammer H,