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): June 24, 2021

MONOPAR THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39070**	**32-0463781**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1000 Skokie Blvd., Suite 350, Wilmette, IL 60091	**60091**
(Address of principal executive offices)	(Zip Code)

(847) 388-0349
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

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, $0.001 par value	**MNPR**	**The Nasdaq Stock Market LLC (Nasdaq Capital Market)**

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 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))

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 June 24, 2021, Monopar Therapeutics Inc. issued a press release announcing a presentation on oropharyngeal cancer (OPC) patient population analysis of the Phase 2 Validive® (clonidine HCl MBT) trial for the prevention of chemoradiotherapy-induced severe oral mucositis in head and neck cancer at the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) 2021 annual meeting.

The press release is furnished as Exhibit 99.1 and the supplemental slides are furnished as Exhibit 99.2 to this report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release Dated June 24, 2021
99.2	Supplemental slides provided in connection with Monopar Therapeutics Inc.'s presentation at the MASCC/ISOO 2021 annual meeting.

SIGNATURE

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.

Monopar Therapeutics Inc.

Date: June 24, 2021

By: /s/ Kim R. Tsuchimoto

Name: Kim R. Tsuchimoto
Title: Chief Financial Officer, Secretary and Treasurer

Exhibit 99.1

Monopar to Present Results from Analysis of Oropharyngeal Cancer Patients in Completed Phase 2 Validive® Trial at MASCC/ISOO

WILMETTE, Ill. June 24, 2021 – Monopar Therapeutics Inc. (Nasdaq: MNPR) a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients, today announced that it will present its oropharyngeal cancer (OPC) patient population analysis of the Phase 2 Validive® (clonidine HCl MBT) trial for the prevention of chemoradiotherapy-induced severe oral mucositis in head and neck cancer at the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) 2021 annual meeting. This analysis provided the rationale for the design of Monopar's Phase 2b/3 VOICE trial, which is open and accruing oropharyngeal cancer patients in the US.

"We are excited to share the data from our analysis at this pre-eminent multidisciplinary conference dedicated to supportive care in cancer and for the opportunity to continue working towards providing a treatment for this debilitating condition," said Andrew Mazar, PhD, Chief Scientific Officer of Monopar.

Session Title: Mucositis - New Dimensions in Research and Clinical Practice, Oral Proffered Paper 2

Presentation Title: Subgroup Analysis of Head and Neck Cancer Patients Treated with Clonidine Mucobuccal Tablet in a Randomized, Double-Blind Phase 2 Trial (Study BA2009-28-01) Supports Further Clinical Development in Patients with Oropharyngeal Cancer

Author: Andrew Mazar, PhD, Chief Scientific Officer of Monopar Therapeutics

Date and Time: The Company's presentation will be available on demand for registered attendees starting Friday, June 25, 2021 at 8:00am EDT. For information on registration, visit: https://www.mascc.org/2021-registration

About Validive®

Validive (clonidine mucobuccal tablet; clonidine MBT) is a novel mucobuccal tablet (MBT) formulation. The mucobuccal tablet provides for prolonged and enhanced local delivery of clonidine to the regions of oral mucosal radiation damage in OPC patients. The tablet is self-administered once daily in the patient's home setting with the patient placing it under the upper lip where it adheres to the gums and dissolves over several hours, continuously releasing clonidine into the saliva. Clonidine agonizes the alpha-2 adrenergic receptor on macrophages (white blood cells present in the immune tissues of the oropharynx), decreasing the macrophages' expression of the destructive cytokines that are released in response to radiotherapy. A completed double-blind, randomized, placebo-controlled Phase 2 clinical trial of Validive showed reduced incidence compared to placebo (absolute decrease of 26%, relative decrease of 40%) in OPC patients treated with Validive 100 µg, a safety profile similar to placebo, and a high rate of treatment compliance (over 90%).

About Monopar Therapeutics Inc.

Monopar Therapeutics is a clinical-stage biopharmaceutical company primarily focused on developing proprietary therapeutics designed to extend life or improve the quality of life for cancer patients. Monopar's pipeline consists of Validive for the prevention of chemoradiotherapy-induced severe oral mucositis in oropharyngeal cancer patients; camsirubicin for the treatment of advanced soft tissue sarcoma; a late-stage preclinical antibody, MNPR-101, for advanced cancers and severe COVID-19; and an early-stage camsirubicin analog, MNPR-202, for various cancers. For more information, visit: www.monopartx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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. Examples of these forward-looking statements include: the Company’s excitement for the opportunity to continue working towards providing a treatment for severe oral mucositis; and the Phase 2 trial supporting further clinical development in patients with oropharyngeal cancer The forward-looking statements involve risks and uncertainties including, but not limited to: that the Phase 2 trial analysis will not provide successful rationale for the conduct and design of Monopar’s Phase 2b/3 VOICE trial; that Monopar may not provide a treatment for severe oral mucositis; that Validive’s Phase 2b/3 VOICE trial may not yield similar results as the Phase 2 trial or successful clinical results;that Monopar may not successfully recruit and complete the Phase 2b/3 VOICE trial;the requirement for additional capital to complete the Phase 3 portion of the VOICE trial and potentially a second smaller confirmatory Phase 3 trial, if required by the regulators and, if successful, to commercialize Validive; not being able to ensure volumes of Validive® can be manufactured and scaled up to meet potential demand; uncertainties about levels of demand if and when a treatment is available for commercialization; and the significant general risks and uncertainties surrounding the research, development, regulatory approval and commercialization of therapeutics. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

CONTACTS:

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Chief Financial Officer
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Follow Monopar on social media for updates:

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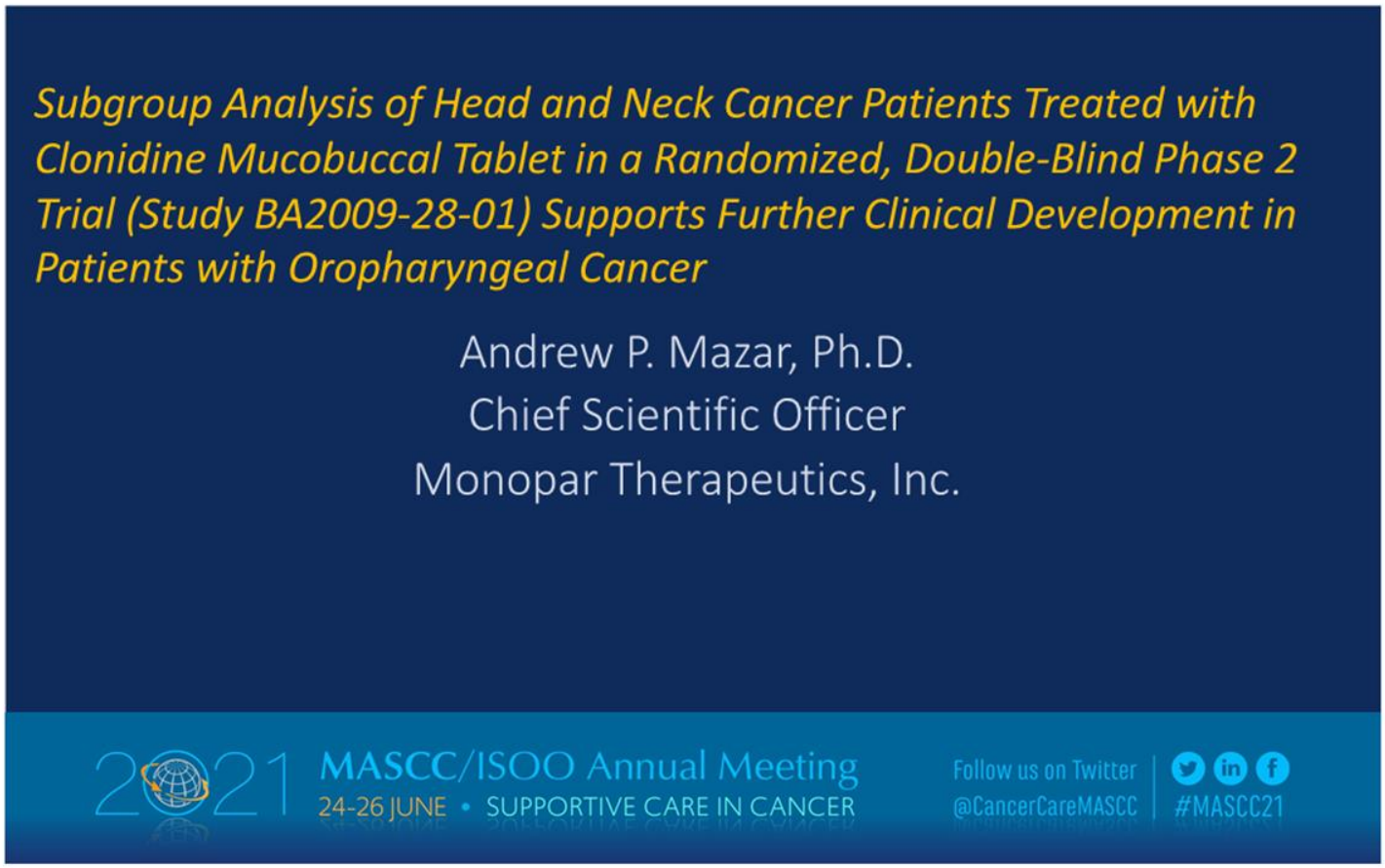
Subgroup Analysis of Head and Neck Cancer Patients Treated with Clonidine Mucobuccal Tablet in a Randomized, Double-Blind Phase 2 Trial (Study BA2009-28-01) Supports Further Clinical Development in Patients with Oropharyngeal Cancer
Andrew P. Mazar, Ph.D.
Chief Scientific Officer
Monopar Therapeutics, Inc.
2021
MASCC/ISOO Annual Meeting
24-26 JUNE • SUPPORTIVE CARE IN CANCER
Follow us on Twitter
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Disclaimer, Forward-Looking Statements

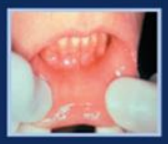
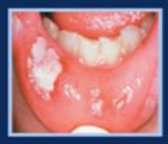
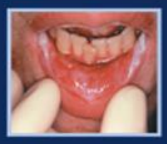
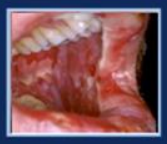
This presentation contains forward-looking statements, which express the current beliefs and expectations of management, within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect Monopar's current beliefs and expectations. Forward-looking statements are not guarantees of future performance. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties, and other factors, many of which are outside of our control. All statements, other than statements of historical facts, contained in this presentation, including statements regarding future events, including statements relating to our business strategy, our clinical development plans, our ability to obtain the substantial capital we require, our plans to secure strategic partnerships and to build our pipeline, our clinical trials and their projected timeline, the efficacy and toxicity of our product candidates, potential new intellectual property, our plans, objectives, expectations and intentions, are forward-looking statements.

These forward-looking statements can be identified by the use of forward-looking terminology, including, but not limited to, the terms "believe," "estimate," "project," "plan," "anticipate," "expect," "seek," "predict," "continue," "possible," "intend," "may," "might," "will," "could," would" or "should" or, in each case, their negative, or other variations or comparable terminology. They appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our product candidates, research and development and clinical trial plans, commercialization objectives, prospects, strategies, the industry in which we operate and potential collaborations. We derive many of our forward-looking statements from our operating budgets and forecasts, which are based upon many detailed assumptions. While we believe that our assumptions are reasonable, we caution that it is very difficult to predict the impact of known factors, and, of course, it is impossible for us to anticipate all factors that could affect our actual results. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we assume no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You are urged to carefully review and consider the various disclosures in our most recent annual report on Form 10-K, our most recent Form 10-Q and our other public filings with the SEC at www.sec.gov/edgar.shtml, especially the risk factors detailed therein.

This presentation does not, and is not intended to, constitute or form part of, and should not be construed as, an offer or invitation for the sale or purchase of, or a solicitation of an offer to purchase, subscribe for or otherwise acquire, any securities, businesses and/or assets of any entity, nor shall it or any part of it be relied upon in connection with or act as any inducement to enter into any contract or commitment or investment decision whatsoever.

Severe Oral Mucositis (SOM) is the most common toxicity induced by CRT in OPC patients

WHO Oral Mucositis (OM) Scale

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
No change	 Soreness/ erythema	 Erythema/ulcers Can eat solid food	 Ulcers/No solid food, liquid diet only	 Oral alimentation not possible

- Most common acute oral side effect of chemoradiotherapy (CRT)
  - Incidence and severity are proportional to the intensity of radiation
- Clinical definition (based on WHO oral mucositis scale)
  - Painful inflammation and ulceration of oral mucosa
  - Inability to eat and/or drink

- Estimated oropharyngeal cancer (OPC) diagnoses (2020): ~40K in the US
- Consensus treatment guidelines recommend CRT to treat OPC
- Approximately 60-70% of patients receiving CRT develop SOM
  - SOM has an adverse effect on clinical outcomes

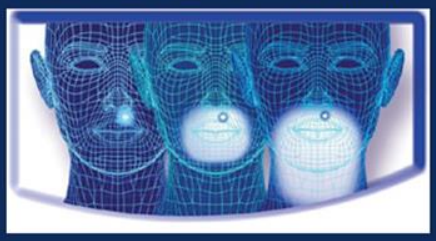
Source: Sonis *et al.*, 2004; Henke *et al.*, 2012; Sher et al., 2017; WHO; Axess Pharma; ASCO; Locust Walk Partners analysis.

Validive (Clonidine Mucobuccal Tablet; Clonidine MBT) Overview

- The active ingredient of Validive®, clonidine, is the most potent currently marketed selective α2-adrenergic receptor agonist, and has a well-established safety profile
- Clonidine MBT is a tasteless muco-adhesive buccal tablet (MBT) administered once daily, resulting in an extended release of clonidine into the local oral mucosa
  - Median duration of adhesion and dissolution in phase 2 was nine hours
- Clonidine MBT's novel formulation for clonidine delivers sustained high/local concentrations of the drug to the oropharynx while minimizing systemic absorption
  - Demonstrated in a phase 1 healthy volunteer pharmacokinetic study
- Clonidine MBT therapy is started on day 1 of radiation treatment and continued daily through the completion of treatment

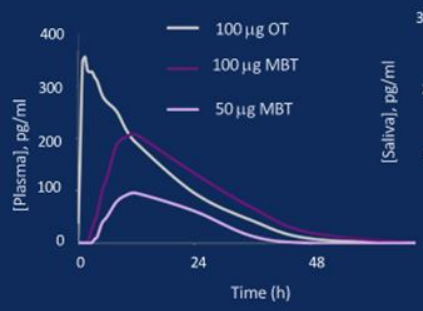
Administered by affixing to upper gum

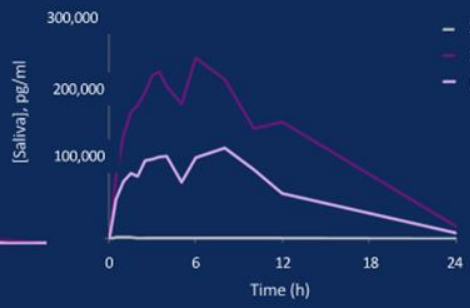
Dissolves slowly over several hours, resulting in the extended release of clonidine into the oropharynx

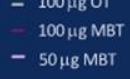


Phase I study comparing pharmacokinetics of oral clonidine (Catapres) to Clonidine MBT

- Phase I PK study in healthy volunteers (Vasseur et al., 2017)
  - 36 patients randomized to two doses of clonidine MBT or Catapres (clonidine oral tablet; OT)
- Daily clonidine dose for hypertension is 200-600 µg OT, which is higher than OT dose tested in Phase 1







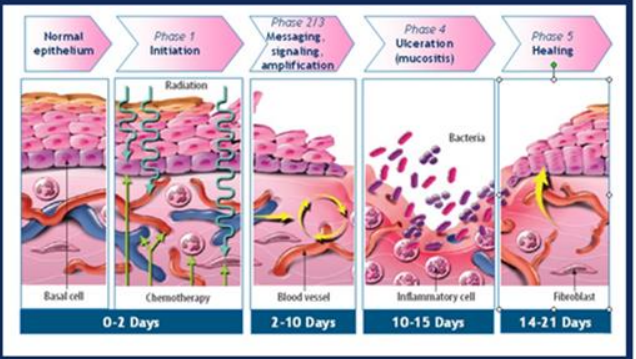
	Saliva		
	50 µg Clonidine MBT (n=35)	100 µg Clonidine MBT (n=35)	100 µg Catapres (n=35)
C_{max} (pg/ml)	176,240.8	359,084.8	2,117.55
AUC_{0-t} (h*pg/ml)	1,152,045.1	2,346,857.0	12,506.67

Vasseur et al. (2017)

- Steady-state PK data from Clonidine MBT Phase 2 in HNC patients shows similar salivary and systemic exposures as observed in Phase 1

Clonidine MBT, a local inhibitor of RT-induced cytokine expression in the oral cavity

- Radiation treatment of OPC leads to local release of cytokines
  - Enhanced by addition of chemotherapy (CRT)
  - Local expression of cytokines triggers destruction of oral mucosa leading to SOM
- Pro-inflammatory cytokines are elevated in the saliva of patients with SOM
  - Increased salivary cytokines correlate with SOM in HNC patients treated with CRT (Bossi, 2016)
  - Increased expression of cytokines in oral smears from HNC patients treated with CRT (Xanthinaki, 2008)
- Macrophages mediate an early response to CRT-induced tissue damage (Smigiel, 2018)
  - Macrophages respond to tissue damage through cytokine release and initiation of inflammatory cascades that recruit antigen presenting cells (APC) and T-cells
  - Cytokine expression in macrophages mediated by $\alpha 2$-adrenergic receptor
- Unique mechanism of action
  - Clonidine is an $\alpha 2$-adrenergic receptor agonist
  - $\alpha 2$-adrenergic receptors on inflammatory cells mediate cytokine expression
  - Analgesic effects
- Non-immune cells are also stimulated to express cytokines in response to CRT



Source: Romero-Sandoval, A. and J.C. Eisenach (2007); Lavand'homme, P. M. and J. C. Eisenach (2003); Bossi et al. (2016)

Data supporting choice of OPC over other forms of HNC as most likely to respond to Clonidine MBT

	Relative risk of developing mucositis in response to CRT by HNC site		
	Any OM vs. none (n=348)	Moderate/severe OM vs. none (n=269)	Severe OM vs. none (n=123)
Larynx	1.0	1.0	**1.0**
Hypopharynx	1.1 (0.4–2.7)	1.2 (0.4–3.0)	**2.0 (0.6–6.3)**
Oral cavity (OC)	2.1 (0.9–5.0)	2.2 (0.9–5.3)	**6.2 (2.3–6.8)**
Nasopharynx	6.1 (1.3–28.9)	5.6 (1.3–24.0)	**10.1 (2.1–49.9)**
Oropharynx	**4.4 (1.7–11.2)**	**4.0 (1.6–9.9)**	**6.9 (2.4–19.7)**

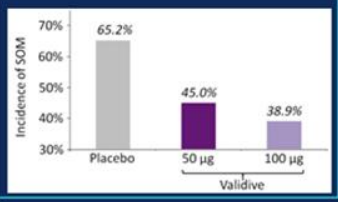
From Vera-Llonch, 2005

Validive Phase 2 Data Supports Further Development of the Product Candidate

- International randomized, double-blind, placebo controlled three-arm study (BA2009/28/01) of all HNC, regardless of anatomical location of disease (N=183) (Giralt et al., 2019)
  - SOM developed in fewer patients receiving Validive (45%) than in patients receiving placebo (60%)
- Very good safety profile
  - Occurrence of adverse events similar between placebo and Validive patients
- Superior outcomes and dose response observed in patients with OPC (N=64)

Reduced Incidence

- Validive has shown a reduction in the incidence of SOM in patients with OPC
- Reduced incidence of SOM may lower the risk of acute and chronic comorbidities and improve quality of life



Delayed Time to Onset

- Validive has demonstrated the ability to delay the time to onset of SOM
- Prolonging time to onset of SOM may lead to fewer missed chemoradiotherapy treatments, resulting in improved overall survival outcomes

Placebo	Validive 50µg	Validive 100µg
37 days	45 days	N.D.*

Decreased Duration

- Validive® has shown a decrease in the median duration of SOM in OPC patients
- Reduced duration of SOM may result in lower risk of malnourishment and feeding tube intervention, and fewer treatment terminations/delays

Placebo	Validive® 50µg	Validive® 100µg
17 days	0 days	**0 days**

** Not determined: median was not reached as too few patients developed SOM*

Additional efficacy analysis in OPC-overview

- All secondary and exploratory endpoints collected in BA2009/028/01 were analyzed for trends in clinical benefit in patients with OPC
- OPC represented ~36% of the patients in this Phase 2 study and OC represented ~50%
- Results in the OPC subpopulation were compared either to the full population of HNC in the Phase 2 study or against OC only (depending on which TLFs were available)
- There were 64 patients total with OPC with 24 in placebo and 19 in the Validive 100 µg group
  - Statistical significance in any subgroup including OPC unlikely because trial design was not powered for this
  - Looking for alignment of trends across multiple data sets
  - QoL as reported by patient (PRO) is at least as important as WHO score in assessing efficacy for the prevention of SOM

Comparison of incidence in OC vs OPC in Phase 2

Absolute incidence of SOM

	Placebo	Validive® (50µg)	Validive® (100µg)
All HNC	60% (n=62)	45% (n=121) p=0.06 (pooled for two doses)	
Oral only	63.3% (n=30)	52% (n=26) p=0.396	52.8% (n=37) p=0.169
OPC only	65.2% (n=24)	45.0% (n=20) p=0.183	38.9% (n=19) p=0.093

Risk of onset of SOM

		Placebo	Validive® (50µg)	Validive® (100µg)
All HNC	Hazard-ratio 95% confidence interval Log-rank p-value		0.698 [0.398 ; 1.223] p=0.199	0.817 [0.493 ; 1.353] p=0.424
Oral only	Hazard-ratio 95% confidence interval Log-rank p-value		0.858 [0.397 ; 1.853] p=0.666	0.839 [0.428; 1.644] p=0.613
OPC only	Hazard-ratio 95% confidence interval Log-rank p-value		0.634 [0.265;1.519] p=0.245	0.481 [0.191;1.209] p=0.104

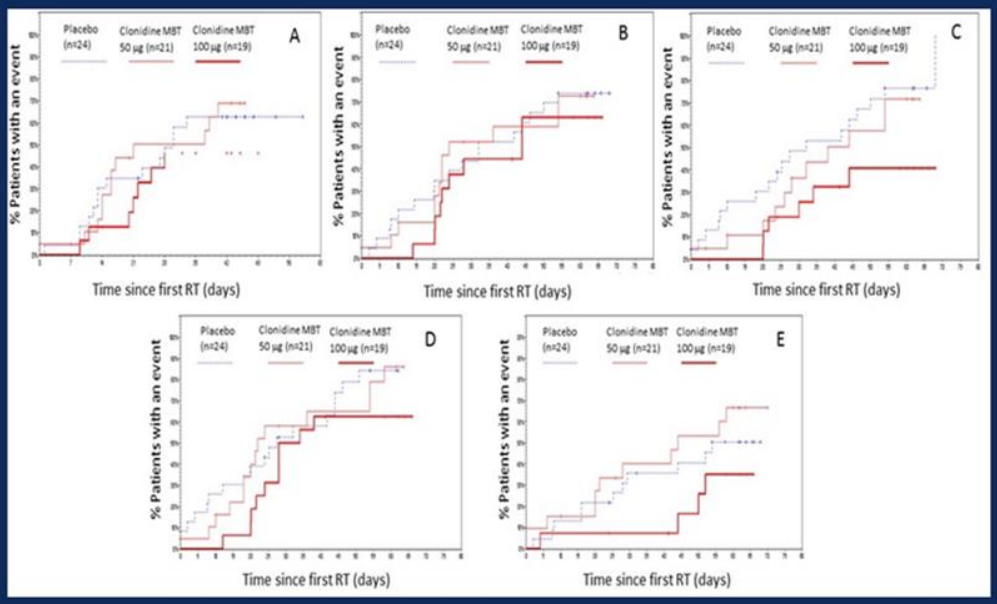
QoL: OMDQ and FACT-G in OPC patients

OPC patient analysis: Validive 100µg MBT vs Placebo MBT	
OMDQ (MTS>2)	**FACT-G**
Mean Limitation in daily activity due to MTS score	**FACT-G mean score:**
Swallowing 2 vs 4	**Lack of energy** 1.5 vs 1.9
Drinking 2.5 vs 4	**Nausea** 0.7 vs 1.3
Eating 2.8 vs 4	**Meeting family** 1.1 vs 1.8
Talking 2 vs 4	**Pain** 1.8 vs 1.8
Sleeping 2 vs 2	**Side effects** 2 vs 1.8
	Ill 1 vs 1.6
Overall MTS 4 vs 5.3 (mean)	**Spend time in bed** 0.4 vs 0.8
	FACT-G mean sub-score:
	Physical sub-score 19.25 vs 17
	Total sub-score 78.68 vs 70.20

The WHO scale has the strongest correlation with the OMDQ PRO– drinking limitation, suggesting that it may be the best objective clinical measure.

Sonis et al (Nat Rev 4:277-284, 2004) hypothesized that OM has a multifaceted mechanism of action where the early indications of the deterioration of the oral mucosa caused by cytotoxic insult may be felt by patients but may not have visible manifestations that are detectable by clinicians using the clinical scales.

OMDQ patient-reported outcomes (severe limitations) for OPC in Phase 2



OMDQ Question 3a-e when MTS>2. A) Time to onset of MTS>2; B) Severe swallowing limitation when MTS>2; C) Severe drinking limitation when MTS>2; D) Severe eating limitation when MTS>2; E) Severe talking limitation when MTS>2. Other endpoints: hospitalization, weight loss, N&V, dysphagia, opiate use all show positive trends in Validive 100 µg cohort.

OPC patient QoL assessments summary

Exploratory or secondary endpoint	Phase 2 OPC only (Clonidine 100 µg dose vs placebo)		Full phase 2 HNC population (Clonidine 100 ug dose vs placebo)	
	Placebo (n=24)	Clonidine MBT (n=19)	Placebo (n=62)	Clonidine MBT (n=65)
Risk of MTS>2		0.644 (p=0.394)		1.077 (p=0.775)
Risk of onset of severe swallowing limitation, MTS>2		0.715 (p=0.444)		1.093 (p=0.712)
Risk of onset of severe eating limitation, MTS>2		0.597 (p=0.209)		0.928 (p=0.755)
Risk of onset of severe drinking limitation, MTS>2		0.348 (p=0.023)		0.904 (p=0.703)
Risk of onset of severe talking limitation, MTS>2		0.506 (p=0.036)		1.158 (p=0.597)

OPC patient QoL assessments

Exploratory or secondary endpoint	Phase 2 OPC only (100 µg dose vs placebo)		Full phase 2 HNC population (100 ug dose vs placebo)	
	Placebo (n=24)	Clonidine MBT (n=19)	Placebo (n=62)	Clonidine MBT (n=65)
Hospitalization (total days during treatment), days	12.2	7.3 (p=0.335)	12.5	11 (p=0.626)
SOM duration (median), days[1]	41	25.5 (p=0.381)	41	36
Weight loss (>10% relative to baseline)	8	2	-7.69%	-6.14% (p=0.078)
FACT-G (total score-higher is better QoL; week 8)	70.2	78.68	72.08	74.71 (p=0.409)
Nausea (events)	22 (91.7%)	11 (57.9%)	44	30
Dysphagia (events)	13 (54.2%)	7 (36.8%)	30	21
Vomiting (events)	14 (58.3%)	6 (31.6%)	24	16

[1]In subjects that developed a SOM; median in ITT shown on slide 8

Opioid Use[1]

Opioid Use	Full phase 2 HNC population (100 ug dose vs placebo), ACTIVE CRT		Full phase 2 HNC population (Clonidine 100 ug dose vs placebo), POST CRT	
	Placebo (n=62)	Clonidine MBT (n=65)	Placebo (n=62)	Clonidine MBT (n=65)
No opioids	32	34 (p=0.865)	37	43 (p=0.381)
Total cumulative Dose (Morphine Equivalent Units)	625	415.49 (p=0.971)	212	76 (p=0.248)

[1]Full population only; OPC only data was not analyzed

Feeding Tube Dependence

Exploratory or secondary endpoint	Phase 2 OPC only (100 µg dose vs placebo)		Full phase 2 HNC population (100 ug dose vs placebo)	
	Placebo (n=24)	Clonidine MBT (n=19)	Placebo (n=62)	Clonidine MBT (n=65)
Feeding tube dependence (at start of CRT)	6	2 (p=0.27)	14	13 (p=0.722)
Feeding Tube Dependence (onset during CRT)	11	4 (0.091)	23	18 (p=0.251)

[1]Prophylactic PEG was more prevalent during the time this trial took place; exclusion criteria in MNPR-301-001 (VOICE)

Dry Mouth (xerostomia)

Exploratory or secondary endpoint	Phase 2 OPC only (100 µg dose vs placebo)		Full phase 2 HNC population (100 ug dose vs placebo)	
	Placebo (n=24)	Clonidine MBT (n=19)	Placebo (n=62)	Clonidine MBT (n=65)
Dysgeusia	5	3	12	11
Odynophagia	3	3	8	14
Dry mouth (xerostomia)	7	3	17	17

Conclusions

- A subgroup analysis comparing the effects of clonidine MBT on SOM in patients with OPC in a completed phase 2 all-HNC population was conducted
- The analysis was initiated based on a relatively higher risk of developing SOM in patients with OPC compared to other HNC and based on the origination of many OPC tumor in lymphoid regions containing a high prevalence of macrophages
- The goal was to see whether the totality of data would support focusing the next clonidine MBT clinical study only in OPC patients
- Multiple data readouts were evaluated and the requirement for all the data favoring OPC patients (no dredging) was met
- A Phase 2b/3 trial evaluating clonidine MBT as a preventive agent for SOM in patients with OPC receiving CRT was initiated in December, 2020; this trial (NCT04648020) is currently accruing patients and expanding sites.