6040 **Poster Session**

Updated results from a phase 2 study of the oral vascular endothelial growth factor receptor 2 (VEGFR2) inhibitor rivoceranib for recurrent or metastatic (R/M) adenoid cystic carcinoma (ACC).

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Background: ACC is a rare tumor that overexpresses VEGF, primarily affecting salivary glands. Often indolent, it can progress, with metastases common in the lungs, liver, and bone. There are no FDA-approved systemic treatments (tx) for R/M ACC. Rivoceranib is an oral tyrosine kinase inhibitor (TKI) that potently and selectively inhibits VEGFR2. **Methods:** In this single-arm, open-label multicenter trial, patients (pts) with R/M ACC with evidence of ≥20% progression by RECIST v1.1 or new lesions within the preceding 6 months (mos) were eligible, with no limit on prior tx. Pts received rivoceranib 700 mg daily until disease progression or withdrawal with pre-planned dose reductions for toxicity. Primary endpoint was overall response rate (ORR) per RECIST v1.1 by investigator (INV) and by Independent Review Committee (IRC). Secondary endpoints included duration of response (DoR), progression-free survival (PFS), time to progression (TTP), overall survival (OS), and safety exploratory analysis included disease control rate (DCR) and ORR using CHOI criteria by IRC. **Results:** As of 11/2022, 80 pts (72 evaluable) were enrolled in the US and Korea (53% male; median age, 54 yrs), and 6 pts remain on tx. Primary tumor sites: major (34%) and minor (59%) salivary glands and other (8%). 74 pts (93%) had metastatic disease. 61.3% had prior systemic tx (18% prior VEGFR TKI). INV and IRC-assessed efficacy data are listed in the table. ORR by CHOI was 52.5% (53.1% VEGFR TKI-naive and 50% VEGFR TKI treated). mOS was 25.3 mos (28.3 mos VEGFR TKI-naïve and 22.6 mos VEGFR treated). Common adverse events (AEs) were hypertension (66%), fatigue (64%), and nausea (54%). Grade ≥3 AEs that occurred in >5% of pts were hypertension (43%), stomatitis (8%), fatigue and anemia (6% each). There were 4 Grade 5 AEs (2 epistaxis [1 related], 1 acute respiratory failure, 1 respiratory failure). **Conclusions:** Updated results with additional 9-month follow-up data continue to demonstrate that Rivoceranib has clinical efficacy and a manageable safety profile in pts with R/M ACC. Clinical trial information: NCT04119453. Research Sponsor: Elevar Therapeutics.

	Total (N=72)		VEGFR TKI-Naïve (n=59)		VEGFR TKI Prior Tx (n=13)	
	INV	IRC	INV	IRC	INV	IRC
ORR* n, (%)	11 (15.3)	7 (9.7)	11 (18.6)	5 (8.5)	0	2 (15.4)
95% CI	7.9-25.7	4.0-19.0	9.7-30.9	2.8-18.7		1.9-45.4
DOR median (mos)	14.9	7.2	13.5	8.3	17.3	6.3
DCR n, (%)	47 (65.3)	48 (66.7)	37 (62.7)	39 (66.1)	10 (76.9)	9 (69.2)
95% CI	53.1-76.1	54.6-77.3	49.1-75.0	52.6-77.9	46.2-95.0	38.6-90.9
mTTP (mos)	9.2	9.3	9.2	10.8	10.6	8.9
mPFS (mos)	9.1	9.2	9.0	9.3	10.6	8.9
6, 12 mo PFS rate (%)	77.4, 38.9	80.8, 38.6	75.8, 39.3	80.3, 40.4	84.6, 37.6	83.1, 31.2
mOS (mos)**	25.3		28.3		22.6	

*all partial responses; ** intention to treat population.