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Safety and Pharmacokinetics of BXQ-350 in a Phase 1a and 1b Trial of Solid Tumors and High-grade Glioma.

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Background: BXQ-350 is composed of the multifunctional, lysosomal-activator protein Saposin C and phosphatidylserine lipid with demonstrated antitumor effects *in vitro* and *in vivo.* In this abstract we update the safety and pharmacokinetic (PK) profile based on an ongoing Phase 1 trial. **Methods:** BXQ-350 was administered in a Phase 1a dose-escalation trial (NCT02859857), and an ongoing Phase 1b trial (data cut off at max of 6 cycles, 01DEC2018) to refractory solid tumor/high-grade glioma patients (pts). In Phase 1a, pts received escalating IV BXQ-350 doses of 0.7, 1.1, 1.4, 1.8, or 2.4 mg/kg on days 1, 2, 3, 4, 5, 8, 10, 12, 15, 22 (cycle 1), 29 (cycle 2), and thereafter 28-day cycles. PK was assessed over a 24-hr period following the first dose. The Saposin C level was analyzed by ELISA and PK parameters were calculated using noncompartmental methods. **Results:** The 1a cohort of 18 pts (age 24-69) had a median of 3 cycles and 1b cohort of 20 pts (age 31-80) had median of 2 cycles with no treatment-related serious adverse events to date. Moderately severe related adverse events (AEs, n case, n events) are reported with serious non-related events. The most common treatment-related AE was fatigue (2 at dose 1.1, 2 at 1.8, 1 at 2.4mg/kg and 3 in 1b), at 2.4 mg/kg, 1 pt had moderate blood pressure elevation. Exposures in the 1.4 and 1.8 mg/kg cohorts were less than dose-proportional, likely due to higher clearance in those groups. The overall mean clearance and half-live values were 66.8 (mL/kg/h) and 4.03 h, respectively. **Conclusions:** BXQ-350 has had no serious related AEs during dose-escalation or in the on-going trial supporting a tolerable safety profile at 2.4 mg/kg.

	Phase 1a					**Phase 1b**
Dose mg/kg	0.7	1.1	1.4	1.8	2.4	2.4
N	1	3	3	3	8	20
Age, mean (SD)	64.0 (-)	53.3 (25.42)	58.3 (1.53)	48.7 (7.51)	54.1 (13.77)	56.8 (12.69)
F:M	0:1	0:3	2:1	1:2	4:4	10:10
Adverse Event (n case, n event)	1, 16	3, 60	3, 38	3, 34	8, 112	20, 201
Moderate severity related	0, 0	3, 5	1, 1	1, 3	2, 3	6, 17
Serious non-related	0, 0	1, 1	1, 2	0, 0	1, 2	6, 12
Pharmacokinetic Parameters						
AUC_{inf} (h*ng/mL)	10240	18740±4751	19700±5160	23710±2059	53953±17763	43856±18649
$T_{1/2}$ (h)	5.16	4.59±1.23	3.75±0.29	3.58±0.26	3.69±0.83	4.18±0.838
CL (mL/h/kg)	68.38	61.78±18.34	74.44±19.56	76.29±6.71	48.39±14.32	70.93±59.03

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No

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Yes

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No

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Continued Trial Accrual:
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