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First-in-human, First-in-class Phase 1a Study of BXQ-350 for Solid Tumors and Gliomas.

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Background: BXQ-350 is a novel agent composed of the multifunctional, lysosomal activator protein Saposin C and phosphatidylserine. BXQ-350 demonstrated antitumor effects *in vitro* and *in vivo*, particularly in glioma and pancreatic cancer models.

Methods: A phase 1a dose-escalation trial (NCT02859857; Phase 1b ongoing) was conducted in refractory solid tumors/high-grade glioma (HGG) patients (Pt) by administering escalating IV BXQ-350 doses of 0.7, 1.1, 1.4, 1.8, or 2.4 mg/kg on days 1-5, 8, 10, 12, 15, 22 (cycle 1) and at 28-day cycles thereafter. Response was assessed at day 113 by RECIST or RANO.

Results: 17 Pt (age 24-67) with a median 7 (range, 2-12) prior systemic therapies completed a median 2 (range, 1-6) cycles without DLTs or treatment-related serious adverse events (AEs). Moderately severe related AEs occurred in 3 (100%), 1 (33%), 1 (33%), and 2 (25%) Pt at 1.1, 1.4, 1.8, and 2.4 mg/kg cohort doses, respectively. The most common treatment-related AEs was transient fatigue (*n* = 4, 23.5%). At 2.4 mg/kg, 1 Pt had moderate blood pressure elevation. Best response in 7 Pt completing to day 113 was 1 PR (appendiceal carcinoma) at 2.4 mg/kg, and 6 SD (1 HGG Pt at 0.7 mg/kg had stable disease >12+ months, and 6 had improved day 113 RANO/RECIST). BXQ-350 pharmacokinetics was dose proportional with half-life and Cmax, consistent with preclinical data.

Conclusions: BXQ-350 showed clinical activity in heavily pre-treated patients with advanced solid and brain tumors. BXQ-350 has a tolerable safety profile with no significant DLT at the highest planned dose, supporting continued monotherapy dose expansion at 2.4 mg/kg.

DOSE (mg/kg)	**0.7**	**1.1**	**1.4**	**1.8**	**2.4**
N	**1**	**3**	**3**	**3**	**8**
Mean Age, F:M	**64, 0:1**	**53, 0:3**	**58, 2:1**	**49, 1:2**	**54, 2.2**
Prior systemic therapy, # cycles, *range*	**7, 6**	**5-7, 2-4**	**2-12, 1-3**	**3-8, 2-6**	**4-12, 1-4**
Solid Tumor *n*, Improved RANO *n/N D 113*	**1, 0**	**2, 1/1**	**1, 1/2**	**1, 0**	**5, 0**

HGG *n*, Improved RECIST, *n/N D 113*	**1, 1/1**	**1, 0**	**2, 0**	**2, 0**	**3, 2/2**
Adverse Event (*n case, n event*)	**1, 15**	**3, 54**	**3, 37**	**3, 32**	**8, 80**
Moderate severity related		**3, 6**	**1, 1**	**1, 2**	**2, 2**
Fatigue		**2, 2**		**1, 2**	**1, 1**
Neutropenia, EKG, Balance, Nerv, Dysarthria, Urin, BP		**3, 4**			
Serious non-related – GI, hyponatremia, weak	**1, 1**	**1, 4**	**1, 3**	**1, 3**	**3, 5**

Title:
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Yes

Is this clinical trial registered?
Yes

Registry Name:
Clinicaltrials.gov

Registration Number:
NCT 02859857

Research Funding Source:
Pharmaceutical/Biotech Company

Research Funding Source Name:
Bexion Pharmaceutical

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No

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No

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No

Type of Research:
Phase I
Research Category:
Clinical
Continued Trial Accrual:

Yes
Received Grant funding:
No
Relevant to geriatric oncology:
No
Sponsor:
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