ASCO 50th ANNUAL MEETING SCIENCE & SOCIETY

Meeting Abstracts

Phase I study of NBTXR3 nanoparticles, in patients with advanced soft tissue sarcoma (STS).

Sub-category:
Soft Tissue

Category:
Sarcoma

Meeting:
2014 ASCO Annual Meeting

Abstract No:
10563

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Session: Sarcoma

Type: General Poster Session

Time: Monday June 2, 8:00 AM to 11:45 AM

Location: S Hall A2

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Abstract Types

LBA
Late-Breaking Abstract

TPS
Trials in Progress Abstract

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Abstracts selected for publication but not presentation at the Annual Meeting

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Abstract Disclosures

Abstract:

Background: Functionalized hafnium oxide nanoparticles (NBTXR3) have been developed as selective radioenhancers, which may represent a breakthrough approach for the local treatment of solid tumors. This is a unique approach where crystalline nanomaterials with high electron density when exposed to radiotherapy, can allow penetrate into the cell and make

feasible the absorption/deposition of a high energy dose within the tumor cell. A phase I/II trial was implemented in patients with locally advanced STS. **Methods**: Patients (pts)received a single intratumor (IT) injection of NBTXR3, volume escalated, followed by 50Gy RTx (see Table). Primary endpoints include feasibility of the IT implantation and safety. Secondary endpoints focus on efficacy such as pathological and RECIST response, IT residency of NBTXR3 over all the RTx period and operability. **Results**: Enrollment was completed for volume 1, 2, and 3 (15 pts). Feasibility of the IT injection was confirmed. The treatment was safe with no SAE, no early DLT and allowed the pts for completion of the planned RTx schedule. No grade 3-4 toxicity occurred, main grade 1-2 toxicities related to NBTXR3 were injection pain/reaction (4 pts), pyrexia (2 pts), abdominal pain (1 pt), pruritus (1 pt) and paresthesia (1 pt). Results demonstrated that a single injection of NBTXR3 provides adequate bioavailability of NBTXR3 IT over five weeks of radiotherapy. No leakage of NBTXR3 to the adjoining healthy tissues was observed. Further, NBTXR3 persistence was established by CT scan before surgery. **Conclusions**: Injection of NBTXR3 was well tolerated. All pts received the planned radiotherapy (50 Gy/25 fractions/ 5 weeks) followed by wide surgical resection of the sarcoma. NBTXR3 with RTx showed a very good safety profile. Encouraging signs of antitumor activity were observed in different sarcoma subtypes, such as undifferentiated sarcoma, rhabdomyosarcoma, and synovial sarcoma, which constitutes a promising feature for this subset of pts whose primary tumor is locally advanced and has an important risk of relapse. Clinical trial information: NCT01433068.

Volume level	Pts	Tumor volume cc	Injected volume mL
1	6	55-1,814 (503)	1.4-45 (12)
2	6	85-3,682 (1127)	4.2-184 (56)
3	3	360-885 (590)	36-100.5 (60)
4	Screening		

Other Abstracts in this Sub-Category:

1. Prognostic/predictive biomarkers in advanced soft tissue sarcomas (STS): Translational research associated to randomized phase II trial comparing trabectedin-doxorubicin versus doxorubicin—A GEIS study.

Meeting: 2014 ASCO Annual Meeting Abstract No: 10500 First Author: Javier Martin Broto
Category: Sarcoma - Soft Tissue

2. ANGIOTAX-PLUS trial: A randomized phase II trial assessing the activity of weekly paclitaxel (WP) plus or minus bevacizumab (B) in advanced angiosarcoma (AS).

Meeting: 2014 ASCO Annual Meeting Abstract No: 10501 First Author: Nicolas Penel
Category: Sarcoma - Soft Tissue

3. Randomized phase 2b trial comparing first-line treatment with aldoxorubicin versus doxorubicin in patients with advanced soft tissue sarcomas.

Meeting: 2014 ASCO Annual Meeting Abstract No: 10502 First
Author: Sant P. Chawla
Category: Sarcoma - Soft Tissue

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