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Weekly nab-paclitaxel for progressive or symptomatic desmoid tumors: A multicenter single arm phase II trial from the Spanish Group for Research on Sarcoma (GEIS)

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Background

Desmoid tumors (DT) are locally aggressive tumors, which can significantly impact on patients' quality of life and function. Systemic therapy can be considered in progressive cases or in symptomatic patients (pts). Regimens such as methotrexate-based schemes are usually administered for long periods. The aim of this phase II trial was to explore the activity of short-regimen of weekly nab-paclitaxel (nab-P) in DT.

Methods

Adult pts with clinically/radiologically progressive DT received 3 cycles of nab-P (125 or 240 mg/m2 days 1,8,15 every 28d in pts > 21y and 18-20 y, respectively). Primary combined end-point was overall response rate (ORR) by RECIST 1.1 and/or the proportion of pts with pain improvement in at least 2 points based on Brief Pain Inventory (BPI) scale. H0= ORR 20% or pain reduction 20%; H1= ORR 40% or pain reduction 40%. Central pathology and radiological review were mandatory.

Results

From May 2017 to September 2019, 40 pts were enrolled in 8 sites: 26F/14M, median age 38y (18-76), site (limbs 14/40; trunk wall 13/40, abdominal cavity 7/40, head and neck 6/40). Reason of inclusion: RECIST PD in 13/40 (32.5%), symptomatic progression (SP) in 12/40 (30%), both RECIST and pain in 15/40 (37.5%). All but 1 pts completed therapy (1 pt stopped due to allergic reaction after 1 cycle). ORR by RECIST (central review) was 20.5% (8/39 evaluable pts had PR; 30/39 (76.9%) SD (19/39 with shrinkage), 1/39 (2.5%) PD. Median worst pain at baseline was 6.5 (0-10) and median worst pain at the end of therapy was 2 (0-6), with a median reduction in 4 points (0-8). 32/40 (80%) pts experienced at least reduction in 2 points in worst pain. 4 pts had G3 toxicities (2-G3 neutropenia, 1 G3 mucositis,1 G3 peripheral neuropathy). There were no G4 toxic effects. With a median of FU of 18 mos, there were 2 PD, 6 SP and 2 both, PD and SP. Neck and proximal upper-extremity sites had worse 18m-PFS: 24% vs 86% in other locations (p< 0.001).

Conclusions

Short-regimen nab-paclitaxel was safe and active in this cohort of DT, with 80% of pts having clinical improvement and 20.5% achieving a radiological response. In patients with DT in neck or proximal upper extremity this regimen was related with less efficacy in terms of 18m-PFS.

Clinical trial identification

NCT03275818.

Legal entity responsible for the study

Spanish Group for Research on Sarcoma (GEIS).

Funding

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Disclosure

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