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### **Ribociclib plus letrozole and concomitant palliative radiotherapy for metastatic breast cancer**

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16 **Keywords:** breast cancer; concomitant radiotherapy; ribociclib; safety.

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32 **Abstract**

33 Ribociclib is a CDK4-6 inhibitor recently approved by the Food and Drug Administration (FDA) and the European  
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35 significant improvement in progression-free survival when compared to endocrine therapy alone. However, having a  
36 challenging toxicity profile in comparison with exclusive endocrine therapy, safety may be a concern when combined to  
37 radiotherapy (RT) with palliative approach.

38 There are no available published data regarding the combination of ribociclib and palliative RT. We reported our  
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## 63 **Viewpoints and Debates**

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72 There are no available published data regarding the combination of ribociclib and palliative RT in a clinical setting. A  
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82 Hematological and non-hematological **toxicities were assessed during the second 21-days cycle of ribociclib, following**  
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86 Ribociclib treatment suspension was required in two cases, for two weeks. Treatment recovery (first dose reduction;  
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88 At time of the present analysis, all the patients are still on first-line treatment: three patients received four cycles and  
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**Conflicts of interest statement**

None declared.

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Table 1

Table 1. Main patients and treatments characteristics.

Case	Age	PS	RT treated site	Dose (Gy)/Fx	Technique	Ribociclib cycle	G3-4 hematological toxicity*	G3-4 non hematological toxicity*	RT suspension required	Pain relief <sup>o</sup>	Ribociclib suspension required*	Weeks of suspension
1	71	0	Left femoral neck	30/5	VMAT	1	Neutropenia	No	No	Yes	Yes	2
2	55	0	Bilateral femoral neck	20/5	3DCRT	1	No	No	No	Yes	No	0
3	76	2	Right hip	20/5	3DCRT	1	No	Diarrhea Vomiting	No	Yes	Yes	2
4	79	1	Lumbar spine (L2-L3)	20/5	3DCRT	1	No	No	No	Yes	No	0
5	36	0	Cervical/thoracic spine (C3-T2)	20/5	3DCRT	1	No	No	No	Yes	No	0

Abbreviations: PS, performance status; Dose/fx, total dose (Gy)/number of fractions; G3-4, grade 3-4; RT, radiotherapy; VMAT, volumetric modulated arc therapy; 3DCRT, 3-dimensional conformal radiotherapy.

\*Toxicity recorded after the cycle of combined treatment ribociclib/letrozole with palliative radiation.

<sup>o</sup>If pain at palliative radiation start.

## Highlights

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