

Panobinostat as part of induction and maintenance for elderly patients with newly diagnosed acute myeloid leukemia: phase Ib/II panobidara study

Enrique M. Ocio,¹ Pilar Herrera,² María-Teresa Olave,³ Nerea Castro,⁴ José A. Pérez-Simón,⁵ Salut Brunet,⁶ Albert Oriol,⁷ Marta Mateo,⁸ Miguel-Ángel Sanz,⁹ Javier López,² Pau Montesinos,⁹ María-Carmen Chillón,¹ María-Isabel Prieto-Conde,¹ María Díez-Campelo,¹ Marcos González,¹ María-Belén Vidriales,¹ María-Victoria Mateos¹ and Jesús F. San Miguel¹¹

On behalf of the PETHEMA Group

¹Complejo Asistencial Universitario de Salamanca (IBSAL), Centro Investigación del Cáncer-IBMCC (USAL-CSIC), Salamanca; ²Hospital Ramón y Cajal, Madrid; ³Hospital Lozano Blesa, Zaragoza; ⁴Hospital Universitario 12 de Octubre, Madrid; ⁵Hospital Virgen del Rocío, Instituto de Biomedicina de Sevilla (IBIS), Seville; ⁶Hospital de la Santa Creu y Sant Pau, Barcelona; ⁷Hospital Germans Trias i Pujol, Badalona; ⁸Hospital San Carlos, Madrid; ⁹Hospital Universitario La Fe, Valencia; and ¹⁰Clínica Universidad de Navarra, Centro de Investigaciones Médicas Aplicadas (CIMA), IDISNA, Pamplona, Spain

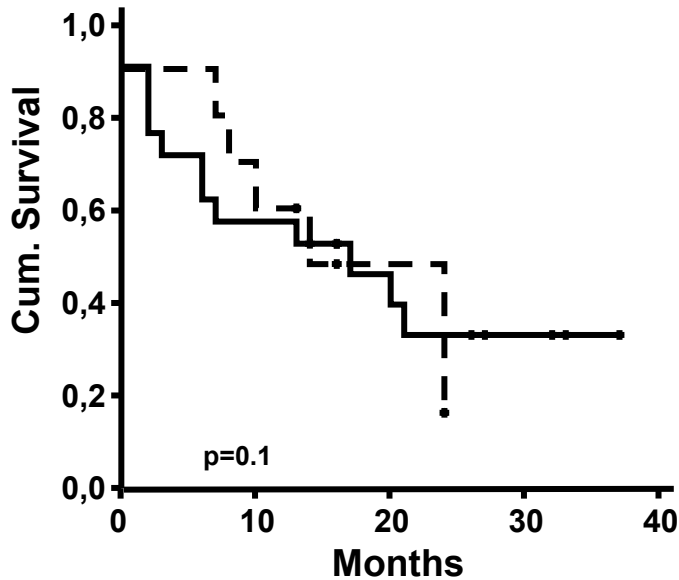
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Correspondence: emocio@usal.es

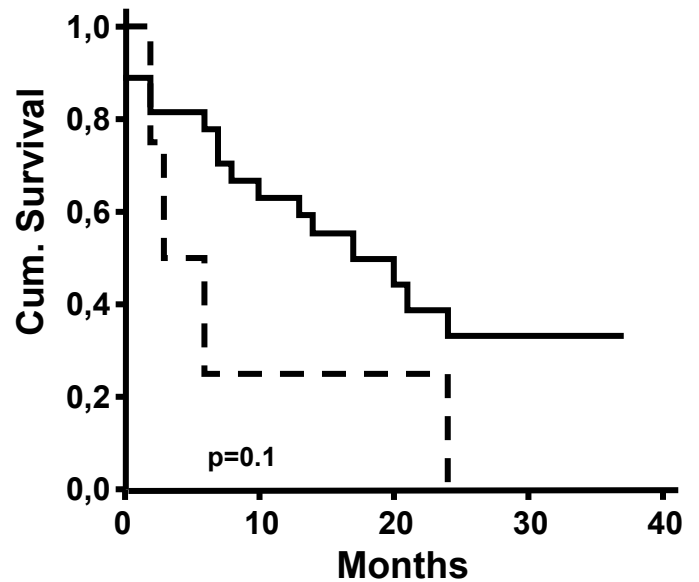
Supp. Figure 1

Overall Survival according to Age



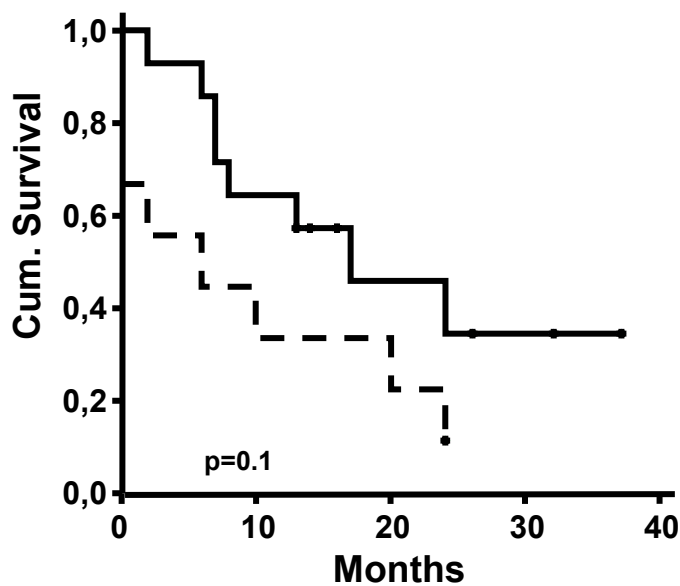
— < 75 17 months (0.0 – 34.3)
 - - ≥ 75 13 months (6.8 – 19.1)

Overall Survival according to Leucocytes at diagnosis



— < 50,000 17 months (6.2 – 27.7)
 - - ≥ 50,000 3 months (0.0 – 6.9)

Overall Survival according to cytogenetics



— No adverse cytogenetics or FLT3 ITD 17 months (3.1 - 30.8)
 - - Adverse cytogenetics or FLT3 ITD 6 months (0.0 - 17.6)

Supplemental Table 1: Criteria for defining dose-limiting toxicities

TOXICITY	ANY OF THE FOLLOWING CRITERIA
NON-HEMATOLOGIC	
<i>Gastrointestinal</i>	≥ CTCAE grade 3 vomiting or ≥ CTCAE grade 3 nausea, despite the use of standard anti-emetics
	≥ CTCAE grade 3 diarrhea despite the use of optimal anti-diarrheal treatments (in the absence of septic symptoms)
<i>Hepatic</i>	CTCAE grade 3 AST or ALT for >7 consecutive days
	CTCAE grade 4 AST or ALT
	Inability to administer panobinostat for >7 consecutive days past the intended day of dosing due to ≥CTCAE grade 2 bilirubin
	≥CTCAE grade 3 bilirubin
<i>Cardiac</i>	Any ≥CTCAE grade 3 cardiac event (including CHF NYHA III or IV)
	Cardiac – QTc prolongation: please refer to Section 7.4.4 LVEF – asymptomatic drop - please refer to Section 7.4.5
<i>Renal</i>	Calculated GFR ¹ ≤ 30 ml/min but ≥ 20 mL/min for > 7 consecutive days
	Calculated GFR ¹ < 20 mL/min, or chronic dialysis or renal transplantation)
	Inability to administer panobinostat for >7 consecutive days past the intended day of dosing due to CTCAE grade ≥2 creatinine elevation
	≥CTCAE grade 3 serum creatinine
<i>Other / any</i>	Any CTCAE grade 3 event lasting >7 days to resolve to grade ≤1 or recurring in the same cycle
	Any CTCAE grade 4 event despite of appropriate (prophylactic) treatment
<i>Treatment delays or omissions</i>	Defined as DLT if: <ul style="list-style-type: none"> Day 1 of next cycle is delayed >7 days of intended dose due to failure to recover from treatment-related toxicity Any panobinostat dose in cycle 1 is omitted due to a panobinostat-related toxicity