

Flowchart HGUS 62113-55115:

	Prior to registration	Study treatment period		End of protocol treatment	Post-treatment period	Follow-up
		Prior to randomization <sup>5</sup>	Within 3 days prior to each cycle	Within 30 days after last dose	30 - 37 days after last dose <sup>5</sup>	
Informed consent	X					
Medical history		X				
Physical examination (PS, body weight, height*, blood pressure, temperature)	Weight & Height	X	X	X		X****
Demographics	X*					
Tumor tissue sent for central pathology review		To be sent immediately after registration				
Adverse event**		X	X	X <sup>13</sup>		X****
Clinical laboratory tests <sup>1</sup>		X <sup>u</sup>	X <sup>2</sup>		X	X****
Urine analysis and UPCR ☼		X <sup>u</sup>	X <sup>2</sup>		X	X****
PT/INR, PTT		X <sup>u</sup>	X <sup>4</sup>			
TFTs (TSH, free T3, free T4) <sup>5</sup>		X <sup>u</sup>	X		X	
12-lead ECG		X <sup>3</sup>	X <sup>4</sup>	X		X <sup>4</sup> ****
LVEF		X	X <sup>7</sup>	X <sup>7</sup>	X <sup>7</sup>	X <sup>7</sup> ****
Pregnancy test <sup>6</sup>		X <sup>u</sup>	X		X	
Disease evaluation J II	X	X	X <sup>6</sup> ⚠	X <sup>9</sup>		X <sup>9</sup>
QoL ▲	X	X	X <sup>10</sup>	X		
TR samples ♣		X	X <sup>11</sup>	X		
Treatment given after disease progression					X <sup>12</sup>	X <sup>12</sup>
Survival					X	X