

To: European Medicines Agency

Palermo, 7th October 2022

Dear EudraCT Team,

We inform you that the study entitled "**Controlled randomized pilot study for characterization and identification of CD34+ stem cells in the splanchnic district after G-CSF stimulation in cirrhotic patients**", and identified by our Center with the code IRRB/19/09, has been interrupted prematurely on 12th October 2012 (end data of the trial). Regarding to the information on 'the last patient, last visit': the last visit was performed on 3rd August 2012. The reason of the interruption was because in the first 5 enrolled patients we measured, by cytofluorimetry, a median of '0.74 CD34 positive cell' in the blood samplings withdrawn. Then, by considering, the potential harmful effect of G-CSF in cirrhotic patients and the low probability to find a significant statistical result completing the study we decided to conclude the clinical study in advance. We did not record side effects due to G-CSF injection.

In attachment the study protocol in brief.

We remain at disposal for any further question and information.

Thank you.

Best regards,

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