



Bresso (Milan), June 13, 2024

**RE: Declaration of early termination of Clinical Study PREFOCIR 2 "*Cross-over pharmacokinetics study and pharmacodynamics of two different folates (5-MTHF and folic acid) in patients with liver cirrhosis of viral etiology. A randomized, open-label trial.*"**

**EudraCT Number 2011-005643-26.**

To whom it may concern

Zambon Italia Srl, as Sponsor of the above-mentioned clinical study declares that 15 patients were enrolled and randomized in this clinical trial. However, the Sponsor decided to early terminate the PREFOCIR 2 study due to issues related to IMP labelling, since that made impossible to clearly establish proper correlation between each patient and the assigned treatment. No data are available because no plasma samples analyses were carried out after the study termination.

If you have any questions or require additional information, please contact:

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