

September 2009

Dear Valued Customer,

In our previous customer letter related to the HOVON 82 study in February of this year (http://www.interceptbloodsystem.com/customer_letter_pdfs/CERS_2009-02_Platelets-HOVON_status.pdf), we committed to provide an update with additional information related to the study when it became available. Accordingly, we provide the following information.

- An AABB abstract was published this week, entitled “Clinical Effectiveness and Safety of Pooled, Random Donor Platelet Concentrates, Leucoreduced and Stored up to Seven Days in Either Plasma or Additive Solution with and Without Pathogen Reduction in Hemato-oncological Patients.”
- The results reported in the abstract are inconsistent with data reported from previous well-powered, blinded, randomized clinical studies and in extensive routine clinical practice.
- The AABB abstract contains no information about the study conditions that might suggest a reason for the discrepancy in the study results. However, customers should be aware of the following facts:
 - The study protocol contains no provisions for blinding, nor for use of a validated assessment tool for evaluation of haemostasis.
 - The distributions of transfusions per patient were not comparable between study arms.
 - The interim study report on which the abstract was based noted that 73% of the patients in the INTERCEPT arm received off-protocol platelet products during the course of the study. This data calls into question any conclusions from the study.
- There are a number of other confounding factors presented in the interim study report. Cerus is prepared to provide further information and details to address concerns and provide appropriate context to correctly evaluate data presented from the study.

In light of the above considerations, combined with the extensive safety and efficacy data already available, we remain confident in our conclusion that there are no safety or efficacy concerns related to transfusion of INTERCEPT platelet components.

INTERCEPT has been in routine use for several years in centers throughout Europe with an estimated 400,000 transfusions to date. No safety or efficacy concerns have been reported from this routine use, even among the >35,000 transfusions which have been closely monitored in an active hemovigilance program. Peer-reviewed publications describing this clinical experience have been published and are available on request.

Further, the platelet components prepared with the INTERCEPT Blood System have received independent national registrations from established European regulatory authorities (Afssaps, PEI, Swissmedic).

Please feel free to contact us at any time with your questions on this matter.

Yours sincerely,

Cerus BV