



February, 2009

Dear Valued Customer,

We have recently been informed of the early conclusion of INTERCEPT data collection for the HOVON 82 "TriPlate" study. We would like to take this opportunity to share with you the information currently provided to us by HOVON and Sanquin, to review information regarding the safety and efficacy of INTERCEPT Platelets, and to outline the steps we will take to clarify the results of this trial and ensure that you receive updated information as it becomes available.

The HOVON 82 study is a three-arm clinical trial comparing (a) platelets collected in 100% plasma, (b) platelets collected in reduced plasma (35%) with Intersol platelet additive solution, and (c) platelets collected in reduced plasma with Intersol and treated with the INTERCEPT Blood System. Platelet components are stored for up to 7 days and all are treated with gamma irradiation when ordered by treating physicians. The study was designed to include approximately 300 patients, resulting in approximately 100 patients for each study arm. The primary endpoint is 1-hour CCI, and secondary endpoints include 24-hour CCI and measures of hemostatic efficacy and safety. The study has been conducted by the HOVON foundation of Dutch oncology centers, in the role of principal investigator, with Sanquin supplying blood products. The study was initiated in 2007.

Cerus was not involved in the design, conduct or data analysis for the HOVON 82 study. Periodically, we have received informal reports that the study was ongoing and that the study was projected to finish in late 2008 or early 2009. Recently, we were informed that enrollment had been halted in the INTERCEPT test arm due to observation of lower CCI data. Cerus has not received data or analyses related to INTERCEPT or the other treatment conditions, and we understand from the study organizers that their analysis of the data is ongoing.

Apart from the HOVON 82 study, the efficacy and safety of INTERCEPT Platelets have been evaluated in eight Phase III/IV clinical studies and an ongoing haemovigilance program documenting over 30,000 transfusions to more than 5000 patients. In comparison to untreated platelets, some studies have observed reduced CI and/or CCI values for INTERCEPT Platelets. However, the studies have not shown clinically significant differences in hemostatic efficacy, and the data supported our 2002 CE mark approval confirming that INTERCEPT Platelets are not clinically different from conventional platelets. Furthermore, the INTERCEPT Platelet clinical dossier has been reviewed and approved by both Afssaps and the Paul Ehrlich Institute.

Our hemovigilance data have documented INTERCEPT Platelet safety in a broad patient population, and longitudinal analyses by long-term users in Belgium and France before and after INTERCEPT implementation have not revealed increased use of platelet components to patients receiving pathogen inactivated platelets.

We are confident that any results emerging from the HOVON data analysis will not change the safety and efficacy conclusions from the existing body of INTERCEPT studies. A summary of these studies is attached for your convenience.

We take the safety and efficacy of our products very seriously. We are in contact with the HOVON study investigators, and are attempting to gain access to the trial data. As soon as results are available to us, and in cooperation with HOVON, we will provide you with updated information.

Thank you for choosing INTERCEPT as your platelet pathogen inactivation treatment. Please feel free to contact us at any time with your questions on this or any other matter.

With kind regards,

Cerus Europe BV



Platelet Clinical Trials

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Buffy-Coat Platelets (EuroSprite Phase III Clinical Trial)

Trial Size:	103 patients (52 INTERCEPT + 51 control)
Primary Endpoint:	1-hour CI, 1-hour CCI
Study Sites:	Rotterdam, Netherlands Stockholm, Sweden Bristol, UK Strasbourg, France

This was a randomized, controlled, double-blinded clinical trial with 103 patients to evaluate the efficacy and safety of pooled buffy-coat platelets treated with the INTERCEPT Blood System. The majority (90 out of 103) of patients had a primary diagnosis of hematological diseases. Each patient received either untreated reference or INTERCEPT treated platelets for up to an 8-week period of transfusion support followed by a 4 week surveillance period. Efficacy data on platelet CI/CCI and safety data using assessments of clinical hemostasis based on WHO bleeding scores are reviewed in the following summary. Full results of the clinical trial have been reported (D van Rhenen et al. *Blood* 2003;101(6):2426-33).

The mean 1-hour CI for the INTERCEPT group ($27 \times 10^9/L$) was significantly less than the mean 1-hour CI for the reference group ($36 \times 10^9/L$, $p=0.03$). Similarly, the mean 24-hour CI for the INTERCEPT group ($16.4 \times 10^9/L$) was also significantly less than the mean 24-hour CI for the reference group ($24.7 \times 10^9/L$, $p=0.004$). However the mean INTERCEPT platelet dose was $3.89 \pm 1.0 \times 10^{11}$ per transfusion compared to $4.32 \pm 1.2 \times 10^{11}$ per transfusion for the reference group ($p \leq 0.001$). When the 1-hour CI was corrected for body size and platelet dose using the CCI, there was no significant difference between INTERCEPT (13.1×10^3) and reference (14.9×10^3) groups. However, there was a significant difference in the 24-hour CCI between INTERCEPT (7.4×10^3) and reference (10.6×10^3) groups. When all transfusions (INTERCEPT = 390; reference = 256) were analyzed for 1- and 24-hour platelet count increments using longitudinal regression analysis with multiple covariates, INTERCEPT platelets and reference platelets demonstrated comparable 1-hour CI ($p=0.53$) and 24-hour CI ($p=0.19$) for equal platelet doses.

Despite the observed differences in the 1-hour CI, 24-hour CI, and 24-hour CCI, INTERCEPT platelets demonstrated similar hemostatic efficacy to reference platelets. Before platelet transfusion, 71% of patients in the INTERCEPT group and 63% patients in the reference group had at least one episode of bleeding. After platelet transfusion the incidence of bleeding events was lower and similar in both groups (54% INTERCEPT and 49% reference; $p=0.62$).

CONCLUSIONS: The results of this trial show that equal doses of INTERCEPT buffy coat platelets provided similar 1- and 24-hour post-transfusion platelet CI, and patients treated with INTERCEPT buffy coat platelets exhibited adverse event profiles similar to those who received reference platelets.

Apheresis Platelets (SPRINT Phase III Clinical Trial)

Trial Size:	645 patients (318 INTERCEPT + 327 control)
Primary Endpoint:	Proportion of patients with Grade 2 bleeding (WHO criteria)
Study Sites:	12 blood centers in the United States

This was a randomized, controlled, double-blinded clinical trial with 645 patients to evaluate the efficacy and safety of apheresis platelets treated with the INTERCEPT Blood System. The majority (565 out of 645) of patients had a primary diagnosis of hematological diseases and 75% of patients in each group underwent hematopoietic stem cell transplant (HSCT). Each patient received either untreated reference or INTERCEPT treated platelets for up to a 4-week period of transfusion support followed by a one week surveillance period. Efficacy data on the proportion of patients with WHO Grade 2 bleeding and platelet CI/CCI are summarized in the following sections. Full clinical trial results have been published previously (J McCullough et al. *Blood* 2004;104(5):1534-41, S Murphy et al. *Transfusion* 2006;46(1):24-33, S Murphy et al. *Transfusion* 2006;46(1):24-33).

SPRINT was a powered non-inferiority trial to detect a small difference in Grade 2 bleeding in patients. The primary endpoint of the trial was met despite significant differences in the surrogate efficacy endpoints. INTERCEPT platelets were not inferior to reference platelets in maintaining hemostasis in severely thrombocytopenic patients for up to 28 days. The proportion of patients with Grade 2 bleeding was 58.5% for INTERCEPT group compared to 57.5% for reference group. The trial was not highly powered to demonstrate small differences in more severe bleeding of WHO Grades 3 or 4. These grades of bleeding were comparable between treatment groups (4.1% INTERCEPT group compared to 6.1% Reference group).

The mean 1-hour and 24-hour CI for the INTERCEPT group ($21.4 \times 10^9/L$ and $13.2 \times 10^9/L$) was significantly less ($p < 0.001$) than the mean 1-hour and 24-hour CI for the Reference group ($34.1 \times 10^9/L$ and $21.5 \times 10^9/L$). Similarly, the mean 1-hour and 24-hour CCI for the INTERCEPT group (11.1×10^3 and 6.7×10^3) was significantly less ($p < 0.001$) than the mean 1-hour and 24-hour CCI for the Reference group (16.0×10^3 and 10.1×10^3). Similar to the buffy-coat clinical trial, this finding primarily reflected the lower mean platelet dose of 3.7×10^{11} per transfusion in the INTERCEPT group compared to 4.0×10^{11} per transfusion in the Reference group ($p < 0.001$).

The time to onset of Grade 2 bleeding after beginning the study was not significantly different between INTERCEPT patients and reference patients ($p = 0.78$). However, Grade 2 bleeding occurred on a mean of 3.2 days in the INTERCEPT group as compared with 2.5 days in the reference group ($p = 0.02$). This finding again reflected the differences in the mean platelet dose per transfusion in the two groups. More INTERCEPT patients received platelet doses containing less than 3.0×10^{11} ($n = 190$) than reference patients ($n = 118$, $p < 0.01$). Comparison of patients receiving comparable platelet doses showed no significant differences between INTERCEPT and reference groups for bleeding or number of platelet or RBC transfusions; despite observation that the CI in response to INTERCEPT platelets (and transfusion intervals) were statistically significantly greater for the reference group. The lower CI values for INTERCEPT platelets suggested that some platelet injury may occur during the INTERCEPT process. This injury does not appear to result in a detectable increase in bleeding, however (S Murphy et al. *Transfusion* 2006;46(1):24-33).

CONCLUSIONS: These data support the conclusion that INTERCEPT platelets may be used according to standard transfusion guidelines whenever platelet transfusions are required. INTERCEPT platelets appear to be safe and effective in management of thrombocytopenic patients.

Pediatric Study

Trial Size:	83 patients (all INTERCEPT)
Primary Endpoint:	Frequency of acute transfusion reactions
Study Site:	Gent, Belgium

Following the CE mark registration, an investigator study of INTERCEPT Platelets in the pediatric population in routine clinical setting has been conducted in one center in Belgium (I Van Haute et al. *Vox Sang* 2006;91(s3):177).

The investigators transfused 500 INTERCEPT platelet components prepared by the buffy coat method to 83 pediatric patients with predominately hematology-oncology diagnoses. The platelet concentrates were prepared by pooling 5 whole blood-derived buffy coats. The pooled platelets were leukoreduced by filtration followed by INTERCEPT treatment for pathogen and leukocyte inactivation. The INTERCEPT Platelet concentrates were not gamma irradiated or tested for CMV. Platelet transfusions were ordered according to hospital guidelines and patients managed according to hospital clinical practice. Eligible pediatric patients were thrombocytopenic, expected to develop thrombocytopenia, diagnosed with a condition associated with thrombocytopenia or receiving therapy that will result in severe thrombocytopenia. Patients were mainly in oncology. Safety and efficacy, assessed by registration of adverse reactions < 24h after transfusion and calculation of corrected count increment [CCI] < 1.5hr post transfusion, were monitored.

Of the 500 transfusions, seven acute transfusion reactions in 6 patients have been noted. No transfusion reactions were of clinical severity greater than grade 1, including fever, urticaria, skin rash, nausea, vomiting, and abdominal pain. Bacterial cultures on INTERCEPT Platelet concentrates were negative. Efficacy was assessed for 493 of the 500 transfused INTERCEPT platelet concentrates. Transfusion episodes per patient was a mean of 6 (range 1 to 49). The number of platelets transfused per unit was a mean of 3.1×10^{11} . Mean platelet 1-hour CCI per transfusion episode was 12,300 (SD 9,450).

CONCLUSIONS: Transfusion of pediatric patients with INTERCEPT platelets provided therapeutic count increments. No unexpected transfusion reactions were attributed specifically to the use of INTERCEPT Platelets.

Open-Label Transfusion Study - Germany

Trial Size:	52 patients (all INTERCEPT)
Primary Endpoint:	Frequency of acute platelet transfusion reactions
Study Site:	University Lünebeck, Germany

This was an observational, single arm, open label study (P Schlenke et al. 2007 *Vox Sang* 2007;93:(s1):171). INTERCEPT platelets were transfused into thrombocytopenic patients according to standard local practices. The primary endpoint was the frequency of overall acute platelet transfusion reactions. INTERCEPT Blood System for platelets was used in place of gamma irradiation for prevention of TA-GVHD. Fifty-two patients were enrolled (54% male/ 46% female) with a median age of 57.5 yrs (range 22 to 78 yrs). All patients had hematological malignancy as primary disease with the largest proportion 40.4% (21/52) having a diagnosis of Acute Myelogenous Leukemia (AML). Most patients had received chemotherapy without stem cell transplant in 65.4% (34/52) and while 32.7% (17/52) patients had received autologous stem cell transplant with chemotherapy and/or radiotherapy.

A total of 560 INTERCEPT platelet components were administered with the mean number of transfusions per patient being 11.0 (median = 6, range 1-71). For 553 reported transfusions, 10 acute transfusion reactions were associated with 9 transfusions (ATR, 1.6%). All ATR were of low Grade 1 severity. Mean 24- hour CI and CCI were $10.9 \times 10^9/L$ and 6.6×10^3 , respectively.

CONCLUSIONS: No bleeding complications were attributable to the INTERCEPT platelets. This study confirmed the safety and efficacy of INTERCEPT platelets for support of thrombocytopenia.

Open-Label Transfusion Study - Switzerland

Trial Size:	46 patients (all INTERCEPT)
Primary Endpoint:	Frequency of acute platelet transfusion reactions
Study Site:	University Hospital Basel, Switzerland

This was an observational, single arm, open label study (L Infanti et al. *Vox Sang* 2008; 95(s1):289). INTERCEPT platelets were transfused into thrombocytopenic patients according to standard local practices. The primary endpoint was the frequency of overall acute transfusion reactions (ATR). INTERCEPT Blood System for platelets was used in place of gamma irradiation for prevention of TA-GVHD.

A total of 551 INTERCEPT platelet components were administered to 46 patients (61% male/39% female), median age 52.8 yrs (range 22 to 80 yrs). The majority (38 patients, 82.6%) of the patients had hematological malignancy as primary disease receiving chemotherapy without stem cell transplant (22 patients) or with stem cell transplant (12 allogeneic, 3 autologous). Preliminary analysis showed that the mean number of transfusion per patient was 12.0 ± 12.52 (range 1-58) and the mean 1-hour CCI was $10.12 \pm 8.06 \times 10^3$.

The rate of adverse events reported in this study was low; 97.8% of INTERCEPT platelet transfusions were without reported ATR.

CONCLUSIONS: This observational study found that transfusions with INTERCEPT platelets were well tolerated, in routine use and exhibited a safety profile consistent with that generally observed with conventional platelet components.

Post-Marketing Surveillance – Summary to Date

Transfusions Monitored: 31,225
 Study Sites: 21 sites / 11 countries

An active haemovigilance (HV) program was implemented following CE marking of INTERCEPT Blood System for platelets. This is an open label observational surveillance program to characterize and extend the safety profile of transfusing platelet components treated with the INTERCEPT process in a routine use setting and to document any unexpected adverse events that were not reported in early clinical trials and in patient populations that were not studied before. Please refer to haemovigilance publications for detailed analysis (Osselaer et al. *Vox Sang* 2008;94;(4):315-323, Osselaer et al. *Transfusion* 2008;48(6):1061-71, Osselaer et al. *Vox Sang* 2008; 95(s1):284, Osselaer et al. *Transfusion* 2009:in press, Cazenave et al. *Vox Sang* 2008;95(s1):302-6).

INTERCEPT Haemovigilance Program

Study	Transfusions	Countries	Sites	Locations
HV1	5,106	4	5	Mont Godinne, Belgium Pescara, Italy Bergen, Norway Trondheim, Norway Madrid, Spain
HV2	7,437	3	7	Brugge, Belgium Erasme, Belgium Mont Godinne, Belgium Rennes, France Strasbourg, France St Etienne, France Valladolid, Spain
HV3 (open)	~4,800*	8	11	Luebeck, Germany La Reunion, France Rennes, France St Etienne, France Reykjavik, Iceland Bergen, Norway Lisbon, Portugal Barcelona, Spain Madrid, Spain Uppsala, Sweden Basel, Switzerland
EFS Alsace	13,241	1	1	Strasbourg, France
Pediatric	641	2	2	Vienna, Austria Gent, Belgium

* Including 1,950 transfusions in La Reunion during CHKV epidemic and 489 transfusions in pediatric patients

To date approximately 200,000 doses of INTERCEPT platelets have been administered in patients and over 30,000 transfusions have been documented in the HV program. Data are summarized in three large interim analyses:

INTERIM ANALYSIS #1

One of the interim analyses was a meta-analysis of 16,631 transfusions of INTERCEPT platelet components to 3,274 patients (1,973 (60.3%) males/ 1297 (39.7%) females) with a mean age of 57 years (range <1 to 96 years) (Osselaer et al. *Vox Sang* 2008;94;(4):315-323, Osselaer et al. *Transfusion* 2008;48(6):1061-71, Rasongles et al. *Vox Sang* 2008;95(s1):15). Half of the recipients were hematology/oncology patients (1,643, or 50.2%) many of whom received hematopoietic stem cell transplants (n=307).

Transfusions associated with “related” (possibly related, probably related, or related) adverse events following INTERCEPT platelet transfusion were infrequent (110/16,631 n=0.66%). Eighty-two pts (2.5%) experienced at least one related adverse event following one or more INTERCEPT transfusion. Most reactions were of grade 1 severity and were representative of the events expected with conventional platelet transfusion. The most frequently reported signs/symptoms were chills, fever, and urticaria. Eleven SAE’s were reported, with one having causal relationship (hypotension possibly related) to INTERCEPT platelet transfusion. No cases of Transfusion Related Acute Lung Injury (TRALI), TA-GVHD, transfusion-related sepsis, or death due to an INTERCEPT transfusion were reported.

CONCLUSIONS: In summary, 99.34% of INTERCEPT platelet administrations were without a related transfusion reaction. Adverse events following INTERCEPT platelet transfusions classified as related to transfusions were infrequent, mild in severity, and representative of the events expected with platelet transfusion.

INTERIM ANALYSIS #2

The second analysis was based on the routine use experience from EFS-Alsace (Cazenave et al. *Vox Sang* 2008;95(s1):302-6). More than 99% of the patients hospitalized in Alsace that were transfused, according to conventional medical indications, in period 1 (1/1/2003-1/2/2004) with conventional leukoreduced platelet components (100% plasma) or in period 2 (1/9/2006-1/8/2007) with leukoreduced inactivated platelet components (INTERCEPT). Platelet components were prepared either from apheresis or buffy-coats (40/60). The average dose for all platelet components was $4.2 \pm 0.8 \times 10^{11}$. The demography of patients for both periods 1 versus 2 were, respectively, similar in terms of number of patients, age, and gender, and clinical indications: oncohematology (56%/58%), cardiovascular surgery (7%/6%), general medicine and surgery (37%/36%).

The number of platelet components transfused in period 1 was 10,629 (to 2,050 patients); and during period 2, 13,241 (to 2,069 patients) INTERCEPT platelet components were transfused. Although processing conditions changed during the two periods, the mean total dose of platelets per patient required in each period remained the same (26.0×10^{11} vs. 27.0×10^{11}). Thus no increase in platelet utilization was observed. During periods 1 and 2, 83.7%/85.2% of patients receiving platelet components were transfused with red blood cell concentrates (RBCC). Mean RBCC transfusions were similar in both periods (14.4 vs. 13.5 units/patient). Responses to platelet transfusion within 48 hours after transfusions were reported for $\geq 99.4\%$ platelet components transfused. The incidence of transfusion reactions per transfusion and per patient decreased with INTERCEPT platelet components (0.53% vs. 0.14% per transfusion, or 2.9% vs. 1.7% per patient). During the two periods, severity and imputation of transfusion reactions was similar and no bacterial sepsis was reported.

CONCLUSIONS: In summary, transfusion of platelet components treated with INTERCEPT to a broad patient population for a spectrum of indications was well tolerated in routine practice. The incidence of adverse events was less than untreated platelet components suspended in plasma. INTERCEPT offers the potential to improve the safety and availability of platelet components for transfusion. Importantly, an increase in the total platelet dose and RBCC transfused to patients in this study was not observed.

INTERIM ANALYSIS #3

The third analysis was based on the routine use experience in the Blood Transfusion Center of Cliniques Universitaires Mont Godinne (Osselaer et al. *Vox Sang* 2008;95(s1):284. Universal routine use of INTERCEPT platelets were initiated in 2003 for transfusion support of patients with thrombocytopenia. The blood component usage and clinical outcome observed for 3 years after adoption of INTERCEPT was compared to those observed during 3 years before INTERCEPT adoption.

The number of patients supported with platelets increased in the period after adoption of INTERCEPT, and approximately 91% required RBCC transfusions in both periods. The distributions (%) of indications for platelet transfusions (Hematology/Cardiovascular Surgery/Medical/Oncology), respectively, were approximately similar in the two periods (Pre: 39/32/22/7 vs. Post: 34/35/22/9). To compensate for loss of platelets due to INTERCEPT processing, approximately 10% more platelets were harvested for INTERCEPT components, resulting in larger average platelet collections (6.3 vs 6.8×10^{11}).

Days of platelet transfusion support (14.2 vs. 13.1), number of platelet transfusions per patient (9.9 vs. 10.1), and total platelet dose per patient (41.5×10^{11} vs. 42.0×10^{11}) did not increase significantly with universal implementation of INTERCEPT. INTERCEPT platelets had no impact on RBCC use.

CONCLUSIONS: In summary, the adoption of INTERCEPT Blood System into routine practice did not affect platelet or RBCC component usage over a 3 year observation period.

OVERALL POST-MARKETING SAFETY EXPERIENCE CONCLUSION: Periodic review of post-marketing surveillance data by Cerus indicates that INTERCEPT Platelet components, transfused in routine practice to a broad patient population, are safe and well tolerated. No unexpected safety issues related to the INTERCEPT Platelet product have been identified.

EUROSPRITE TRIAL

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SPRINT TRIAL

McCullough J, Vesole DH, Benjamin RJ et al. Therapeutic efficacy and safety of platelets treated with a photochemical process for pathogen inactivation: the SPRINT Trial. *Blood* 2004;104(5):1534-41.

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HAEMOVIGILANCE PROGRAM

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Rasongles P, Angelini-Tibert MF, Simon P et al. Transfusion of platelet components prepared with photochemical pathogen inactivation treatment during a chikungunya virus epidemic in Ile de la Reunion. *Transfusion* 2009. In press.

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Janetzko K, Cazenave JP, Kluter H et al. Therapeutic efficacy and safety of photochemically treated apheresis platelets processed with an optimized integrated set. *Transfusion* 2005;45(9):1443-52.

Simonsen AC, Johansson PI, Conlan MG et al. Transfusion of 7-day-old amotosalen photochemically treated buffy-coat platelets to patients with thrombocytopenia: a pilot study. *Transfusion* 2006;46(3):424-33.

Slichter SJ, Raife TJ, Davis K et al. Platelets photochemically treated with amotosalen HCl and ultraviolet A light correct prolonged bleeding times in patients with thrombocytopenia. *Transfusion* 2006;46(5):731-40.

Snyder E, Raife T, Lin L et al. Recovery and life span of ¹¹¹indium-radiolabeled platelets treated with pathogen inactivation with amotosalen HCl (S-59) and ultraviolet A light. *Transfusion* 2004;44(12):1732-40.

van Rhenen DJ, Gulliksson H, Cazenave JP, et al. Therapeutic efficacy of pooled buffy-coat platelet components prepared and stored with a platelet additive solution. *Transfus Med* 2004;14(4):289-95.