The Need for Pathogen Inactivation, and Choice of the INTERCEPT Blood System

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Agenda

- Why pathogen inactivation?
- Why INTERCEPT?
  - Product description
  - Safety
    - » Robustness: MOA, Process Control
    - » Pathogen Inactivation Efficacy
    - » Emerging pathogens
  - Operational efficiency
    - » Allows for increased availability
- Highest quality end product
  - Defined therapeutic efficacy and safety
  - Preserves platelet function and plasma proteins activity
  - HV program: Documented reduction in adverse events
- INTERCEPT as the choice for PI

Why Pathogen Inactivation?

- Recent concerns over emerging pathogens such as H1N1, West Nile virus, and dengue
- Bacterial contamination transmitted by platelets has occurred and can cause sepsis and fatalities; detection technologies are insufficient
- Pathogen inactivation steps are already standard for plasma derivatives and transfused biologics
- Pathogen inactivation can provide blood components that offer the same efficacy, but with an extra margin of safety and with fewer reactions

The safety standards of plasma derivatives are now possible for platelets and plasma for transfusion.

Avoiding Risk with the INTERCEPT Blood System: Quality Product - with the Security of Pathogen Inactivation

- Precautionary principle for emerging pathogens
  - In 2007 and 2008, panels of international experts advised that due to concerns over emerging pathogens, use of a proactive approach such as pathogen inactivation be required. **This statement has proven to be correct, in light of the recent H1N1 Pandemic.**
- Many published articles reference concern over the transmission of blood born pathogens.
- Addresses bacterial risk like no other technology
- Consistent with PI standards already in place for plasma derivatives
- Helps increase availability (logistics and economical impact)

INTERCEPT in Europe & Middle East

Routine use in >100 blood centers in 17 countries

[Belgium, France, Greece, Italy, Spain, Sweden, Norway, Slovenia, Kuwait, Saudi Arabia, Chile, Portugal, Russia, Kazakstan, Switzerland, Qatar, Ukraine]

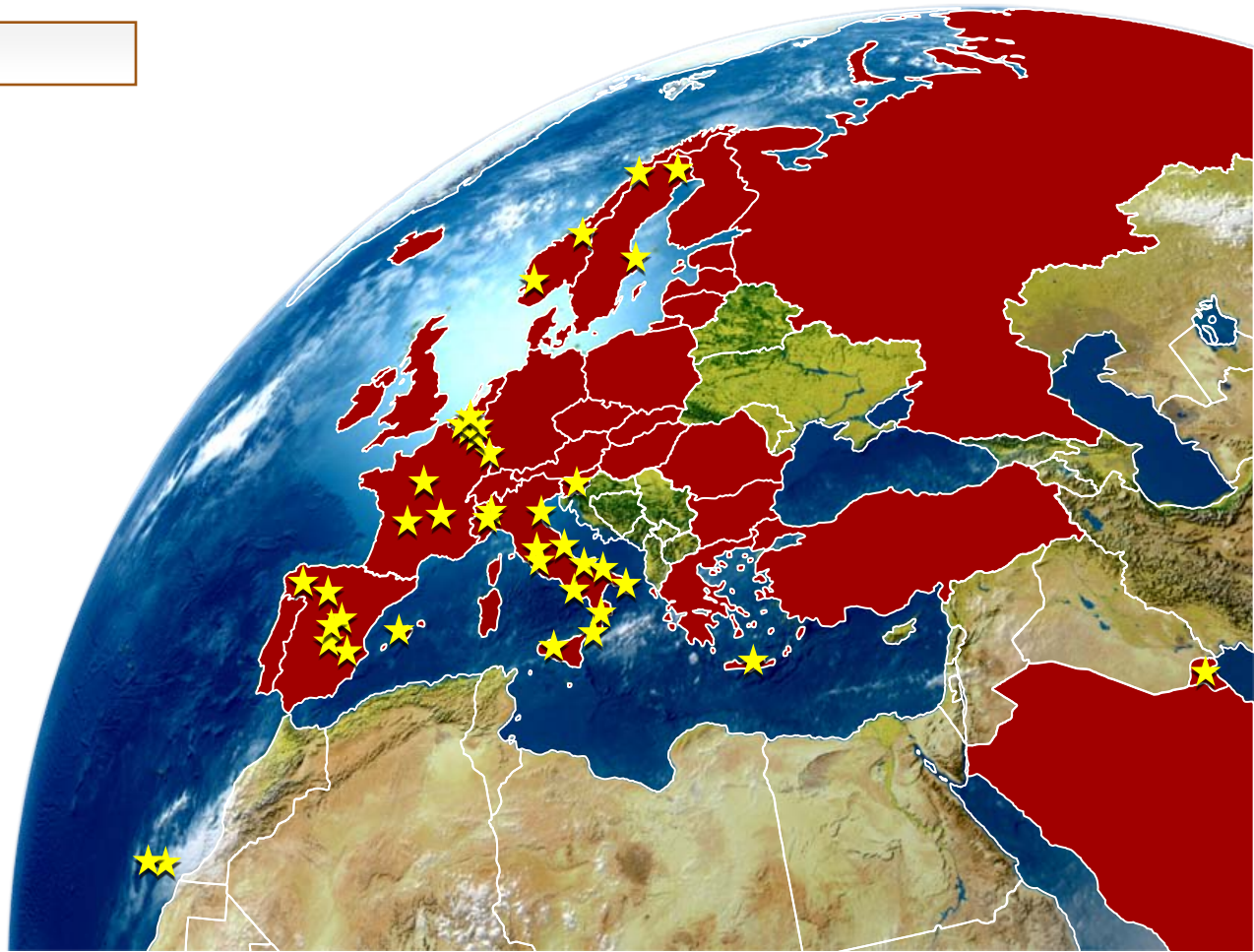
Regulatory Approvals

- **CE mark – 2002 (plt), 2006 (ffp)**
- **Afssaps – 2003 (plt), 2007 (ffp)**
- **PEI – 2007 (1st plt MA)**
- **Swissmedic – 2009**

Transfusion Experience

- **>1,250,000 transfusions**
- **>60,000 in HV program**

Clinical studies or ongoing evaluation in additional centers and countries, including Estonia, Germany, Ireland, Portugal, Luxembourg, Poland, Iceland, UK, Russia, Qatar



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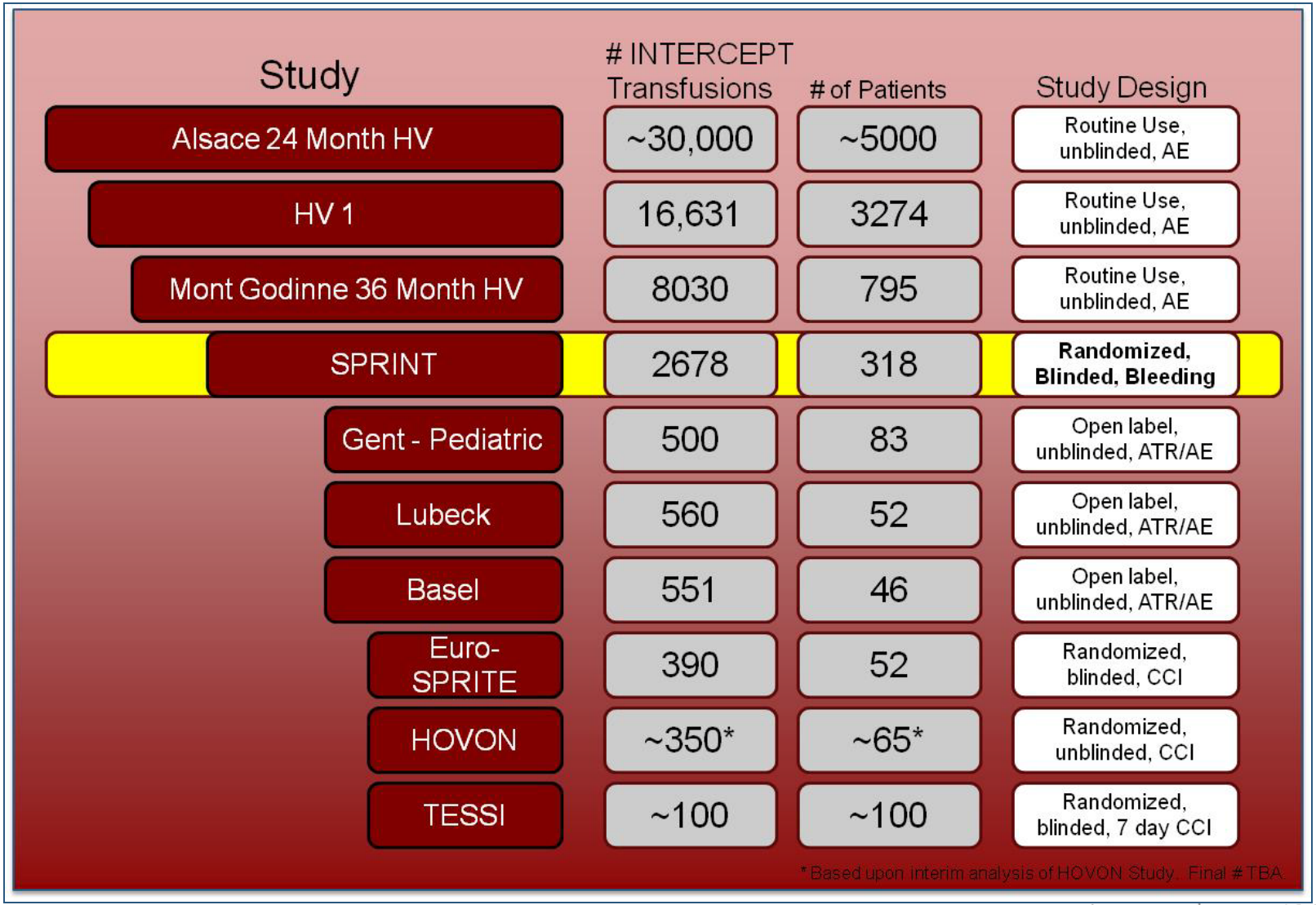
Why INTERCEPT: Proven in Numerous Studies



INTERCEPT Overview
How it Works and Safety Review

Transfuse with Confidence from Day ONE.

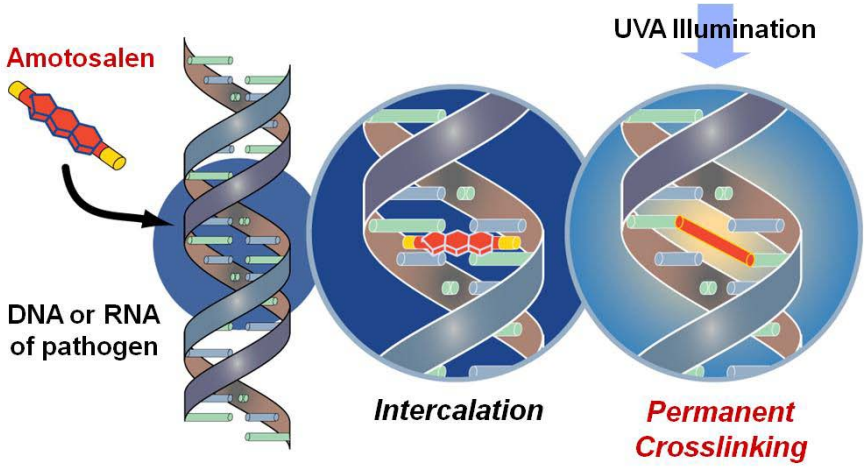
Indications for Use

- INTERCEPT Platelets
  - For transfusion support of patients requiring platelet transfusions according to clinical practice guidelines. INTERCEPT Platelets are not clinically different from untreated platelets.[1]
    - » No patient population exclusions
- INTERCEPT Plasma
  - For support of patients requiring plasma transfusions or exchange, according to clinical practice guidelines. INTERCEPT Plasma is transfused according to standard methods.[1]
    - » No patient population exclusions

[1]Approved product claims.

Mechanism of Action Creates Robust Pathogen Inactivation Efficacy

- Specific mechanism of action against pathogens
  - Minimal non-specific reactions (no active oxygen species)
- Reproducible process
- Multiple points to document process control



The INTERCEPT Blood System for Platelets

Step 1 Amotosalen
Step 2 Illumination
Step 3 CAD
Process Complete Storage

The INTERCEPT Blood System for Plasma

Pathogens Inactivated by INTERCEPT (Approved Label Claims)

Enveloped Viruses

- HIV-1/2
- HBV
- DHBV
- HCV
- BVDV
- HTLV- I/II
- CMV
- WNV
- SARS-CoV4
- Vaccinia4
- Chikungunya5
- Dengue6
- Avian flu virus (H5N1)7

Non-Enveloped Viruses

Bluetongue virus, type 11

Simian adenovirus 15

Feline calcivirus

Parvovirus B19

Human adenovirus 5

Gram-Negative Bacteria

- *Klebsiella pneumoniae*
- *Yersinia enterocolitica*
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Salmonella choleraesuis*
- *Enterobacter cloacae*
- *Serratia marcescens*

Gram-Positive Bacteria

- *Staphylococcus epidermidis*
- *Staphylococcus aureus*
- *Streptococcus pyogenes*
- *Listeria monocytogenes*
- *Corynebacterium minutissimum*
- *Bacillus cereus (vegetative)*
- *Lactobacillus sp.*
- *Bifidobacterium adolescentis*
- *Propionibacterium acnes*
- *Clostridium perfringens*

Spirochetes

- *Treponema pallidum*
- *Borrelia burgdorferi*

Parasites

- *Trypanosoma cruzi*
- *Plasmodium falciparum*
- *Leishmania sp.*
- *Babesia microti*

Leukocytes

INTERCEPT Results in a Quality Product Which is Safer for Patients

Transfuse with Confidence from Day ONE.

Result of INTERCEPT Treatment

- Platelet and plasma components may be used as they were before introduction of pathogen inactivation
  - Used for the same patient populations
  - Used for same indications
- Provides patient with safer product
  - Optimal product for immunocompromised patients
- Has been shown to result in fewer acute transfusion reactions than standard products
- May allow for an increase in supply by improving logistics

Why INTERCEPT is the ONE Choice for Inactivating Platelets & Plasma

Transfuse with Confidence from Day

ONE.

Cerus Stands Behind INTERCEPT:
Proven in Studies and Validated by Third Parties

- Proven in numerous studies
  - The efficacy and safety of INTERCEPT Platelets have been proven in eight Phase III/IV clinical studies and in an ongoing haemovigilance program (documenting over 40,000 transfusions to more than 5000 patients).
  - Studies show that in comparison to untreated platelets, reduced CI and/or CCI values for INTERCEPT Platelets have been seen. Independently, the studies have shown neither clinically significant differences in hemostatic efficacy nor increased platelet or RBC utilization.
- Validated by third parties
  - 2002 CE mark approval as a Class III medical device, confirming that INTERCEPT Platelets are not clinically different from conventional platelets.
  - INTERCEPT Platelet clinical dossier has been approved by ~~both~~ Afssaps, the Paul Ehrlich Institute and Swissmedic.
  - There have not been unexpected adverse events with the routine use of INTERCEPT and this has been monitored extensively in the context of their quality system.

Advantages of Pathogen Inactivation and INTERCEPT

Pathogen Inactivation

- Will increase availability of blood components
- Will protect against emerging pathogens
- Reduce risk of bacterial transmission in platelet units

INTERCEPT

- Documented safety and efficacy in numerous clinical studies
- Approved by third parties (PEI, Afssaps and Swissmedic) and successfully implemented by numerous centers
- INTERCEPT provides “ONE” System for both platelets and plasma
- Provides you with the same quality product, at increased standard of safety

For More Information:

www.InterceptBloodSystem.com

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