



## Overview of Emergent BioSolutions' Biosciences Business

[To Be Spun-Out As Aptevo Therapeutics Mid-2016]

May 2016



## **Forward-Looking Statements**



This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including our financial guidance, and any other statements containing the words "believes", "expects", "anticipates", "intends", "plans", "forecasts", "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this presentation, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including whether the planned spin-off of the biosciences business is completed, as expected or at all, and the timing of any such spin-off; whether the conditions to the spin-off can be satisfied; whether the operational, marketing and strategic benefits of the spin-off can be achieved; whether the costs and expenses of the spin-off can be controlled within expectations; appropriations for BioThrax procurement; our ability to enter into and maintain selective collaboration and partnership arrangements; the timing of and our ability to achieve milestones in collaboration and partnership contracts; our ability to expand our manufacturing facilities and capabilities; our ability and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations; the results of regulatory inspections; the rate and degree of market acceptance and clinical utility of our products; the success of our ongoing and planned development programs; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.



## Spin-Off Announcement (08/06/2015)





#### Biosciences Business Spin-off Establishes Two Highly Attractive Independent Public Companies

Creating opportunities in distinct markets and generating long-term value for shareholders

Tailoring Business Strategies Aligning Appropriate Resources Pursuing Distinct Capital Structures Clarifying Investment Thesis

#### Emergent BioSolutions **New Biosciences Company** Leading Biodefense Company Leading Oncology Platform Recognized as a leader in Innovative ADAPTIR™ platform Industry the biodefense and emerging technology utilizing a promising Leading infectious diseases fields approach in the highly attractive immuno-oncology field since 1998 Leveraging Technology Clarifying Focus Targeted investments in bi- Growing markets Driving specific ADAPTIR therapeutics . Expanding product portfolio Continued · Increased awareness of the · Platform technologies RTCC mechanism of action Success Manufacturing expertise · Enhanced potential for · Attractive M&A opportunities collaboration Accelerating Growth Funding R&D · Continued revenue growth \$50M-\$70M cash contribution Solid Strengthened balance sheet from Emergent **Financial** · Improved cost structure · Commercial product revenue Profile · Enhanced capital deployment · Partnership funding flexibility Future collaborations Proven Leadership Daniel J. Abdun-Nabi Marvin L. White President & CEO President & CEO (designate)



## **Spin-Off Details**



## **Post-Spin**

**Marketed Products** 

**Services** 

**Product Pipeline** 

**Platform Technologies** 

**Employees** 

**Sites** 

**Divisions** 

**Focus** 



emergent Aptevo" 5 CMO: Bulk, Fill, Finish None MFG: Support for SpinCo Clinical: 2 2 Clinical Candidates **Preclinical:** Multiple **Multiple Pre-clinical Candidates** Hyperimmunes | EMERGARD™ **ADAPTIR**<sup>TM</sup> **Anti-bacterials Anti-virals** ~130 ~1250 400P (HQ) | DC (Ofc) **HQ/PD:** Seattle Mfg: Lan, Win, Hatt, Bay, Cam PD: 300P, Mun, Comm'l Ops: Berwyn Comm'l Ops: UK, Sing None **Public Health Threats Public Health Threats** PRIMARY: I/O; Hem-Onc (CBRNE & Emerging **Infectious Diseases**) **SECONDARY: AIID** 

## **Spin-Off Mechanics**



Structure	<ul> <li>Tax-free distribution to Emergent shareholders of common stock of Aptevo</li> <li>Stock distribution ratio to be determined</li> </ul>
Timing	<ul> <li>Transaction anticipated to be completed in mid-2016 (subject to closing conditions)</li> </ul>
Naming	<ul> <li>Aptevo Therapeutics</li> <li>Emergent BioSolutions will retain its name</li> </ul>
Capitalization	<ul> <li>\$50-\$70M from Emergent at time of spin-off</li> </ul>
Operational Relationships	<ul> <li>CMO agreements with Emergent for product manufacturing</li> <li>Transition Service Agreements (TSA) with Emergent for support services</li> </ul>
Closing Conditions	<ul> <li>Receipt of a favorable opinion from outside tax counsel and private letter ruling from the Internal Revenue Service</li> <li>Execution of agreements by Emergent and Aptevo</li> <li>Effectiveness of the Form 10 registration statement</li> <li>Final approval of the transaction by Emergent's board of directors</li> </ul>







Aptevo Therapeutics' **mission** is to extend and enhance patients' lives.

Aptevo Therapeutics' **strategy** is to become a high growth biopharmaceutical company primarily focused on bringing novel oncology and hematology therapeutics to market, leveraging the innovative ADAPTIR platform technology and its unique approach to cancer immunotherapy, in order to meaningfully improve patients' lives.







- 1. Advance the ADAPTIR platform, primarily in I/O;
- 2. Expand collaborations and partnerships;
- 3. Market and sell a product portfolio to meet patients' needs;
- 4. Generate capital to support R&D investment; and
- 5. Enhance our corporate culture to create a sustainable competitive advantage.



## Leadership



## **Senior Management**

#### Marvin White - CEO

Emergent Director; Former CFO, St. Vincent's Health;
 Former Exec. Director & CFO, Lilly USA

#### Jeff Lamothe - SVP, CFO

Emergent VP, Finance; Former CFO, Cangene Corporation

#### Dr. Scott Stromatt - SVP, CMO

Emergent SVP, CMO; Former CMO, Trubion

#### Dr. Jane Gross - VP, Res/Non-Clin. Dev.

 Emergent VP, Research/Non-Clinical Development; Former VP Immunology Research ZymoGenetics Inc.

#### Mike Adelman – VP, Commercial Ops.

 Emergent VP, Commercial Operations; Former, VP Commercial Operations, Cangene Corporation.

#### **Shawnte Mitchell – VP, Gen'l Counsel**

Emergent VP, Associate General Counsel

### **Board of Directors**

#### **Marvin White**

Emergent Director; Former CFO, St. Vincent's Health;
 Former Exec. Director & CFO, Lilly USA

#### Fuad El-Hibri

Founder, Executive Chairman, Emergent BioSolutions

#### **Daniel Abdun-Nabi**

President & CEO, Emergent BioSolutions

#### **Grady Grant, III**

Mead Johnson Nutrition; Eli Lilly & Co.

#### Zsolt Harsanyi, Ph.D.

N-Gene Research Labs; Exponential Biotherapies; Porton Int'l

#### **Barbara Lopez Kunz**

DIA; Battelle; Thermo Fisher Scientific; ICI/Uniqema

#### John Niederhuber, M.D.

Inova Translational Medicine Institute; NCI; Johns Hopkins Univ.



## **Intellectual Property Estate**



- APTEVO will own or exclusively license patent rights protecting
  - IXINITY
  - ADAPTIR
  - otlertuzumab
  - MOR209/ES414
  - ES210
  - ES425
  - 5E3mAb

## **APTEVO'S General Patent Filing and Prosecution Strategy**

- Will seek patent protection on all products and platforms
  - Exception existing hyperimmune products
- Will practice life cycle management
  - File new patent applications as products and related methods evolve
- Will seek broad geographic scope
- Will seek exclusive licenses as available for supporting technologies



## **Product Portfolio**



Product/Candidate	Indication	Pre-Clinical	Clinic	Marketed		
Product/Candidate			Phase I	Phase II	Phase III	iviai keteu
IXINITY	Hemophilia B					
WinRho	ITP					
HepaGam B	HBV					
VARIZIG	Varicella					
Otlertuzumab	CLL					
MOR209/ES414	mCRPC Immuno-oncology		*			
ES210	IBD					
ES425	Hematological , Solid Tumor Malignancies					
5E3 mAb	Alzheimer's Disease					
Additional ADAPTIR Candidates	Immuno-oncology					



## **ADAPTIR Product Pipeline Under Development Using RTCC**



 Validated Platform Technology: Bispecific ADAPTIR molecules have been shown to redirect T-cell cytotoxicity against multiple tumor targets in preclinical models

	Target		Development Activity					
Molecule	Antigen Type	Target Indication(s)	Design	in vitro RTCC	in vivo POC	Tox/IND	Clinical: Phase 1	
αPSMA x αCD3 (MOR209/ES414)	Enzyme (PSMA)	CRPC, RCC, CRC, bladder					*	
αROR-1 x αCD3	Tyrosine Kinase (ROR-1)	Hematologic malignancies and solid tumors						
Coded x αCD3	Undisclosed target	Hematological malignancies						
New RTCC candidates	Undisclosed targets	Several						

<sup>\*</sup> Partnered with MorphoSys.



## **ADAPTIR Product Pipeline Under Development Using RTCC**



#### MOR209/ES414

- Humanized bispecific protein therapeutic targeting PSMA, a prostate cancer tumor antigen, and CD3, a component of the Tcell receptor
- Extended half-life
- Partnered with MorphoSys AG
- Phase 1 development initiated for treatment of metastatic castration-resistant prostate cancer (mCRPC)

### **ROR-1/ES425**

- ROR-1 is expressed in several hematologic malignancies and solid tumors (i.e. CLL, triple-negative breast cancer, ovarian cancer, NSCL, prostate and kidney)
- Advancing rapidly to clinic; in vitro and in vivo POC achieved, initiating IND enabling activities



## **ADAPTIR Bispecific Molecule – Platform Overview**



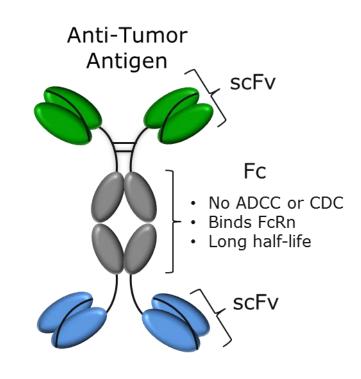
- ADAPTIR<sup>™</sup> (modular protein technology) represents a promising platform technology within the rapidly growing field of immunooncology therapeutics
  - Redirected T-Cell Cytotoxicity (RTCC)
  - Targeted Cytokine Delivery
- ADAPTIR RTCC platform has potential distinct advantages over other immuno-therapeutics and other bispecific T-cell technologies
- In preclinical studies, ADAPTIR therapeutics have demonstrated:
  - High potency, active at low doses
  - Long half-life
  - Minimal side effects
  - Antibody-like manufacturing properties
- ADAPTIR platform is supported by experienced scientific, antibody engineering, manufacturing, and commercial leadership



#### **ADAPTIR Platform – Characteristics**



- Bispecific Platform Technology
  - Focus on RTCC as Immuno-oncology therapeutic
  - Ultimate flexibility for testing different mechanisms of action
- Tailored Fc function (mutations to remove or enhance ADCC and CDC activity)
- Modular technology
  - New bispecifics are readily assembled
  - Rapid screening of different combinations of binding domains, cytokines, receptors
- Scaffold optimized for stability and manufacturability
  - GMP manufacturing up to 2000 L to date



Anti-CD3



## **ADAPTIR Therapeutic Development Capabilities**



#### Facilitate Rapid Drug Development from Concept to Clinic

## **Protein Engineering**

 Generate new binding domains or take partner's mAbs and convert to ADAPTIR format

- Optimize for:
  - Screening to reduce potential for immunogenicity
  - Binding affinity
  - Activity
  - Expression
  - Manufacturability

### **Process Development**

- Generate CHO production cell lines
- Utilize platform cell culture and purification processes, optimize as needed
- Produce material for NHP studies
- Develop formulation

## **Preclinical Development**

- Evaluate new ADAPTIR bispecifics using standard in vitro assays to assess function
- Determine PK and in vivo activity in mouse models
- Assess NHP PK and tolerability with CRO

## **Clinical Manufacturing**

- Experience with GMP process validation, scale-up and tech transfer
- Emergent facilities supports clinical manufacturing and fill-finish of ADAPTIR lead candidates

## Clinical Research & Ops.

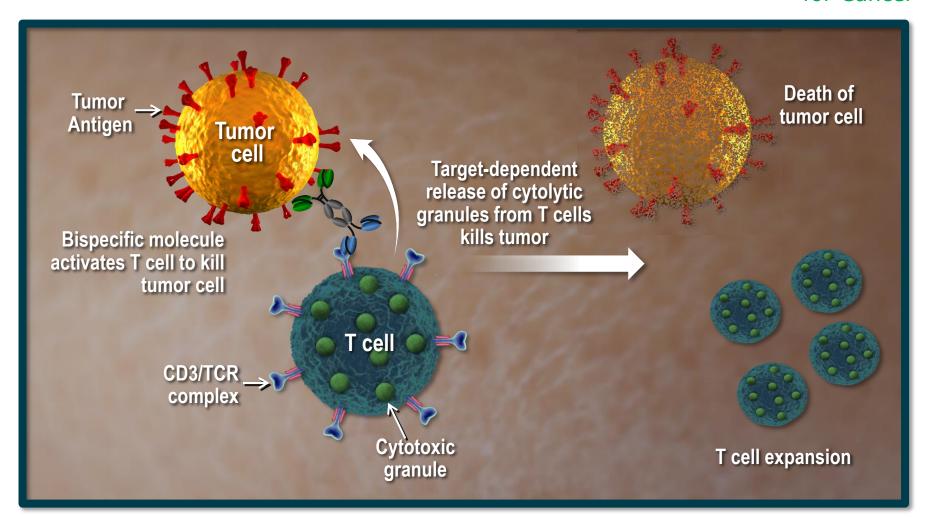
- Regulatory Affairs
- Medical Affairs
- Pharmacovigilence
- Biostatistics



## **ADAPTIR Platform – RTCC Mechanism of Action**



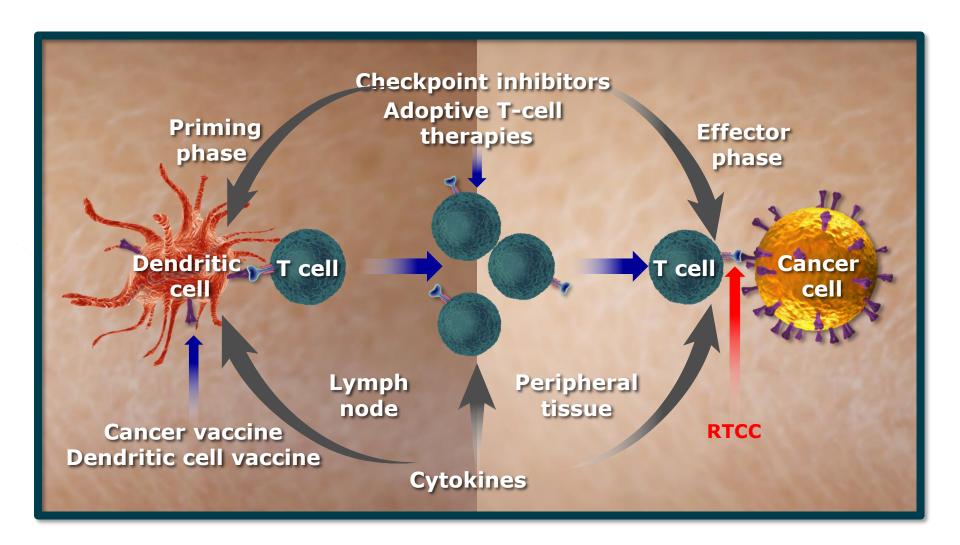
ADAPTIR Bispecific Molecules Mediate RTCC: A Potent Immunotherapeutic for Cancer





# ADAPTIR Platform – Opportunity for Synergy with Immunotherapeutics







## Clinical Stage Candidate – otlertuzumab (CLL)







- Humanized monospecific protein therapeutic targeting the CD37 signaling pathway involved in B-cell malignancies
- Built on ADAPTIR™ (modular protein therapeutic) platform
- Demonstrated anti-tumor activity
- Prolonged serum half-life in mouse and NHP compared to antibody fragments
- In Phase 2 development for treatment of chronic lymphocytic leukemia (CLL)

Partnering

- Currently 100% owned by Emergent BioSolutions (in future Aptevo Therapeutics)
- Actively pursuing potential partnership opportunities

aCD37 scFv

Clinical Development

- Multiple clinical trial data published at ASH 2013, establishing clinical proof-of-concept
- PHASE 2 STUDY (16201): Combination of otlertuzumab and bendamustine in patients with relapsed CLL produced higher response rates than bendamustine alone
- PHASE 1b STUDY (16009): Combination of otlertuzumab and rituximab in patients with previously untreated CLL was active and well tolerated
- Additional triple combination study is underway

**OBJECTIVE:** 

Position to initiate Phase 3 in collaboration with development partner



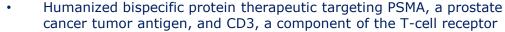
Human IgG₁ Fc

## Clinical Stage Candidate – MOR209/ES414 (mCRPC)







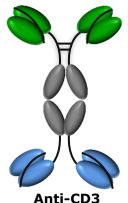


- Built on ADAPTIR™ (modular protein therapeutic) platform
- Demonstrated redirection of T-cells to kill tumor cells expressing PSMA in vitro and in vivo
- Prolonged serum half-life in mouse and NHP compared to antibody fragments
- In Phase 1 development for treatment of metastatic castration-resistant prostate cancer (mCRPC)

**Partnering** 

Co-development/Co-commercialization partnership with MorphoSys AG established August 2014







- PHASE 1 STUDY (ongoing): Evaluate safety, tolerability, and clinical activity in patients with metastatic castration-resistant prostate cancer (mCRPC). The study will be conducted in two stages.
  - Stage 1: Primary Objective -- identify MTD administered intravenously.
     Secondary Objectives -- evaluate tolerability, PK, PD, immunogenicity, cytokine response, and clinical activity.
  - Stage 2: Primary Objective -- evaluate clinical activity in patients that have or have not received prior chemotherapy.
     Secondary Objectives -- further characterize safety profile, PK, PD, and immunogenicity.
  - Open-label Phase 1 clinical study, conducted in the U.S. and Australia.

**OBJECTIVE:** 

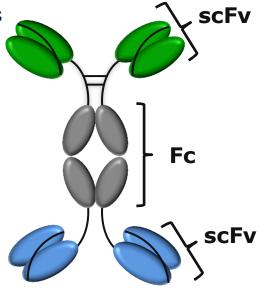
Complete Phase 1 study and advance into Phase 2 development in partnership with MorphoSys



## **ADAPTIR Platform – Key Takeaways**



- ADAPTIR's platform for bispecific RTCC in oncology has clear differentiation over other bispecific technologies in preclinical studies
  - Demonstrated increased potency in preclinical studies when directed compared to competitor molecules
  - Demonstrated increased half-life, and potential for better dosing schedules
- ADAPTIR platform for bispecific RTCC is readily adaptable to new oncology targets, including solid and hematologic malignancies
  - E.g., hematologic, breast, lung, ovarian, prostate, kidney, melanoma, and pancreatic cancers
- ADAPTIR bispecific RTCC therapies offer the potential to fight cancer on multiple fronts
  - E.g., as single, sequential, or combination immunotherapeutic approaches
- Seeking Partnerships for ADAPTIR Platform or preclinical programs



Bispecific ADAPTIR Therapeutic



#### **Marketed Products Portfolio**



# Commercial Operations Therapies for Disorders and Rare Conditions





An intravenous recombinant human coagulation factor IX therapeutic for use in patients with Hemophilia B



## WINRHO<sup>®</sup>SDF

US: [Rho (D) Immune Globulin Intravenous (Human)] Canada: (Rh<sub>O</sub>(D) Immune Globulin (Human) for injection)

Immune Thrombocytopenic Purpura (ITP) and suppression of Rhesus (Rh) isoimmunization



## HEPAGAM B

US: [Hepatitis B Immune Globulin Intravenous (Human)] Canada: (Hepatitis B Immune Globulin (Human) Injection)

Prevention of hepatitis B recurrence following liver transplantation in HBsAg-positive patients and post exposure prophylaxis after acute hepatitis B exposure



## WARIZIG\*

US: VARIZIG<sup>®</sup> [Varicella Zoster Immune Globulin (Human)] Canada: VariZIG® (Varicella Zoster Immune Globulin (Human))

Post-exposure prophylaxis of varicella zoster in high risk individuals



## **Financial Highlights**



Revenue (\$M)

**Product Sales:** Four marketed products generate ~\$30M/yr.

<u>Collaborations:</u> Development milestone payments from current

MorphoSys partnership

Up-front and development milestone payments from possible future development partnerships

based on ADAPTIR

### Cash (\$M)

At spin, Aptevo will receive between \$50 to \$70M in cash from Emergent, which is anticipated to fund Aptevo R&D for 18-24 months



#### Milestones – Next 18-24 Months



### **Development**

- Complete Phase 1 study for MOR209/ES414 and advance into Phase 2 development in partnership with MorphoSys
- Advance new preclinical ADAPTIR-based candidates into the clinic
- Generate new ADAPTIR-based RTCC candidates to increase internal pipeline portfolio
- Publish ADAPTIR technology and candidates in peer-reviewed journals

## **Operational/Financial**

- Complete spin-off from Emergent BioSolutions by mid-2016
- Capture incremental market share of Hemophilia B market with expanded sales of IXINITY
- Expansion of markets through new regulatory filings in select foreign jurisdictions
- Continue current and establish future partnering discussions around product candidates



## **Key Takeaways**



- 1 Leading edge development-stage biopharmaceutical company
- 2 Novel bispecific platform targeting immuno-oncology
- Robust pipeline of clinical and preclinical development candidates focused on I/O and other specialty indications
- Commercial product portfolio generating ~\$30M in annual revenue
- Cash balance of \$50-70M; \$0 debt; well capitalized to achieve potential near term partnering and development milestones





# Appendix

mergent







#### IXINITY® [coagulation factor IX (recombinant)]

IXINITY® is an intravenous recombinant human coagulation factor IX therapeutic for the control and prevention of bleeding episodes and for perioperative management in adults and children,  $\geq 12$  years of age, with Hemophilia B.

**What is Hemophilia B?** Hemophilia B is a bleeding disorder caused by a mutation on the factor IX gene resulting in a deficiency of clotting factor IX in the blood, which controls bleeding. The primary aim of care is to prevent and treat bleeding by replacement with the deficient clotting factor.

**How does IXINITY work?** IXINITY contains recombinant coagulation factor IX (trenonacog alfa) which replaces the deficient clotting factor.

IXINITY was approved by the FDA in April 2015 and launched into the market in June 2015.









US: [Rh<sub>O</sub> (D) Immune Globulin Intravenous (Human)] Canada: (Rh<sub>O</sub> (D) Immune Globulin (Human) for injection)

WinRho® SDF is a  $Rh_0(D)$  Immune Globulin Intravenous (Human) product indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomized,  $Rh_0(D)$ -positive:

- Children with chronic or acute Immune Thrombocytopenic Purpura (ITP)
- · Adults with chronic ITP
- Children and adults with ITP secondary to HIV infection

What is ITP? Immune Thrombocytopenic Purpura (ITP) is a type of autoimmune bleeding disorder. It occurs because of a reduction in cells (platelets) that normally cause blood to clot. Sometimes, ITP occurs after an infection, especially in children.

**How does WinRho SDF work?** WinRho is a sterile, liquid gamma globulin (IgG) fraction containing antibodies to the  $Rh_0(D)$  antigen (D antigen). WinRho has been shown to increase platelet counts through the formation of red blood cell complexes which spare antibody coated platelets from removal.

WinRho SDF has been used to treat ITP in the U.S. since 1995.









# US: [Hepatitis B Immune Globulin Intravenous (Human)] Canada: (Hepatitis B Immune Globulin (Human) Injection)

HepaGam B® is the only Hepatitis B Immune Globulin approved by the FDA for the prevention of hepatitis B recurrence following liver transplantation in HBsAg-positive patients. HepaGam B is also approved for post-exposure prophylaxis after acute exposure to the hepatitis B virus (HBV).

**What is HBV?** HBV causes the liver disease Hepatitis B. The virus interferes with liver functioning and causes pathological damage. A small percentage of infected people cannot get rid of the virus and become chronically infected – these people are at higher risk of death from cirrhosis of the liver and liver cancer.

**How does HepaGam B work?** HepaGam B is a sterile solution of purified gamma globulin (IgG) fraction of human plasma containing antibodies to hepatitis B surface antigen. HepaGam B provides passive immunization for individuals exposed to the hepatitis B virus, by binding to the surface antigen of the virus and reducing the rate of hepatitis B infection.

HEPAGAM B is the ONLY hepatitis B immune globulin (HBIg) approved by the FDA to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in HBsAg-positive patients and provide post-exposure prophylaxis









US: VARIZIG® [Varicella Zoster Immune Globulin (Human)]
Canada: VariZIG® (Varicella Zoster Immune Globulin (Human))

VARIZIG® is intended for use as post-exposure prophylaxis to reduce the severity of chickenpox infections in high risk patient groups (see respective U.S. and Canadian prescribing information for details).

**What is Varicella?** Varicella-zoster virus (VZV) causes an illness commonly known as chickenpox. This easily spread disease can be a serious health issue for high risk patient groups. Chickenpox causes a blister-like rash, itching, tiredness, and fever.

**How does VARIZIG work?** VARIZIG is a sterile lyophilized preparation of purified human immune globulin G (IgG) containing antibodies to VZV that can reduce the severity of varicella infections.

VARIZIG was approved by the FDA in 2012 and is the <u>only</u> <u>approved post exposure treatment for VZV</u>.

