

R&D Strategy in RedBio:

GREEN CROSS



2015 Bio-Future Forum
December 01, 2015

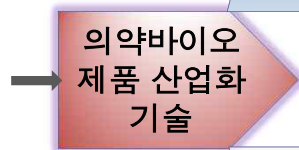
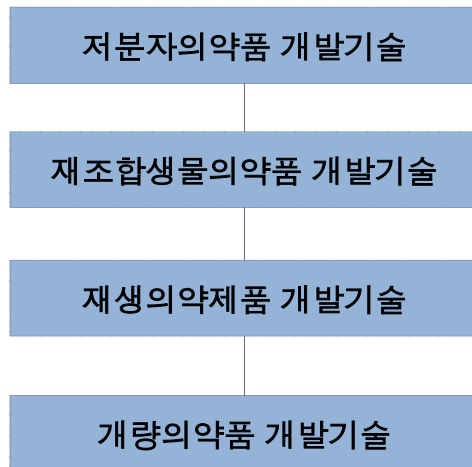
Forward-Looking Statement

The forward-looking statements contained in this document involve risks and uncertainties that may affect the Company's operations, markets, products, services, prices and other factors. These risks and uncertainties include, but are not limited to, economic, competitive, legal, governmental and technological factors. Accordingly, there is no assurance that the Company's expectations will be realized. The Company assumes no obligation to provide revisions to any forward-looking statements should circumstances change, except as otherwise required by securities and other applicable laws.

Classifications in RedBio



Megatrends in RedBio



3P 의약(Personalized, Predictive, Preventive)

- ✓ 분자수준의 병인분석 통합기술체계 구축
- ✓ 맞춤형 치료/예방 전략 도출, 산업 인프라 조성
- ✓ 개인별 유전형/표현형에 따른 맞춤형 의약품 산업화

바이오제네릭 의약품 보편화

- ✓ 바이오제네릭 의약품의 실용화기술 구축
- ✓ 슈퍼제네릭 의약품의 상업화

표적 치료

- ✓ 분자의약품, 다중표적의약품의 실용화
- ✓ 적응증 확대를 통한 거대 산업군 형성

삶의 질 향상

- ✓ 난치성/만성질환의 근원적 치료가 가능한 타겟 동정과 치료 후보물질 발굴
- ✓ 난치성/만성질환의 치료율 및 치료편익성 향상

Frame-shift in RedBio

Top 10 forecast worldwide sellers in 2020

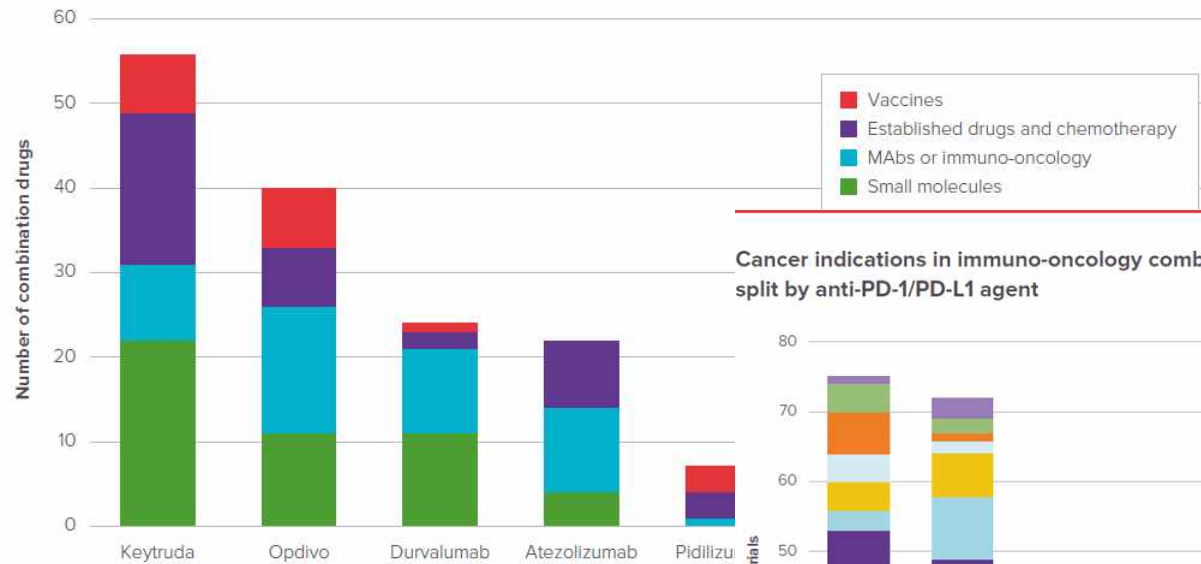
Product	Company	Therapy area (pharma class)	Annual Sales WW (\$bn)		Launch	2015 rank
			2015	2020		
Humira	AbbVie	Anti-rheumatic (anti-TNF Mab)	14.1	13.5	2003	1
Sovaldi + Harvoni	Gilead Sciences	Hepatitis C (NS5B & NS5A polymerase inhibitors)	15.3	12.5	2013	2
Revlimid	Celgene	Blood cancers (immunomodulator)	5.7	8.0	2006	9
Opdivo	Bristol-Myers Squibb	Cancer antibody (anti-PD-1 Mab)	0.6	6.5	2015	249
Tecfidera	Biogen Idec	Multiple sclerosis (Nrf2 pathway activator)	3.9	6.5	2013	21
Avastin	Roche	Cancer antibody (anti-VEGF Mab)	7.2	6.3	2004	5
Remicade	Johnson & Johnson	Anti-rheumatic (anti-TNF Mab)	6.0	5.9	1998	8
Soliris	Alexion Pharmaceuticals	Haematological conditions (anti-C5 Mab)	2.7	5.8	2007	32
Lantus	Sanofi	Diabetes (insulin analogue)	8.0	5.7	2000	3
Xtandi	Astellas Pharma	Cancer (androgen receptor antagonist)	1.8	5.5	2012	63

Source: EvaluatePharma® December 2014

Frame-shift in RedBio

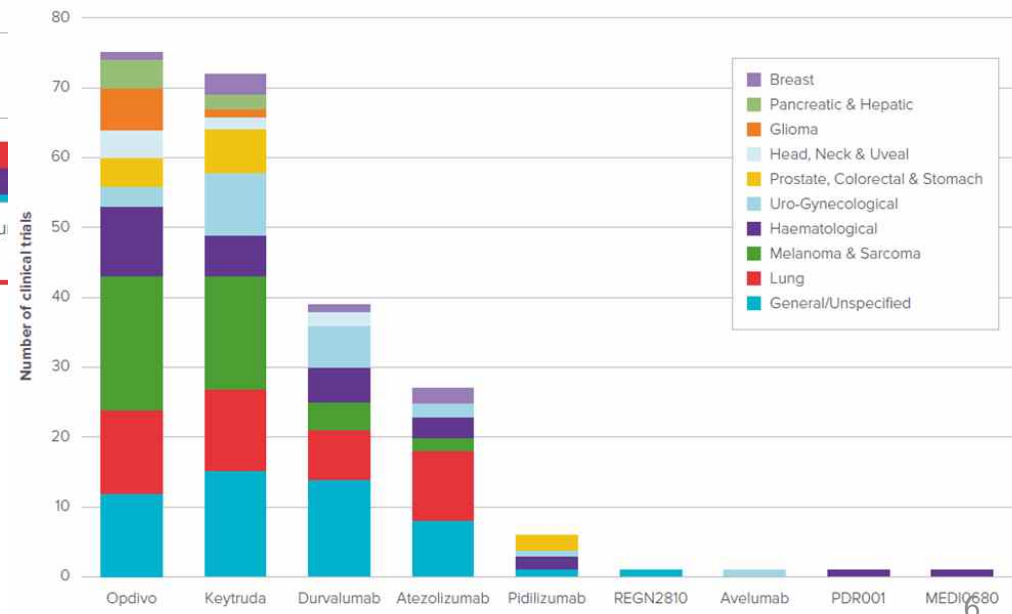
Breakdown of combination studies by anti-PD-1/PD-L1 MAb

Source: EvaluatePharma* September 2015



Cancer indications in immuno-oncology combinations, split by anti-PD-1/PD-L1 agent

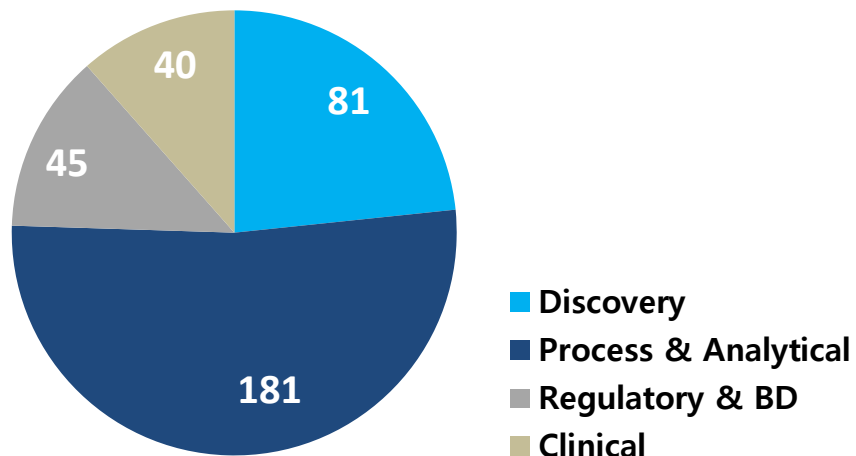
Source: EvaluatePharma* September 2015



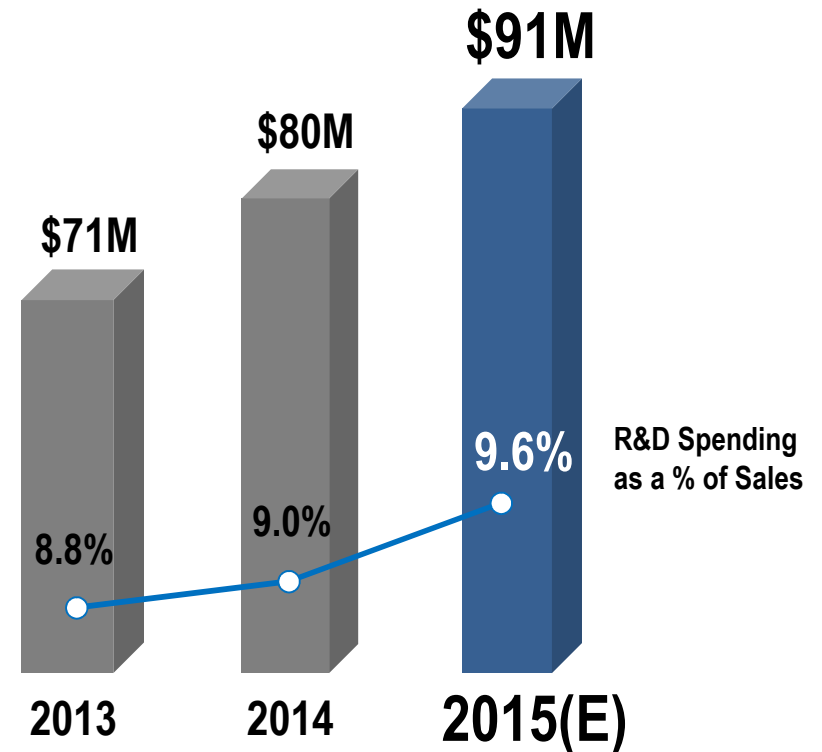
R&D Investment of Green Cross

Personnel

347 Researchers



R&D Spending



R&D Strategy

- ✓ Maintain commitment to extracting **maximum value from existing assets and globalizing current products**
(IVIg, Hunterase, GreenGene-F, QIV, VZV II, etc.)
- ✓ Develop **innovative therapies** focusing on products **that align with our technical and commercial capabilities**
(EGFR mAb, HBIG-gene etc.)

R&D Pipeline

Discovery - PC	Phase 1/2	Phase3	Marketed
GC3114A Seasonal influenza QIV for >65y High Dose	GC3111A (P1 IND) D, T, aP prophylaxis	GC3110A (BLA) Seasonal influenza QIV Egg-based Influenza	GC FLU™ Seasonal Influenza Trivalent Inactivation Influenza
Fibrinogen Acquired deficiency	MG1111 Varicella prophylaxis Live attenuated	GC3106A (P3 IND) Seasonal influenza QIV Cell culture Influenza	GREENFLU™ H1N1 Influenza Monovalent Inactivation Influenza
pdFVIII Hemophilia A	GC1109 (P2) Anthrax Recombinant PA	MG1109 (BLA) H5N1 Inactivated- whole monovalent	Greenplast Q Fibrin Sealant Fibrinogen/Thrombin/FXIII
	GC1118 Solid tumor Monoclonal antibody	GC1107 (BLA) T, D prophylaxis for adult Adsorbed T, D	IVIG-SN 5% Immune Deficiency Immunoglobulin
	Hunterase® (P2 IND) Hunter Syndrome Idursulfase beta US	IVIG-SN 5% (BLA) Immune Deficiency Immunoglobulin US	Hunterase® Hunter Syndrome Idursulfase beta
	MG4101 (P2 IND) Cancer Allogeneic NK cell	IVIG-SN 10% (P3 IND) Immune Deficiency Immunoglobulin US/CA	Neulapeg® Neutropenia Pegylated GCSF
	GC1102 (P2) For liver transplantation Hepatitis B immunoglobulin	IVIG-SN 10% ITP Immunoglobulin	Immuncell-LC® HCC, Glioblastoma Immune Cell therapy
	GC1102 (P1) Chronic Hepatitis B Hepatitis B immunoglobulin	GreenGene® F (P3) US Hemophilia A rhFactor-VIII China	GreenGene® F Hemophilia A rhFactor-VIII
	GC6101A (P2) Gastritis Natural herbal drug		Shinbaro® Osteoarthritis Natural herbal drug

Vaccine
Plasma Derivatives
Recombinant & Others

Pipelines

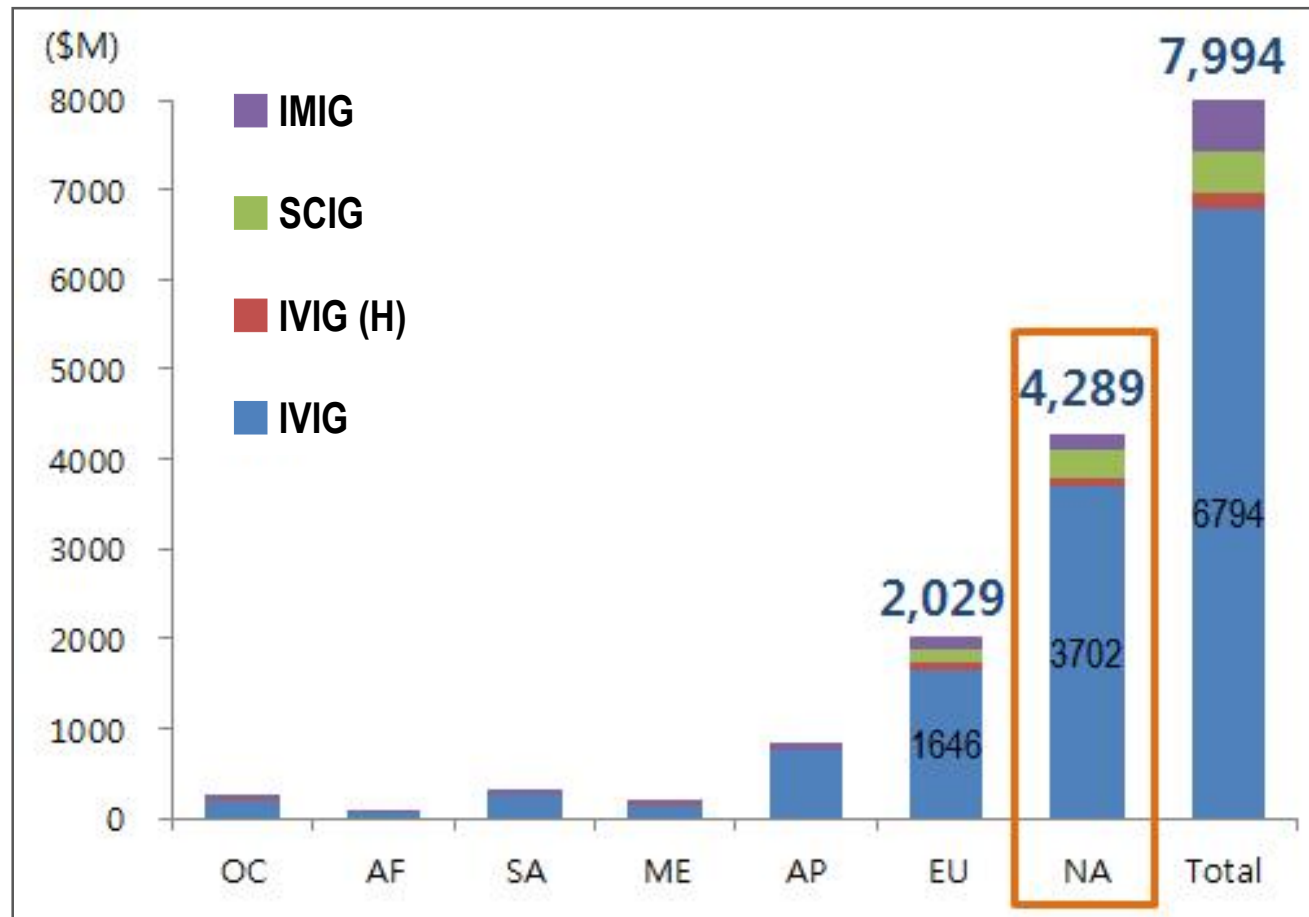
- 1 Plasma Derivatives**
- 2 Vaccines**
- 3 Recombinants**
- 4 Cell Therapy**

R&D Direction

- Maximizing Plasma Economy
- Enhancing Current Portfolio
 - Patient convenience
 - Device
 - Route of administration
 - Dosing flexibility
 - Yield

Plasma Derivatives

Worldwide Market (2012)



Ref. GBI Research Report, 2013

Plasma Derivatives

IVIG-SN™

Indication	<ul style="list-style-type: none">• Severe Infection• Primary Immune Deficiency
Ingredient	<ul style="list-style-type: none">• Human Immunoglobulin G
Status	<ul style="list-style-type: none">• Phase III Completed in US, CANADA
Plan	<ul style="list-style-type: none">• BLA in US (2015)

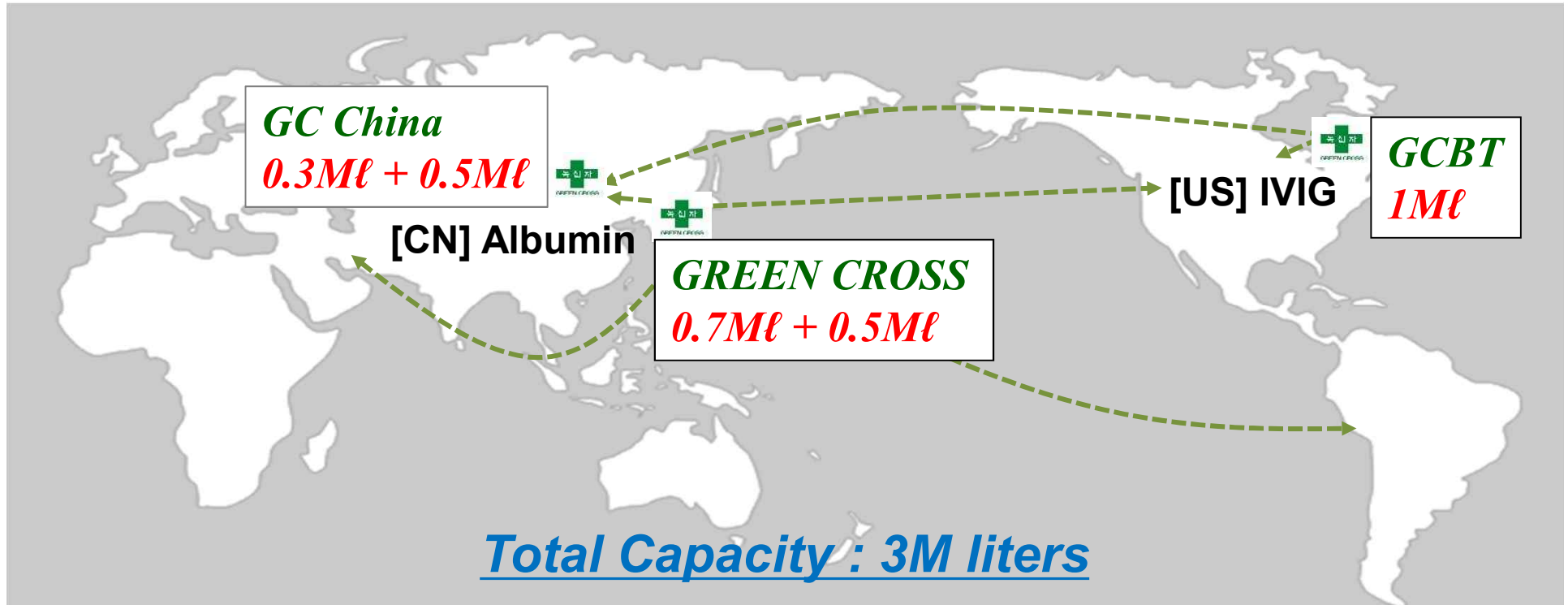


Plasma Derivatives

Plasma Collection Centers in US & China

Affiliate	GCAM	GC China
Established	2009. 11. 18	1995. 10. 26
Status	8 Centers	7 Centers
Plan	30 Centers ('19)	9 Centers ('17)

Plasma Derivatives



Global Competitors Capacity

Baxter	GRIFOLS	CSL™	octapharma plasma	녹십자 GREEN CROSS
10M liters	9.5M liters	6.2M liters	4.25M liters	3M liters (plan)

Pipelines

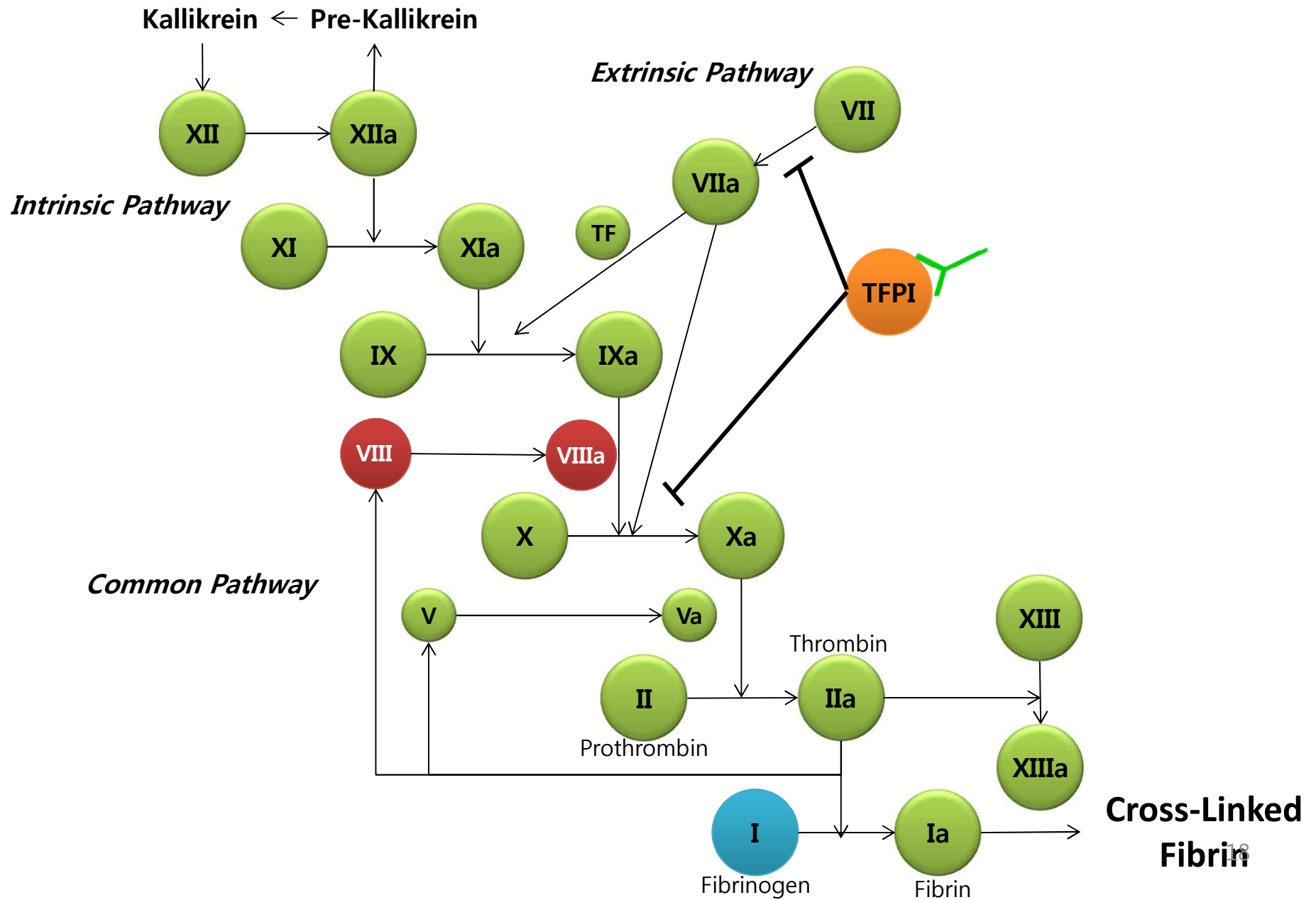
- 1 Plasma Derivatives
- 2 Vaccines
- 3 Recombinants**
- 4 Cell Therapy

Recombinants

- **Hemophilia Treatments**
 - 3rd Generation Factor VIII
 - Long-acting Factor VIII
 - Next Generation Hemophilia treatments
- **Rare Disease Treatments**
 - ERT for LSD
- **Anticancer Treatments**
 - Monoclonal Antibodies
 - Cancer Immunotherapeutics

Recombinants

Blood Coagulation Cascade



Ochang Plant_Main Products

PLASMA DERIVATIVES



17 products

- Albumin injection
- Immunoglobulin inj. for intravenous administration
- Immunoglobulin inj. for intramuscular administration
- Coagulation Factors injection

RECOMBINANT

3 products

- Recombinant Factor VIII
- Recombinant Idursulfase-beta
- Pegylated recombinant G-CSF



Hunterase®

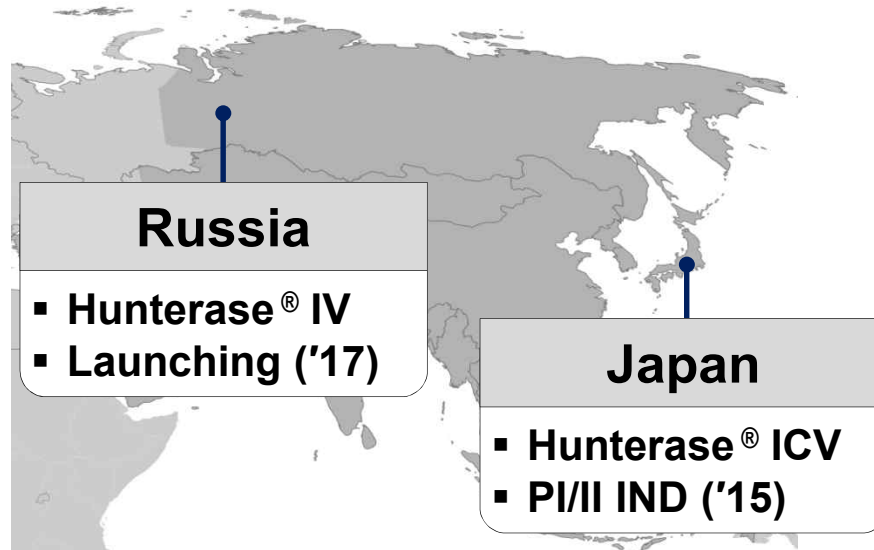
Indication	• Hunter Syndrome (MPS II)
Ingredient	• Idursulfase-beta
Remarks	• Orphan Drug Designation by US FDA (2013)
Status	• Approved in Korea (2012) in Oman, Algeria, Malaysia
Plan	• PII IND in US (2015) • PI/II IND in JP (2015, ICV*)

* ICV : Intracerebroventricular

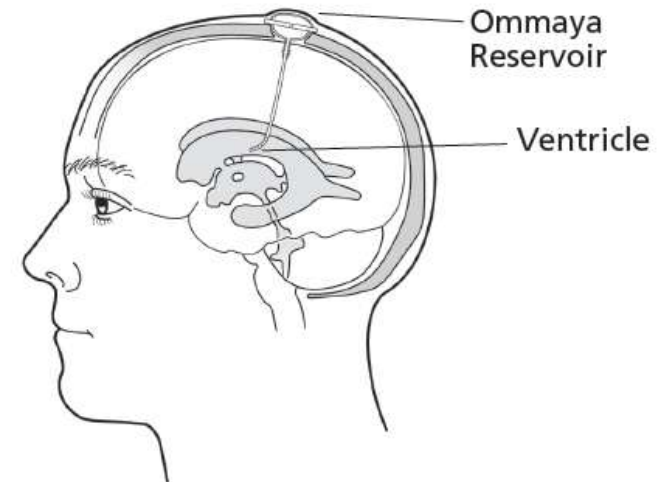


Hunterase®

Globalization plan for Hunterase®



To cure neuropathic symptoms of MPS II via ICV administration



Recombinants

Anti-cancer: Anti-EGFR mAb

anti-EGFR mAb(GC1118)

Indication

• Colorectal Cancer

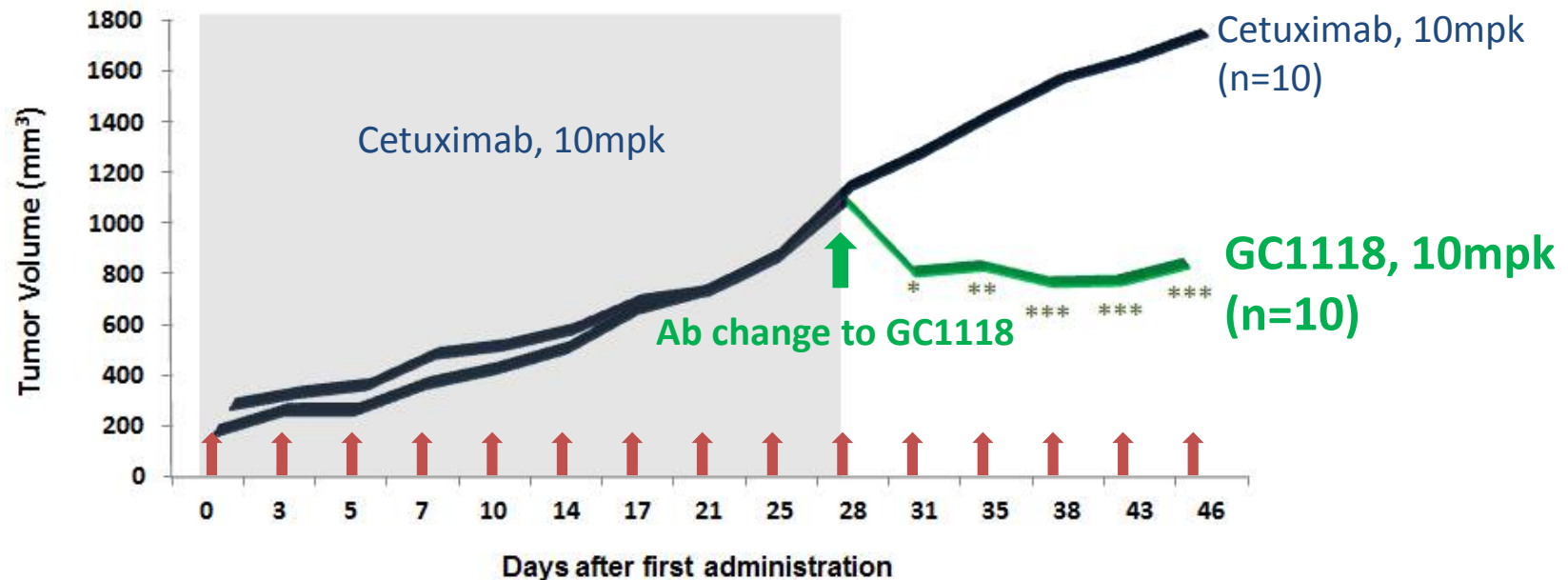
Ingredient

• Fully Human mAb targeting EGFR

Status

• Phase I in Korea

Cetuximab-Refractory Model (Human CRC xenograft model)



*, P<0.05; **, P<0.01; ***, P<0.001, 2-way ANOVA (Cetuximab vs. Cetuximab to GC1118)

Hepabig-Gene

Indication	<ul style="list-style-type: none">• Chronic Hepatitis B• Prevention of HBV recurrence following Liver Transplantation
Ingredient	<ul style="list-style-type: none">• Recombinant Hepatitis B Immunoglobulin
Remarks	<ul style="list-style-type: none">• Orphan Drug Designation by US FDA and EMA (2013)
Status	<ul style="list-style-type: none">• Phase II in Korea



Hepabig-Gene

	Hepabig-Gene	HepaGam B
Origin	CHO cell	Immune-boosted blood
Type	Human IgG ₁ (Monoclonal)	Plasma-derived Hepatitis B Immunoglobulin (Polyclonal)
Activity	3,000 unit/mg	11 unit/mg
Administration Volume	5ml	34ml
Recognition of G145R Mutant	Binding and Neutralizing	No

We have devoted ourselves to the field of special medicines, an area that was difficult to build but is essential to patients.



만들기 힘든 의약품
그러나
꼭 있어야 될 의약품 개발에
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정성은 귀중한 것
때문에 정성을 무척이 투자하려 함
흔히의 물질이 노력을
다하였다는 느낌까지 받을 지어—
녹십자는 1962년 최초의 종합제약회사로
간이 없어 정성을 잃지 않고
해야 한다는 신념을 가지고
만들기 힘든, 그러나 꼭 있어야 할 특수의약품 개발에
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병원에 쓰일 수 있는 물질을 개발하여
병에 대한 이해, 신장질환, 위장질환, 불면증
특수치료용수 등 특수의약품을 개발하여 국민보건
증상에 이바지하여 왔습니다.
이들 신약의 개발에는 항상 철저한 10년을 두고
중요한 노력을 녹십자는 이제 특수의약품을 만들어서
국민보건에 이바지할 목적으로 신성하게 개발하며,
모든 약품들이 이를 위하여는 필요없다고 생각하면
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녹십자는 여러분과 같이 올바른 방향으로
생각할 때 보다 큰 개발성이 있다는 것을 확신하여
정성의 존중을 위한 정서적인 모든 정성을 다하여
노력할 것을 약속드립니다.

녹십자
회사

Newspaper Advertising(1977)

THANK YOU

