Apimeds, Inc.

Technology Overview

1. Background of Technology

(1) Regulatory Status

- New Drug Approval of KFDA (The 6th New Drugs in Korea, The first natural biological drug of its kind). The animal use of this drug (Apimellena) was approved as a New Veterinary Drug on May 2009.
- US FDA IND Approval (Finished Phase IIa, 1989. IND #BB-3142)
- US FDA New IND Approval, IRB Approval (2008.9 #13754)
- *(Additional Study)* Completion of Phase IIa
- Final Report of Phase IIa & Submission of Phase III Protocol (2010.3)

(2) R&D History

- A new biological drug developed by C.M.Kim, M.D. (International Pain Institute, New Jersey, USA) through 20 years of medical research and clinical experiences in the USA & 7 years with the Apimeds, Inc.
- Refer to the Table below

1. Apitox (Regulatory Status)

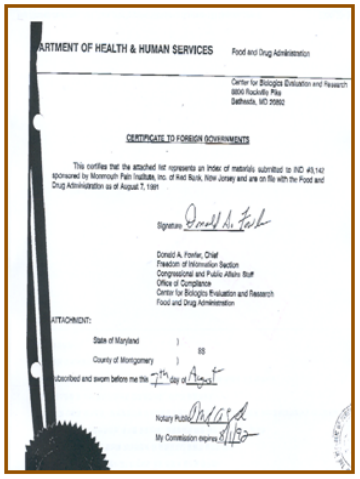
Korean FDA

Stage	Pre Clinical	Phase I	Phase II	Phase III	NDA / BLA
By	Bando Ph. IPI *	Bando Ph. IPI	Bando Apimeds	Guju Ph. Apimeds	Guju Ph. Apimeds
Year	1990~1993	1994	1995~1996	2000~2002	2003.5.3.
Contents	Antigene-city & Toxicity	20 Human Toxicity & Safety	161 Human Efficacy Study	407 Human Clinical Trials 4 Universities	New Drug Approved
Results	Good Results	Good Safety	Good Efficacy	Very Effective	NDA (KFDA)

US FDA / CBER

Stage	Pre Clinical	Phase I	Phase II	Phase III	NDA / BLA
By	IPI	IPI	Apimeds	Apimeds Radiant Gr (CRO)	Apimeds FDA/CBER **
Year	1) 1983~1986 2) Supplement 2008. 1~6 *	1986	1) 1989 2) IIa Supplement 2009. 1~12 **	2010.07~ 2012.01	Latest by 2012.06
Contents	Toxicity	15 Human Toxicity & Safety	180 Human Efficacy	400 Subjects USA 10 M.C. India 12 M.C.	DMF Reg.No. BB-MF #13130 (2006.9.19)
Results	Safe	Good Safety	Excellent Efficacy	Most Optimistic	Confident BLA

1. IND Approved for RA By US FDA (IND, Investigational New Drug, US IND # BB- 3142, 1989.3)
2. IND Phase III #13,754 Clinical Study Protocol - Approved (2010.4)
3. China: New Drug Approval Expected by 4Q, 2011



* IPI : International Pain Institute ** CBER : Center for Biologics Evaluation and Research * Completed ** Completed

2. Description on Technology Applied

(1) Composition

- Peptides & Enzymes: Core Biological Components of Mellitin, Apamin, MCD-Peptides, Adolapin. Protease Inhibitors, Hyaluronidase
- Key Titration Index of Assay : Mellitin, Phospholipase
- Each Vial Contains 1mg of Freeze-Dried Bee Toxin (>0.4 mg of mellitin)

(2) Identifications

i. Melittin: 0.4-0.7 mg/mL

ii. Phospholipase: 0.07-0.14 mg/mL

(3) Specifications

i. Total protein: 800-950 mcg/mL

ii. Hyaluronidase activity: 40-100 HHU/mL (diluted to 100 UG/mL)

iii. Inhibition of gelatin induced aggregation of erythrocytes: 3-5 mm/H

- **Phase III Clinical Study for Multiple Sclerosis**

A Phase III, Multi Center, Randomized, Double Blind, Placebo Controlled, prospective multi-center clinical study to evaluate the safety and efficacy of Intradermal injection of Apitox vs Hstamine placebo in Patients with Relapsing Remitting Multiple Sclerosis (RRMS) or Secondary-Progressive Multiple Sclerosis (SPMS) who are either intolerant to other medications or not receiving adequate clinical benefit from other medications or not receiving adequate clinical benefit from other medications in the improvement of Activities of Daily Living (ADL)

3. Differential Point, Superiority or Characteristics of Technology Applied

(1) Apitox Profile

1) Main Indications

Pharmaceuticals: Acute & Chronic Treatment for Inflammation and Pain of Arthritis, Neuralgia, and for Autoimmune Diseases, Predominantly for Multiple Sclerosis

2) Pharmacological Effects on

- Control of Immune System
- Anti-Inflammation
- Anti-Bacterial/Fungal Effects
- Protection of X-ray Side Effect

3) Efficacy

- Neural Diseases : Neuralgia
- Skeletal Diseases : Acute Arthritis, Bursitis, Frozen Shoulder, Tennis Elbow, Golfer's Elbow,
- Muscular Diseases : Muscular Pain, Fibromyalgia, Chronic Fibrosis
- Autoimmune Diseases : Rheumatoid Arthritis(RA), Psoriasis, Multiple Sclerosis (MS), Systemic Lupus Erythematosis (SLE)

- **Efficacy for MS - 450 Patients : 1987~1998 (12 Years), IPI (USA)**

	Before Treatment	After Treatment
Weakness (Extremities)	**++++**	**+**
Spasticity & Spasm	**+++++**	**++**
Bladder Control	**10~60%**	**50~90%**
Balance	**Poor and Unstable**	**Fair and Stable**
Fatigue	**+++++**	**++**

4) Antiphlogistic Analgesis (Pain Killer Versus Apitox)

PAIN KILLER	APITOX
Compatibility Drugs :	**Biological Medicine :**
- Serious Side Effects	- Less Side Effects
- Use in Acute Illness	- Chronic Disease Cure
- Symptoms Treatment	- Cause Treatment

(2) Medical & Marketing Value of Apitox

1) US FDA NDA Approval Vision (Lowest Cost & Shortest Approval)

- Already approved as a new drug by KFDA
- Potential of Unique Korean-Type Global Blockbuster as Natural New Drug
- Biological Toxin/US FDA Center for Biologicals Evaluation & Research
- US FDA Phase IIa Approval [1989,IND #3142)
- Target Approval Date of US FDA NDA by March 2011

2) Excellent Efficacy for Chronic Arthritis and Validated Safety of Natural Origin

- Fundamental Therapeutics Not Existing for Chronic Arthritis, Rheumatoid Arthritis & Multiple Sclerosis - Broad Scope of Medical Documentation of Biotherapy (CAM, Complementary & Alternative medicine)
- Excellent Safety Profile Compared with NSAIDs During Prolonged Treatment
- Unique Drug of Choice for Chronic Diseases Replacing Neurontin & Enbrel
- Unique Alternative Medical Treatment Overcoming Western Medical Treatment's Limitation

3) Initiating the Product for the American Market where MS is extensive

- Rapid increase in the MS market
- Proven Effectiveness in MSAA as well as added Economic Value

4) R&D Benefits of Natural Drug Against Chemicals

- Low Cost of R&D and More Optimistic Potential of US FDA's NDA Approval
- Unique Medical Treatment for Chronic Intractable Disease
- Safety Profile of Natural Origin

Specific Patent and Publication Information

1. Patent

No.	Name of Patent	Application No.	Date of application /approval	Country	Status (Applied/approval)	Cost for patent (KRW)
1	Bee Venom Treatment Without Bee Sting	# 0405128	01.02.01 03.10.30	Korea	Approved	10,000
2	Bee Venom Treatment Without Bee Sting	# 3989188	01.04.27 07.07.27	Japan	Approved	10,000
3	Bee Venom Treatment Without Bee Sting	09/615,437	00.07.13	USA	Applied	75,000
4	Bee Venom Treatment Without Bee Sting	10/690,772	03.12.22	USA	Div. Applied	
5	A Standardized Bee Venom Preparation	12/152,216	08.08.07	USA	Sep. Applied	

※ *Please provide accurate information for Application No and Date of application/approval. It will be used for patent search.*

※ *In case of Cost for patent, please consider administrative cost for patent application only.*

※ *In case of PCT or overseas patent (application) except domestic patent, Please attach a certificate of application/approval (or patent abstract) as a separate file.*

2. Specific Publication Information

No.	Journal	Title
1	Textbook - Author: Kim, CMH Korean Ed. Pub. Seoul, 1992. (486p)	Bee Venom Therapy and Bee Acupuncture Therapy.
2	Reference Book - Kim, CMH KAS Pub. Seoul, 2005 (430p)	Bee Venom Therapy: References for Published Research Articles.
3	Textbook - Avshalom Mizrahi (*Editor*), Plenum Press, New York. 1997 by Kim, CMH (p. 234-270)	Potentiating Health and the Crisis of the Immune System. Chapter 24. Apitherapy (Bee Venom Therapy)
4	J. of Pain 1992; 1(1): 55-65. Kim, CMH	Honey bee venom therapy for arthritis (RA, OA), fibromyositis (FM) and peripheral neuritis (PN).
5	Rheumatologie 1989; 41: 67-72. Kim, CMH	Bee venom therapy for arthritis.