

Introducing The Sustained-Release  
Cilostazol Tablet of Once Daily 1 Tablet  
Regimen, Having Improved Releasing Rate  
And Reduced Side Effect

Korea United Pharm.Inc.

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<b>Industry Sector</b>	Pharmaceutical
<b>Therapeutic Area</b>	Cardiovascular
<b>Stage of Development</b>	Finished Product

## 1. Summary

- ✓ **THE WORLD'S ONE AND ONLY**  
Cilostazol Controlled-Release 200mg
- ✓ **IMPROVED PATIENT COMPLIANCE**  
One tablet, Once daily (vs. Twice daily, Pletaal)
- ✓ **SAFE & EFFECTIVE**  
Reduced side effects of headache & tachycardia
- ✓ **Korea FDA APPROVAL**  
Approval from Korea FDA on Feb. 28, 2013



## 2. Applications

It is used in the treatment of ischemic symptoms including ulcer, pain and coldness of the extremities in chronic arterial occlusion. It is also indicated in preventing recurrence of cerebral infarction except cardiogenic cerebral embolism

## 3. Market Feasibility

### - Market Sales (2012 IMS 4Q MAT)

Rank	CILOSTAZOL	813,113,845	M/S
1	<b>JAPAN</b> COMBINED	586,644,964	72.1%
2	<b>KOREA</b> COMBINED	37,208,579	4.6%
3	<b>BRAZIL</b> RETAIL	29,234,795	3.6%
4	<b>ARGENTINA</b> RETAIL	23,260,231	2.9%
5	<b>USA</b> COMBINED	20,943,089	2.6%
6	<b>SPAIN</b> COMBINED	16,736,025	2.1%

7	<b>GERMANY</b> COMBINED	14,441,999	1.8%
8	<b>CHINA</b> HOSPITAL	13,648,416	1.7%
9	<b>TAIWAN</b> COMBINED	9,682,120	1.2%
10	<b>PHILIPPINES</b> COMBIN	8,275,684	1.0%
-	Rest of World	53,037,943	6.5%

#### - Patients Profile

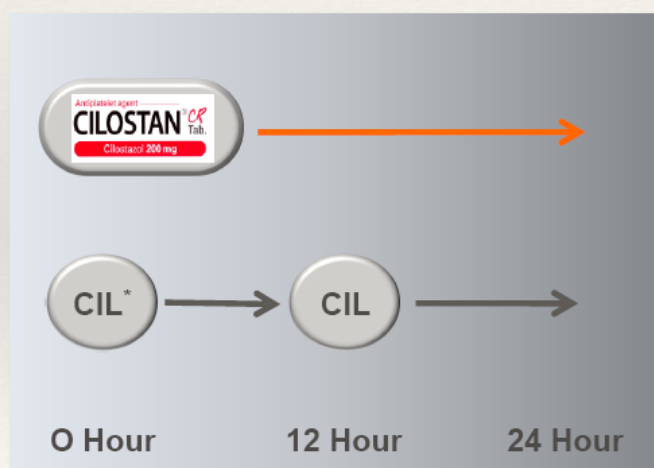
- 60 years old and above: > 76%
- Daily dosing regimen: Mostly 2 tablets per day (> 68%)
- Concomitant drugs: Mostly once daily regimen  
1<sup>st</sup> Statins (44%), 2<sup>nd</sup> Aspirin (32%), 3<sup>rd</sup> Metformin (24%), 4<sup>th</sup> ARB (24%), 5<sup>th</sup> CCB (24%)
- Co-morbidity: Diabetes (14%), Stroke (13%), Hypertension (10%)

#### 4. Type of Business Relationship Sought (include licensing availability)

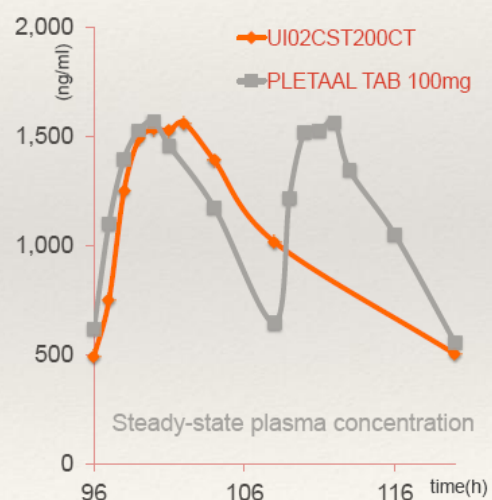
We are seeking a collaboration partner

#### 5. Technical Advantages

- ✓ Improve patient compliance by once daily dosing
- ✓ Minimize adverse effect by reducing fluctuations in plasma concentrations

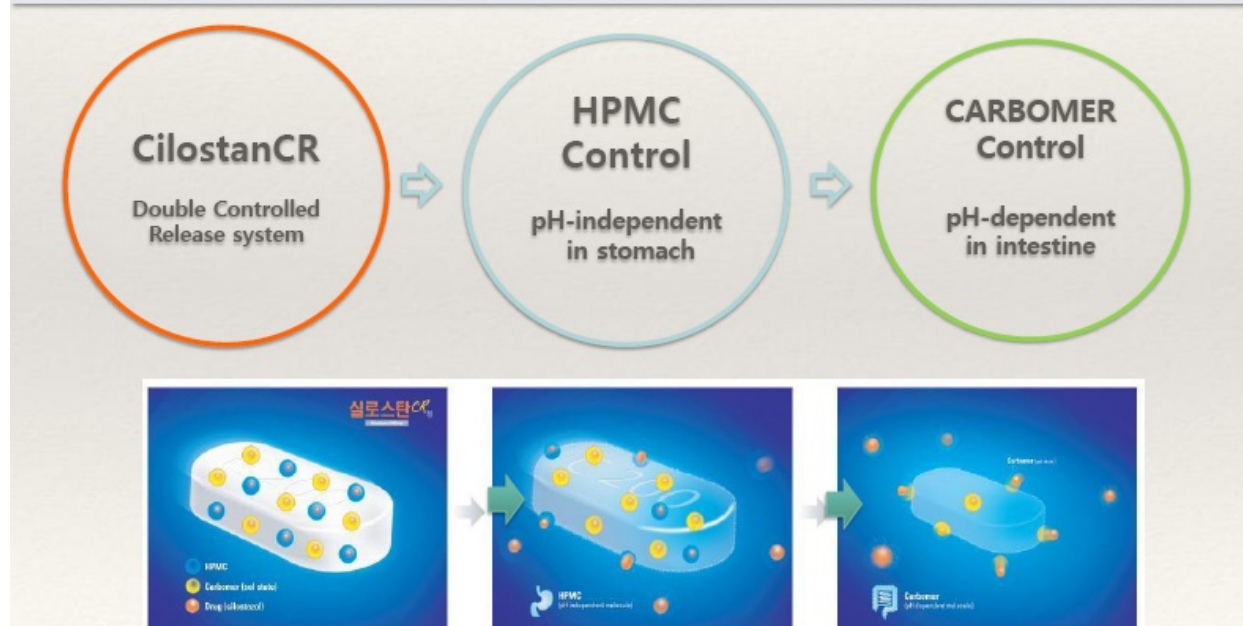


\* Note: 'CIL' indicates Pletaal or other generic of cilostazol



## 6. Technical Highlighted Summary

Maintain effective plasma concentrations over 24 hours for better patient compliance and continued control of the disease



## 7. Mechanism (MOA)

Cilostazol is a selective inhibitor of 3-type phosphodiesterase (PDE3) with therapeutic focus on increasing cAMP. An increase in cAMP results in an increase in the active form of protein kinase A (PKA), which is directly related with an inhibition in platelet aggregation. PKA also prevents the activation of an enzyme (myosin light-chain kinase) that is important in the contraction of smooth muscle cells, thereby exerting its vasodilatory effect.

## 8. Patent Information and Status

### ✓ KOREA PATENT FILING

#### - TITLE

Sustained-release cilostazol tablet having improved releasing rate and reduced side effect

#### - APPLICATION NO.

10-2008-0086215 (September 2, 2008)

#### - APPLICATION NO.

10-2011-0041150 (April 29, 2011)

### ✓ PCT FILING

-INTERNATIONAL APPLICATION NO. PCT / KR2009 / 005420

-INTERNATIONAL FILING DATE September 23, 2009

-EST. EXPIRY DATE **September 22, 2029**

-DESIGNATED STATES US, EU, JP, CN, PH, VH, etc.

## 9. Key Words

Cilostazol, Cilostazol 100mg, Cilostazol 200mg, Cilostan CR, Cilostan SR, Pletaal, Pletaal SR, Double Controlled Release System, Korea United Pharm, KUP, IMD, Incrementally Modified Drug

## 10. Company Description

Korea United Pharm. Inc., which was founded in 1987, has mainly focused on Ethical pharmaceutical products. Ever since the early establishment, it has realized the dream of “Multinational Pharmaceutical Company owned by Korean” by aiming at overseas markets through not only establishing 5 local branches but also constructing overseas factories in Vietnam, USA, Egypt.

With about 12% of current R&D investment out of its turnover which is top-ranked among domestic pharmaceutical companies, it has concentrated on development of IMD(Incrementally Modified Drug) products and is growing into research-oriented pharmaceutical company which has international competitiveness. Starting from release of anti-inflammatory IMD product, “Clanza CR” in 2010, 4 IMD products(Clavixin Duo cap, Cilostan CR Tab, Kalomin Tab.) are now on the market and it will introduce additional IMD products continuously. The Korea United Pharm. Inc., has become a professional company of IMD