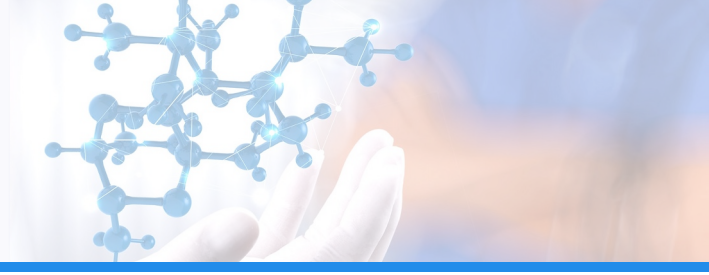
DIAPIN Therapeutics

Developing Novel Transformative Therapies for Cardiovascular and Metabolic Diseases

Non-confidential Presentation –Feb 26

Disclaimer

Diapin Therapeutics, Inc.



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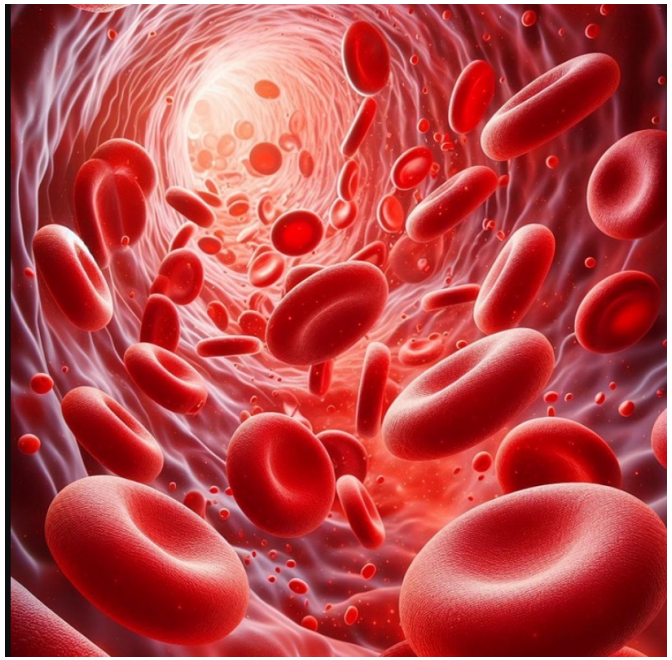
Overview of Diapin Therapeutics DT678

Leading the way to a potential new best-in-class antiplatelet



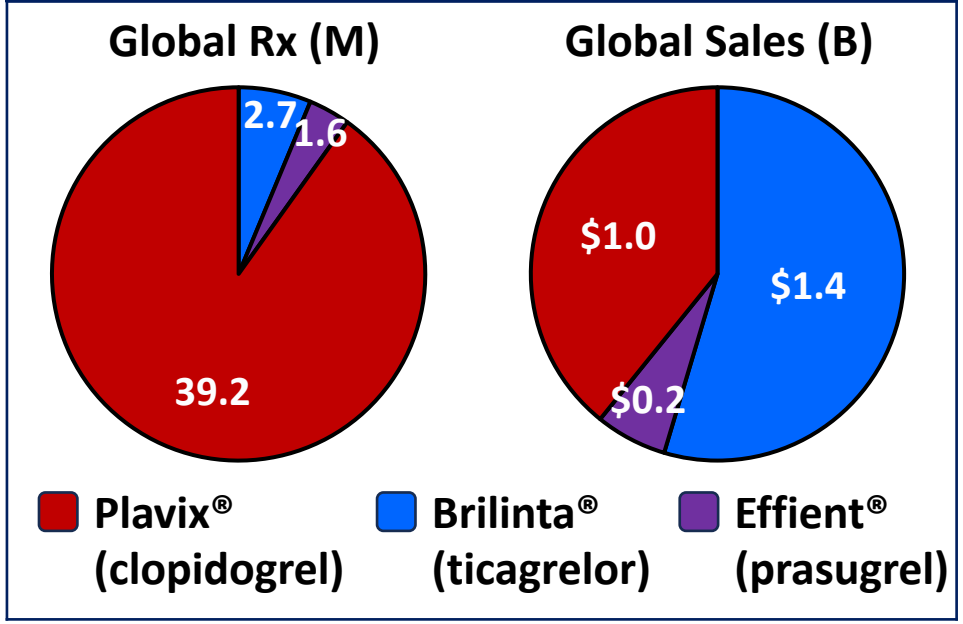
OVERVIEW	A novel prodrug with a clear regulatory path to NDA via 505(b)(2) with extended IP protection and clear market differentiation.
UNMET NEED	P2Y12s: Increased bleeding risk, diminished effect in many patients, slow onset of action and negative side effects
LEAD ASSET	Oral and IV administered P2Y12 inhibitor, unique metabolism, potential for improved efficacy and safety, currently in Ph2.
GOAL	$7.5 million Seed round for US trial and NDA submission. Approval and launch in 2028, short path to revenue generation.
POTENTIAL	Experienced team to develop a safer more effective drug with a multi-billion market opportunity and significant potential for ROI.

Market Landscape

CVD Leading Cause of Death - Opportunity for a Safer Antiplatelet Drug

- Cardiovascular disease leading cause of death with >32M heart attacks and strokes every year[1]
- The AHA Guidelines - dual antiplatelet therapy (aspirin + P2Y12 inhibitor) to reduce risk of future heart attack, stroke and coronary stent thrombosis[2]

P2Y12 Inhibitors Annual Sales and Rx[3]



- Generic clopidogrel leads the market with 90% utilization
- Ticagrelor leads in revenue due to branded pricing, significant safety concerns remain.

New Best-in-Class antiplatelet must be safer and more effective!

1. WHO, 2021, *Cardiovascular Diseases (CVDs)*., 2. 2016 ACC/AHA Guidelines on Dual Antiplatelet Therapy (2016), *Circulation*, 134: e123–e155.,
3. Global Data Forecasted for 2023.

DIAPIN Therapeutics

Plavix® (clopidogrel) – FDA BLACK BOX WARNING!

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PLAVIX safely and effectively. See full prescribing information for PLAVIX.

PLAVIX (clopidogrel bisulfate) tablets, for oral use
Initial U.S. Approval: 1997

WARNING: DIMINISHED ANTIPLATELET EFFECT IN PATIENTS WITH TWO LOSS-OF-FUNCTION ALLELES OF THE CYP2C19 GENE

See full prescribing information for complete boxed warning.

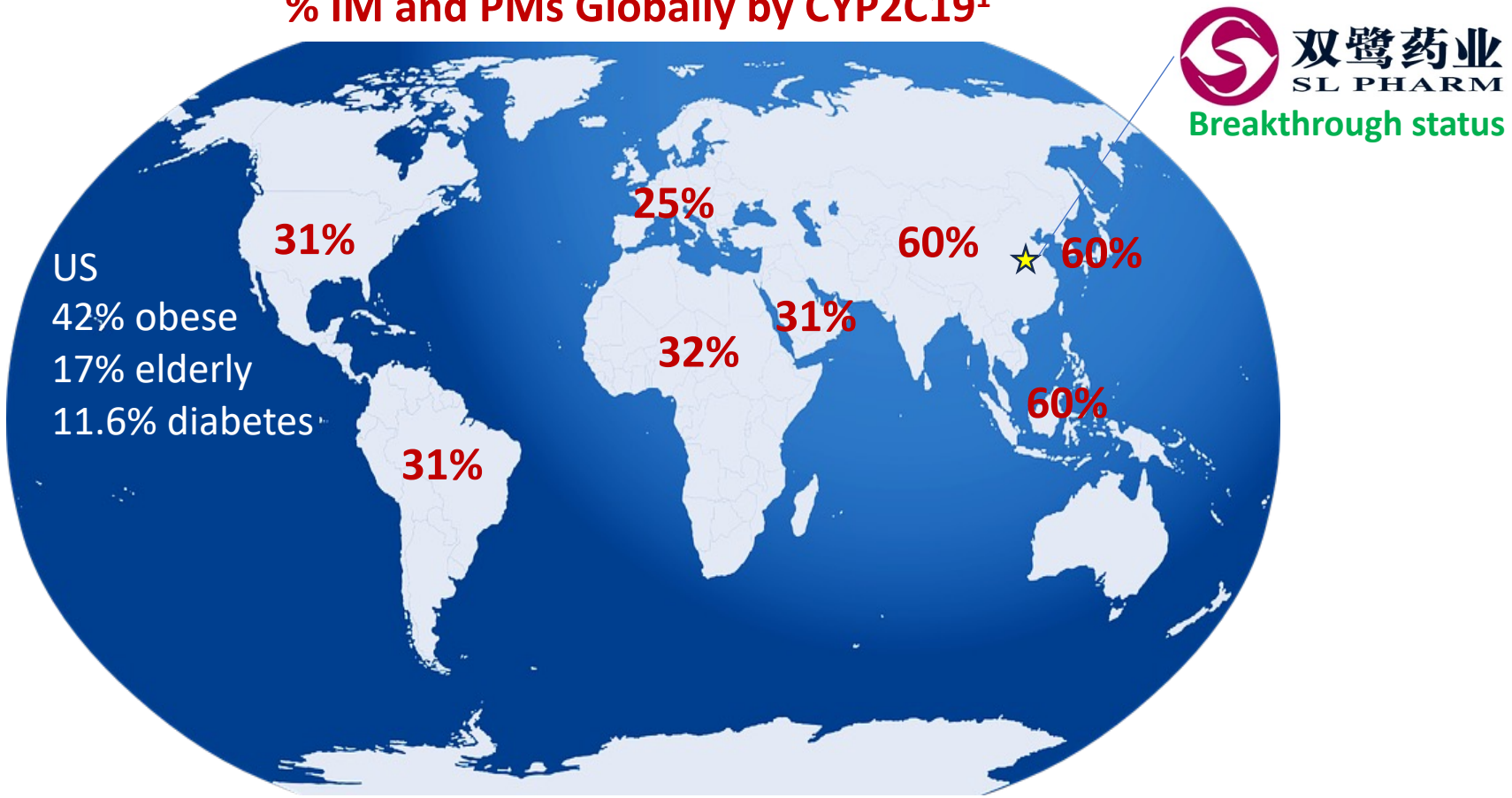
- **Effectiveness of Plavix depends on conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. (5.1, 12.3)**
- **Tests are available to identify patients who are CYP2C19 poor metabolizers. (12.5)**
- **Consider use of another platelet P2Y12 inhibitor in patients identified as CYP2C19 poor metabolizers. (5.1)**

- **Plavix is metabolized to its active metabolite via CYP2C19**
- **Warning guides physicians and patients about serious, life-threatening, known risks**
- **Alternatives to Plavix – not considered as safe, with higher incidence of bleeding and worse side effect profile**
- **DT678 is an alternative that generates the same active metabolite as Plavix® independently of CYP2C19.**
- **Why Now? 1h Point of Care test FDA approved to rapidly identify CYP2C19 mutations.**

Global Opportunity for Improved Antiplatelet Safety

Patients with Reduced CYP2C19 Function Through genetics, Diabetes, Obesity & Age.

% IM and PMs Globally by CYP2C19[1]



Patients with CYP2C19 LoF alleles (IM &PM) have increased risk of major adverse cardiovascular events if treated with clopidogrel[2]

% IM and PMs

- **25-32%** Africa, Americas, Europe, Middle East
- **60%** Asia, India, Pacific Island Nations

Reduced clopidogrel efficacy in diabetics[3], obese[4] & elderly patients[5] with lower CYP2C19 function.[6]

Beijing SL collaboration. Phase 2 in progress. Opportunity for breakthrough designation and sales prior to Phase 3.

1. Klein MD, 2019, *Arter, Thromb, & Vasc Biol*, 39:4., 2. Beitelshees AL, et. al, 2022, *JAHA*, 11(4):e024159.
3. Shahim B. et al, 2023, *JAHA*, 12(1): e026482. 4. Puccini M. Cardiovasc Drug Ther 2023 Aug;37(4):833-837.
5. Abudahab S, Pharmacogenomics 2024, 25(1) 41–54 , 6. Tomlinson B et al, 2023, Exp Opin on Drug Met & Tox, 19:12, 867-870.

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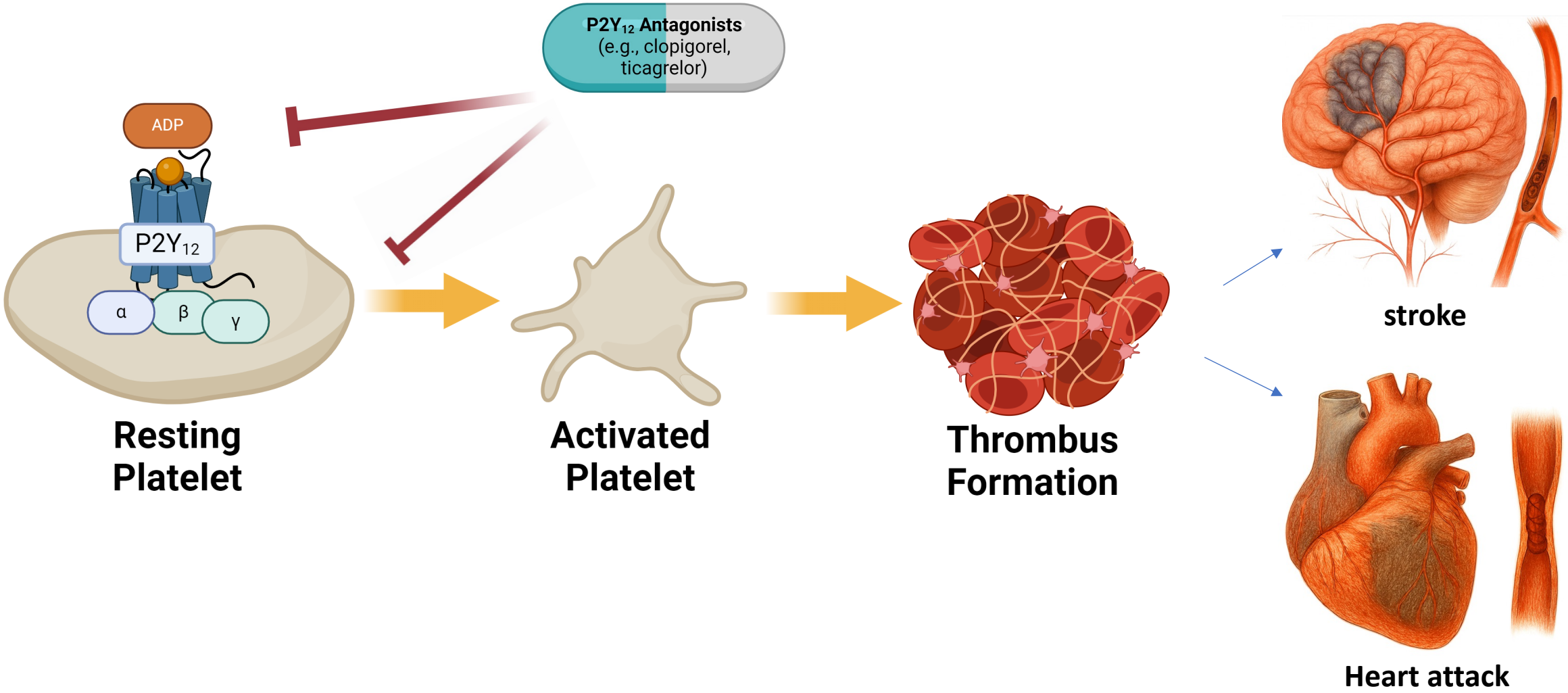
Mechanism of Action $P2Y_{12}$ antagonists



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Introducing DT678

Novel Prodrug Synthesized Using an AI Designed Enzyme

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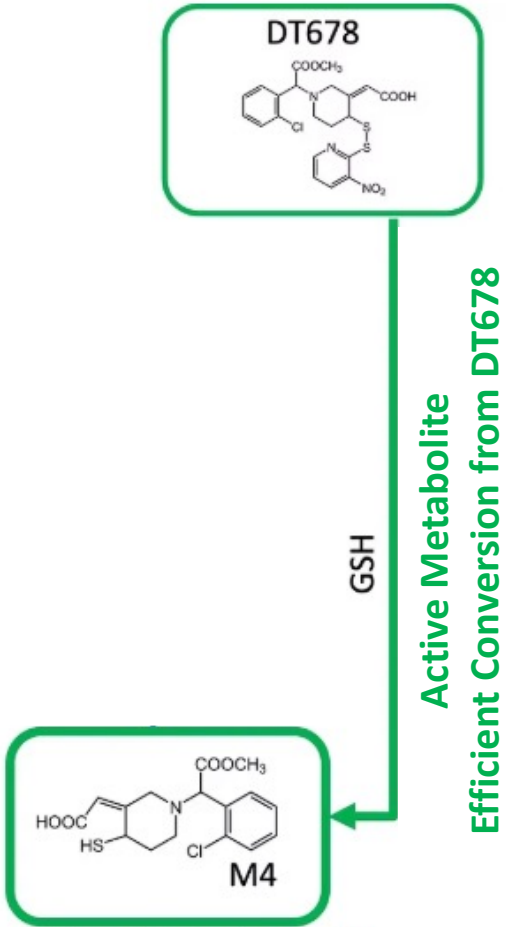

- **DT678 is synthesized using an AI designed CYP enzyme[1]**
- **DT678 is converted to M4, independently of hepatic cytochrome P450 (CYP) enzymes including CYP2C19[4,5]**

1. Zhu, Y. et al., 2018, *Nature Communications* (2018) 9:3952., 2. Pereillo, J. M. et al., 2002, *Drug Metab. Dispos.* 30, 1288–1295. 3. Li, G. et al., 2016, *Int. J. Clin. Exp. Med*. 9, 15607–15620., 4. Zhang, J. et al, 2016, *J Pharmacol Exp Ther.,* 359:11–17., 5. Zhang, J. et al, 2013, *Mol Pharmacol.,* 83:848–856., 6. Kuszynski DS, Lauver DA., 2022, *Purinergic Signal*, 18(3): 253–265.

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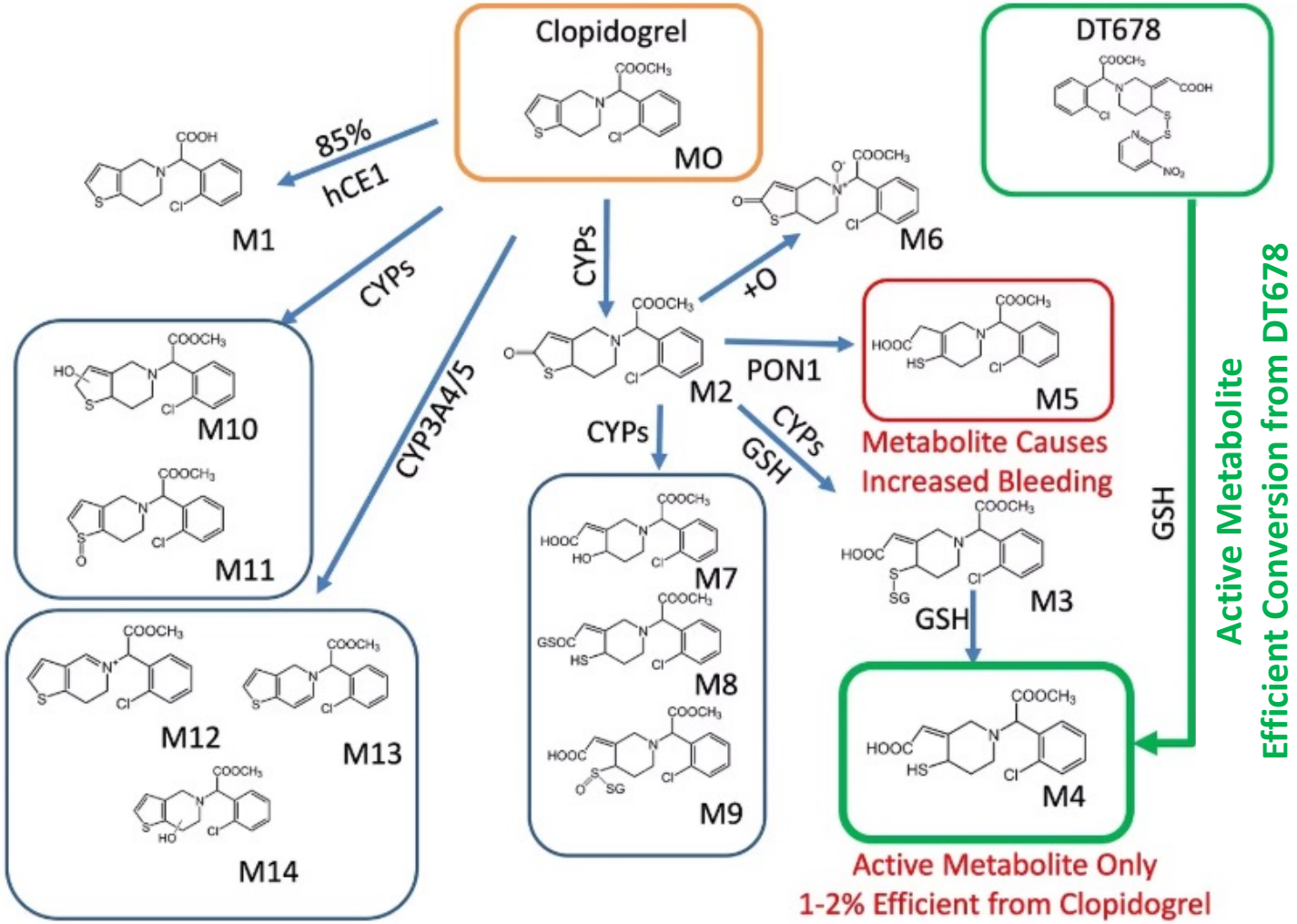

- DT678 is synthesized using an AI designed CYP enzyme[1]
- DT678 is converted to M4, independently of hepatic cytochrome P450 (CYP) enzymes including CYP2C19[4,5]
- Clopidogrel is a prodrug metabolized by CYP2C19 to its active metabolite, M4[2]
- ~1-2% of M4 is formed from clopidogrel, while M4 is formed efficiently from DT678
- Clopidogrel generates many metabolites including M5 which is known to cause increased bleeding risk[1,3,6]

1. Zhu, Y. et al., 2018, *Nature Communications* (2018) 9:3952., 2. Pereillo, J. M. et al., 2002, *Drug Metab. Dispos.* 30, 1288–1295. 3. Li, G. et al., 2016, *Int. J. Clin. Exp. Med*. 9, 15607–15620., 4. Zhang, J. et al, 2016, *J Pharmacol Exp Ther.,* 359:11–17., 5. Zhang, J. et al, 2013, *Mol Pharmacol.,* 83:848–856., 6. Kuszynski DS, Lauver DA., 2022, *Purinergic Signal*, 18(3): 253–265.

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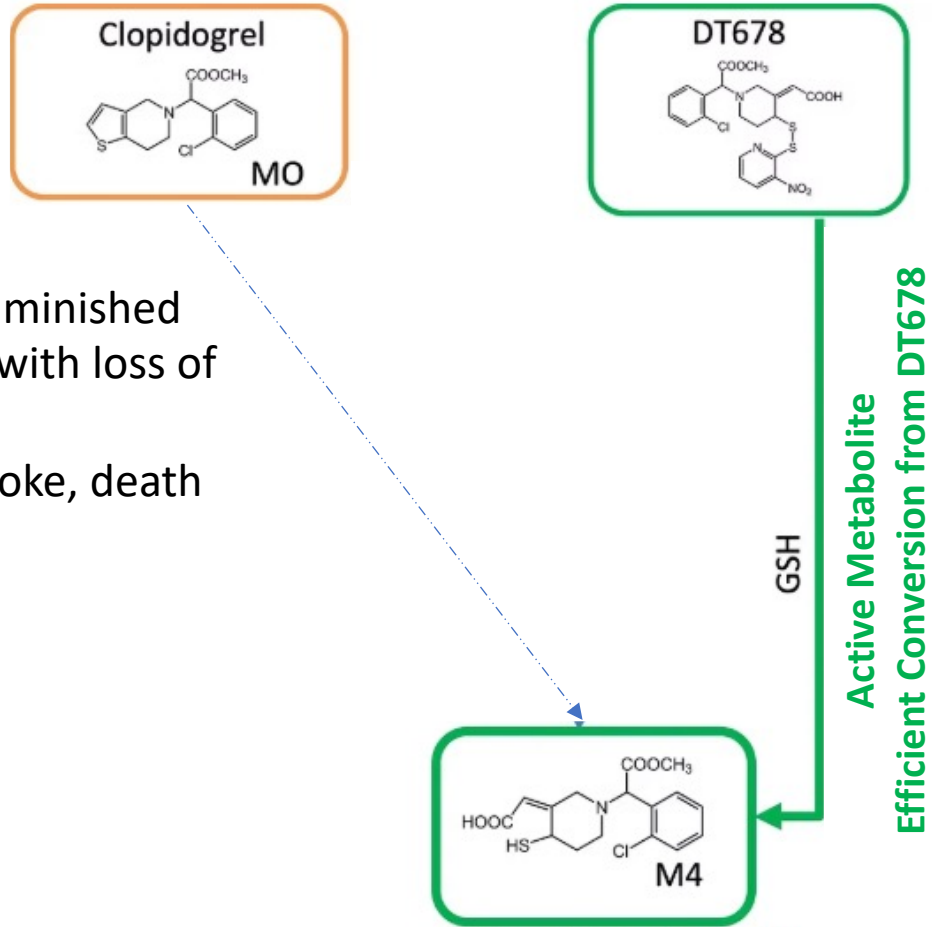

Clopidogrel has diminished effect in patients with loss of CYP2C19 function
= heart attack, stroke, death

- **Same active metabolite M4 – basis of 505b2**
- **Works well for ALL Patients**

1. Zhu, Y. et al., 2018, *Nature Communications* (2018) 9:3952., 2. Pereillo, J. M. et al., 2002, *Drug Metab. Dispos.* 30, 1288–1295. 3. Li, G. et al., 2016, *Int. J. Clin. Exp. Med*. 9, 15607–15620., 4. Zhang, J. et al, 2016, *J Pharmacol Exp Ther.,* 359:11–17., 5. Zhang, J. et al, 2013, *Mol Pharmacol.,* 83:848–856., 6. Kuszynski DS, Lauver DA., 2022, *Purinergic Signal*, 18(3): 253–265.

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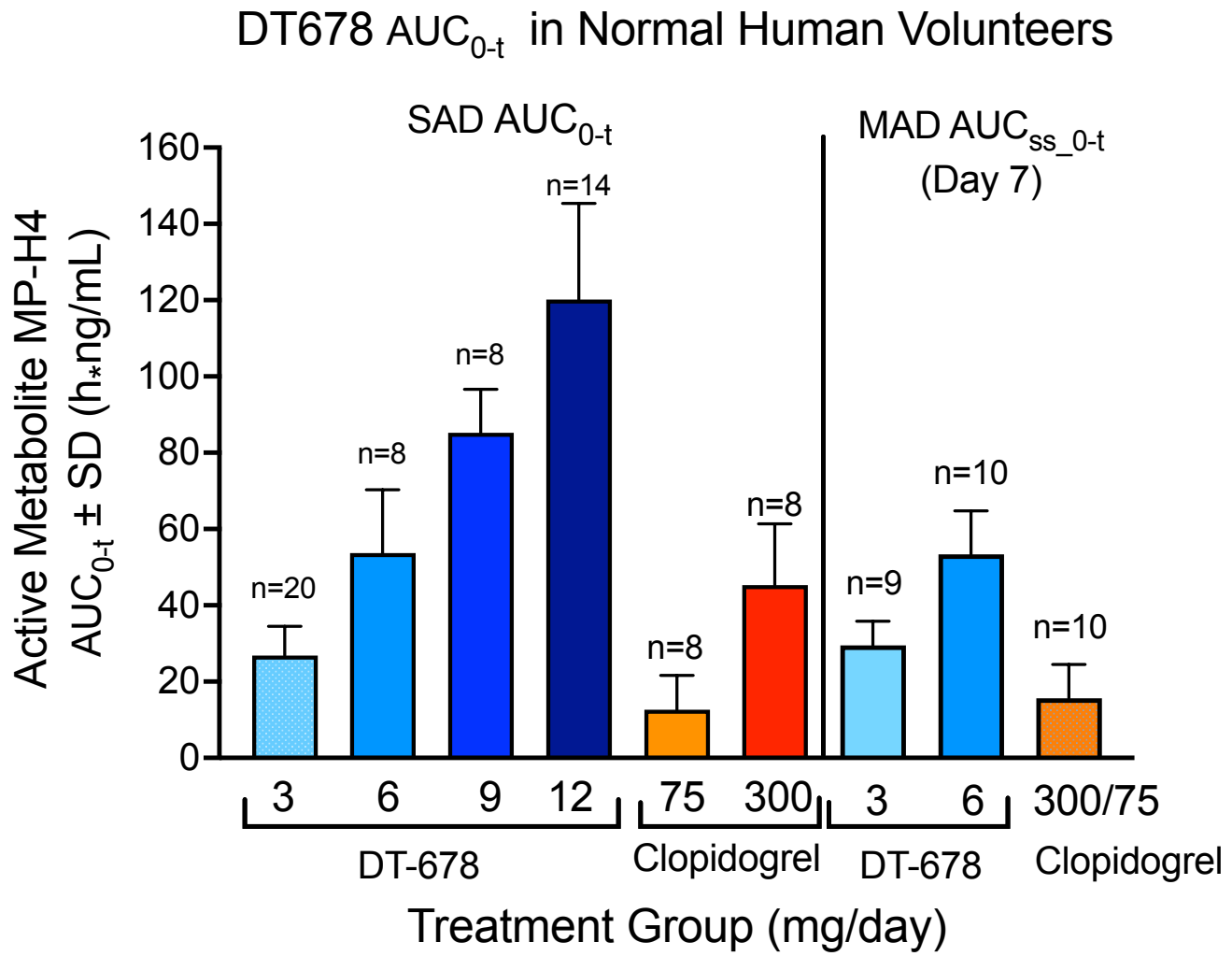
Phase 1 SAD/MAD Study Results

3mg of DT678 Results in Similar AUC_{0-t} as Clopidogrel 75mg

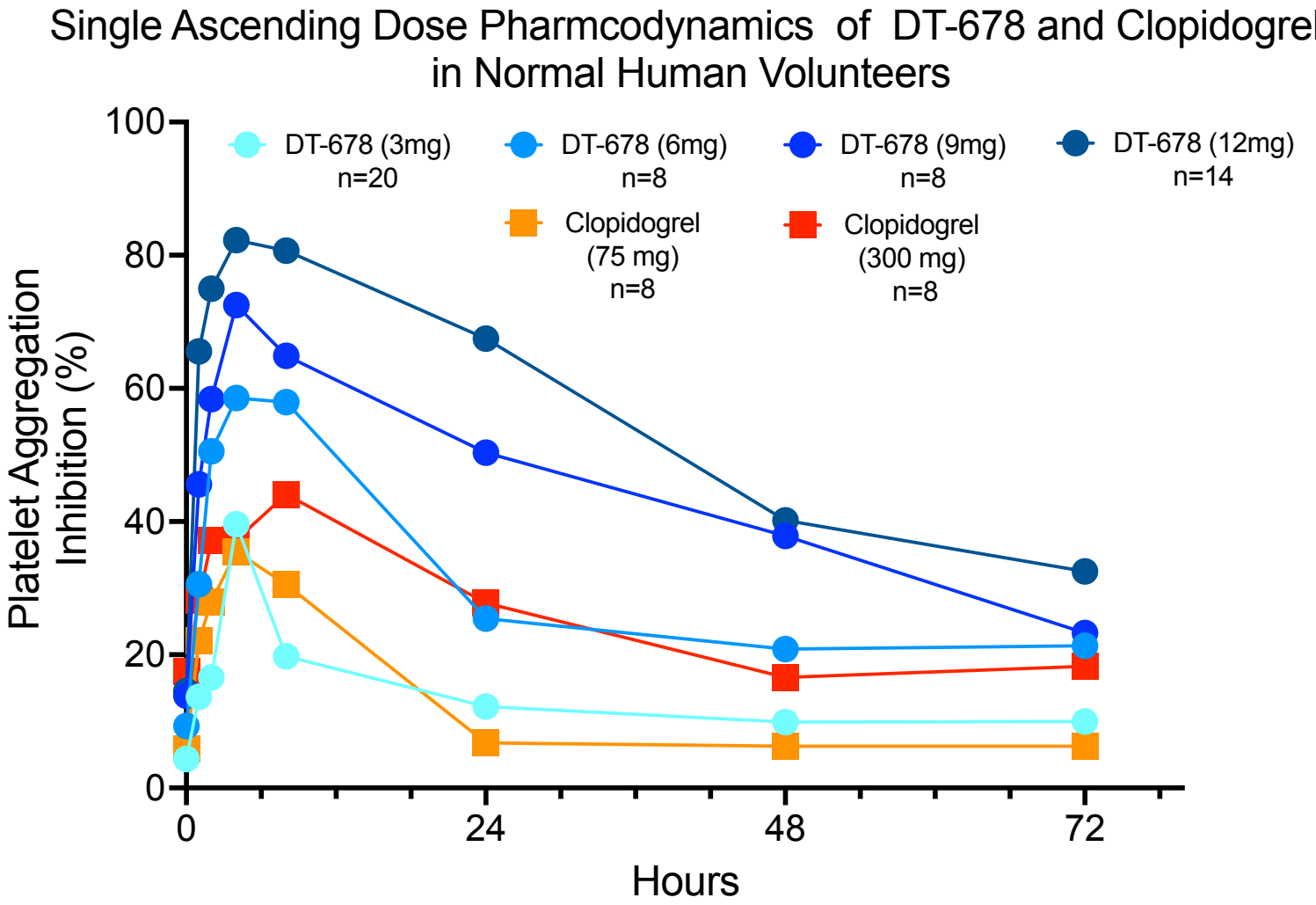


- **IND filed in China and US.**
- **DT678 has nonclinical neuro and cardio protective benefits versus clopidogrel.**
- **DT678 has linear dose proportional PK**
- **The active metabolite is generated efficiently from 3mg DT678 with similar AUC to clopidogrel 75mg at day 1 and day 7**
- **DT678 has a favorable safety profile (Ph1 SAD, MAD, FE, and DDI completed in China)**

Phase I Data
MP-H4 is same as M4

Phase 1 Results

3mg of DT678 is Equivalent to 75mg of Clopidogrel



- DT678 has dose proportional Pharmacodynamic antiplatelet effects - clinical biomarker
- DT678 3mg has similar antiplatelet effects compared to 75mg clopidogrel
- 6 & 9m chronic toxicology studies complete
- Phase 2 in progress

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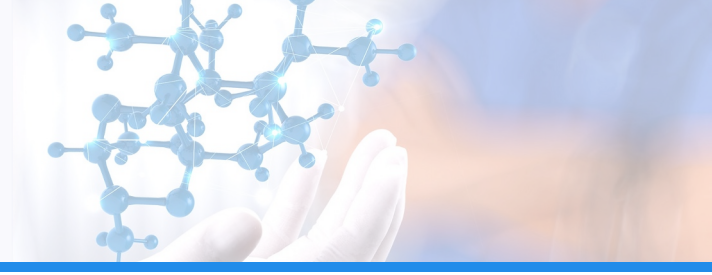
DT678 Clinical Development Plan

Defined Path to NDA Submission and Approval



FDA Endorsed the 505b2 submission pathway:

- FDA agreed to the 505(b)(2) approach and comparative bioavailability (BA) study, endorsing the strategy to bring DT678 to market efficiently
- FDA has agreed that no additional efficacy studies are required if BA study successful
- FDA agreed that if DT678 is not metabolized via CYP2C19 the clopidogrel black box label would not apply

Equivalence:

- DT678 is a novel prodrug where the active metabolite (M4) is identical to clopidogrel
- DT678 shows dose equivalence to clopidogrel in pharmacokinetic (PK) and pharmacodynamic (PD) studies

Superiority:

- DT678 has shown multiple benefits versus clopidogrel and other P2Y12 inhibitors
  - Greater potency, fewer metabolites and off target effects (e.g. bleeding)
  - no CYP2C19 or CES-1 patient variability, linear and predictable PK and PD, no dyspnea, once a day dosing, potential for reduced bleeding, faster onset with cardio and neuroprotection.

1. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER)., 1999, *Applications Covered by Section 505(b)(2)*., 2. Pereillo, J.M. et. al., 2002, *Drug Metab. Dispos.* 30, 1288–1295.

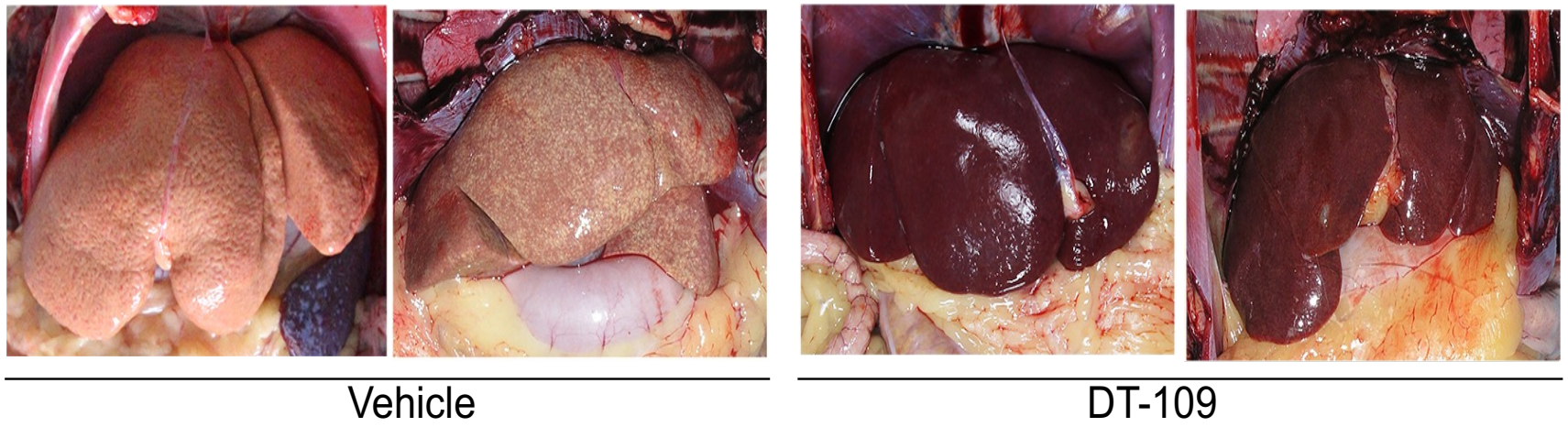
Diapin Pipeline

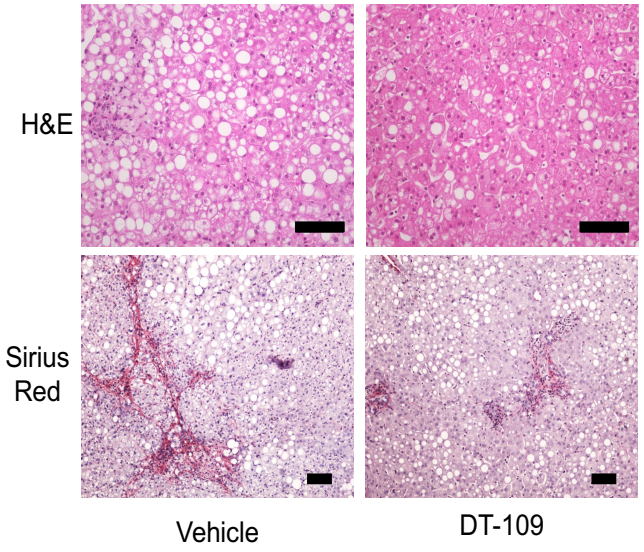
Cardiovascular and Metabolic Disease Treatment Innovation

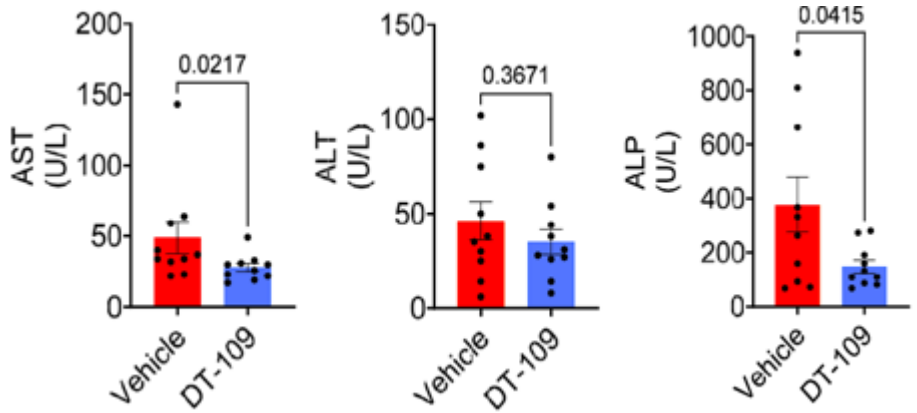
	INDICATION	PRECLINICAL	CANDIDATE SELECTION	IND-ENABLING	PHASE I	PHASE II	PHASE III
DT678 (antiplatelet)	ACS/Myocardial Infarction						
	Stroke						
	Peripheral Artery Disease						
DT-109 (tripeptide)	Metabolic Steatohepatitis						
	Primary Biliary Cholangitis						
	Atherosclerosis - CVD						
	Type 2 Diabetes						
	Familial Hypercholesterolemia						
	Undisclosed Target						

DT109 MASH efficacy in Non-Human Primates

Reduction in Liver Fat, Fibrosis, Scarring and Liver Enzymes after 5m







- **DT109 significantly decreased overall Liver Fat**
- **DT109 reduced liver fat content, fibrosis and scarring**
- **DT109 reduced liver enzymes: AST, ALT and ALP**

Qu P, Rom O, Li K, et al. *Cell Metab*. 2023;35(5)

Diapin Therapeutics Team

Successful Track Record and Exits Through NDA and Commercialization

Charles Bisgaier, Ph.D.
Chairman of the Board
Former Pfizer Research Fellow
Founder and investor of 10+ corporations

Eugene Chen, M.D., Ph.D.
Founder, Board Member
Prof of Medicine, Univ of Michigan
Director for Adv Models for Translational Sciences

Mingo Xu, M.D., Ph.D.
Board Member and GM of Beijing SL Pharmaceutical

Jessica Reed, Ph.D.
CEO, Board Member
Millendo, MMS, Pfizer, Parke-Davis

Michael Iannuzzi, MD, MBA
CMO,
CUNY School of Medicine

Sara Melton
Business Development,
Sales & Marketing Advisor

Paul Jeffrey
Commercialization Advisor
Former Pfizer VP
Early Commercial Development

University of Michigan · Pfizer · Esperion Therapeutics · ProNAi · MMS Holdings Inc. · imagine PHARMA · Parke-Davis People Who Care · HYGIEIA · Gemphire Therapeutics · BIOSAVITA · MILLENDO THERAPEUTICS · GeneToBe The Rare Disease Company

Lipitor atorvastatin calcium tablets · Nexletol (bempedoic acid) tablets · Aricept donepezil HCl tablet 23 mg · Banzel (rufinamide) · AcipHex rabeprazole sodium · Vizimpro dacomitinib

Lopid 600 (Gemfibrozil Tablets, USP) · d-Nav by HYGIEIA A BETTER WAY TO USE INSULIN · Byetta exenatide injection · Fycompa (perampanel) tablets 2mg · 4mg · 6mg · 8mg · 10mg · 12mg · Onfi (clobazam) Tablets · Osphena (ospemifene) tablets 60 mg · Dalvance (dalbavancin) for injection

Diapin Scientific Advisory Team

Best-in-class and diverse medical team guiding development

Dr. Dan Eitzman, MD

Professor of Internal Medicine

University of Michigan Medical School

Dr. Charles Burant, MD, PhD

Dr. Robert C. and Veronica Atkins Professor of Metabolism

University of Michigan School of Public Health

Dr. George King, MD

Chief Scientific Officer at Joslin Diabetes Center & Professor of Medicine

Harvard School of Medicine

Dr. Arun J. Sanyal, MD

Chief of the Division of Gastroenterology, Hepatology and Nutrition & Professor of Medicine

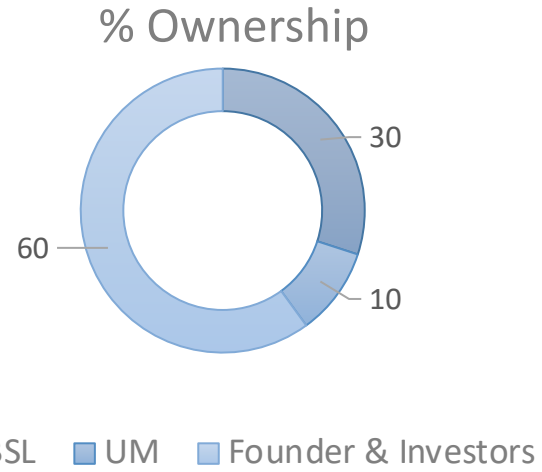
Virginia Commonwealth University/VCU Health

Dr. Shamir Mehta, MD

Douglas A. Holder Endowed Chair and Professor of Medicine

McMaster University

Seeking Investment for Diapin Therapeutics



EXIT

Multiple Investor Exit opportunities: strategic partner, out licensing, acquisition, IPO

DT678 Approval and Commercial Launch — EXIT Revenue generating — NDA approved, Launch DT678

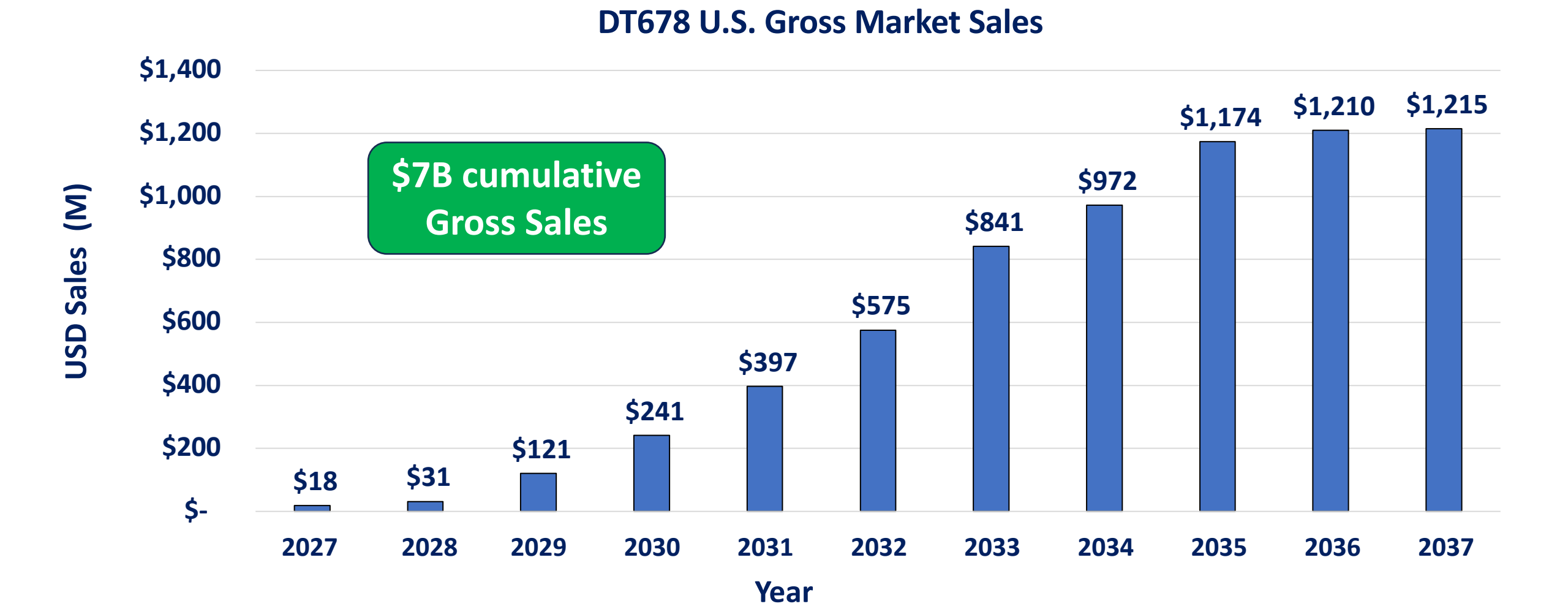
Series A, DT678 launch prep, Org. Growth & DT109 development — EXIT Series A — Prepare for NDA approval, Launch, IPO

Seed Round 7.5 Million — EXIT $7.5M — Bioavailability Study, Response to FDA Requests, file NDA

Phase 1s Completed (China) IND filed (US &China) — $6M — Grants, Beijing SL, Founders, and Investors

DT678 US Forecast Aligned to Brilinta

Peaked at 10% Market Share in the U.S. by 2023



Assumed $495 per month per patient
IMS, GlobalData and Annual Reports

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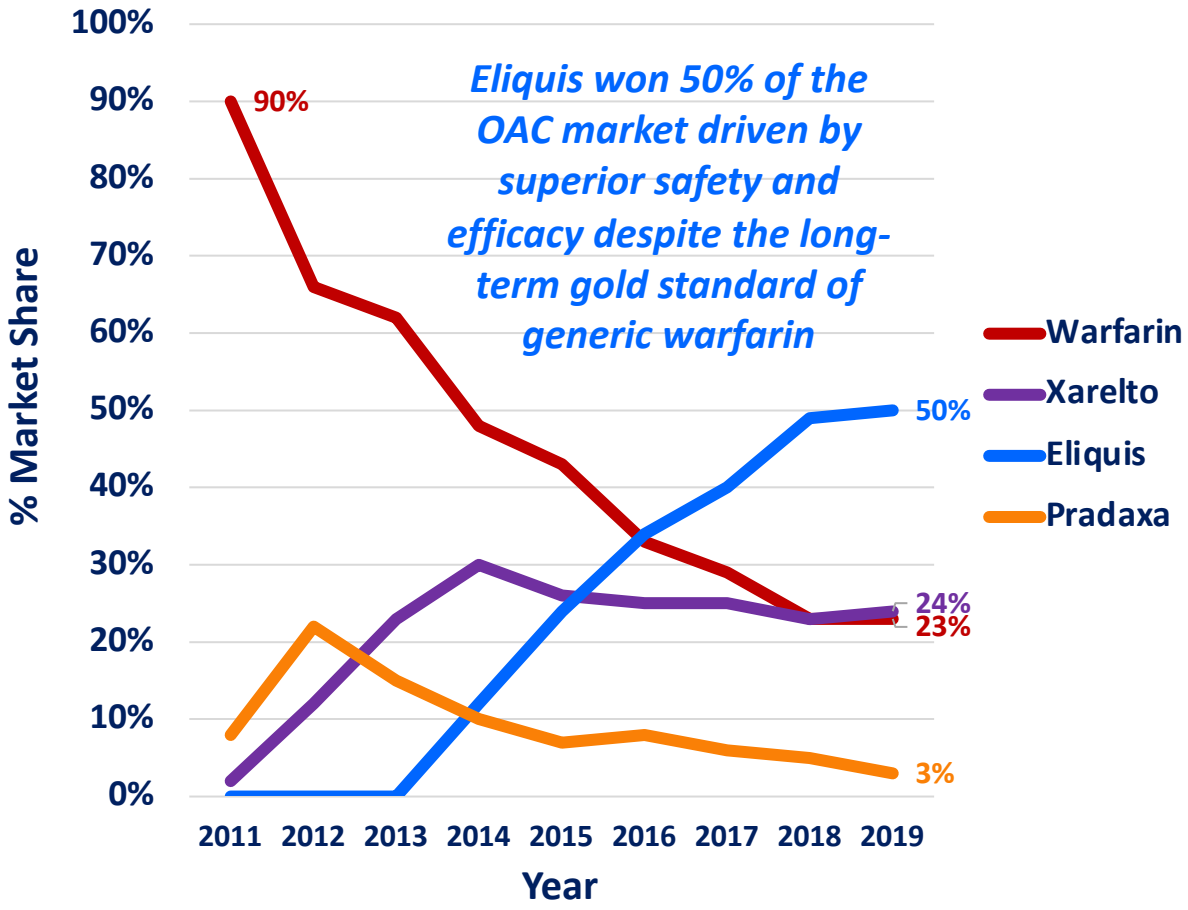
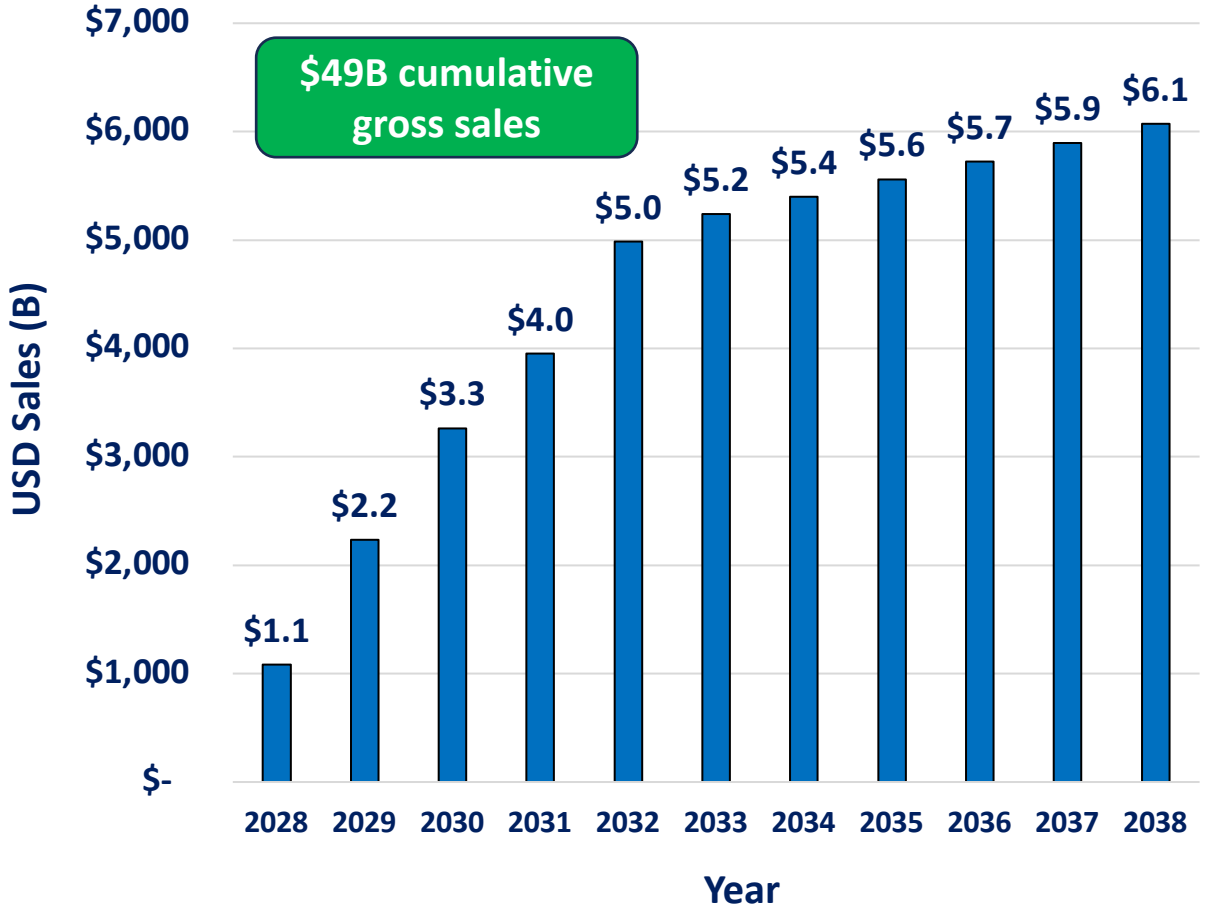
DT678 US Forecast Aligned to Eliquis

Peaked at 50% Market Share in the U.S. by 2023

NOAC Market Share Trends US



DT678 US Sales based on Eliquis Analog



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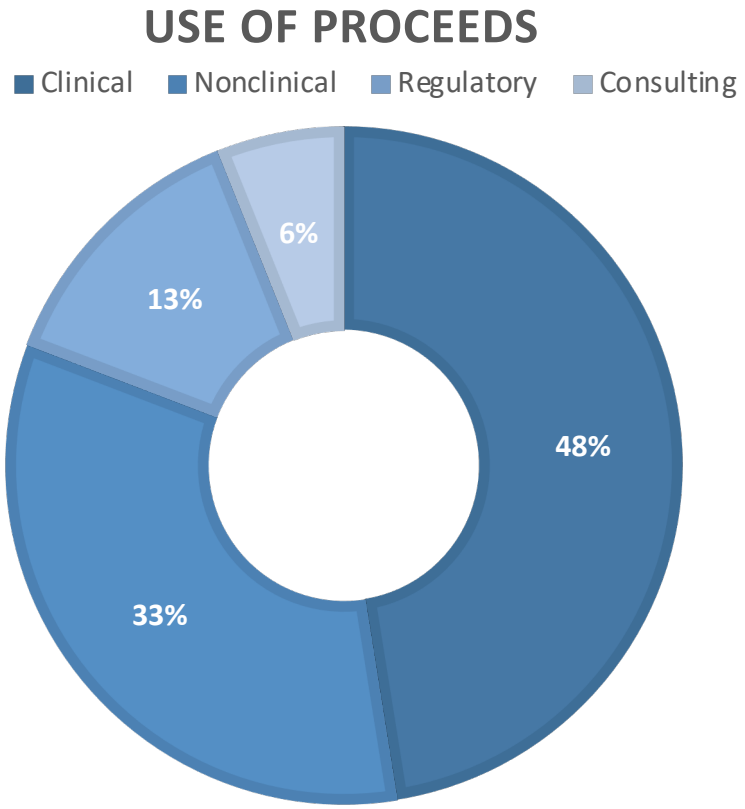
IMS, GlobalData and Annual Reports

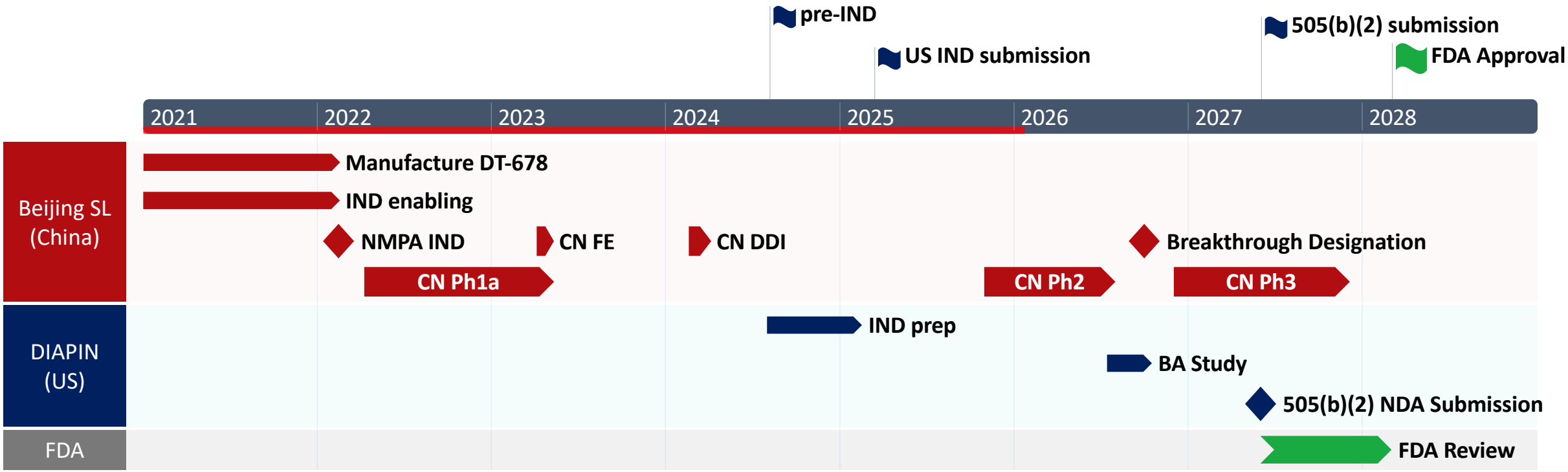
Use of Proceeds -7.5 Million to File DT678 NDA



Planned Use of 7.5 Million

- **3.5 million - Clinical Study - CRO single site PK/PD study (48%)**
- **2.5 million – Nonclinical studies and FDA requests (33%)**
- **1 million – NDA regulatory filing (13%)**
- **0.5 million – Consulting, Clinical, PK/PD, Nonclinical, Regulatory (6%)**

DT678 NDA Approval Timeline*



Key Milestones:

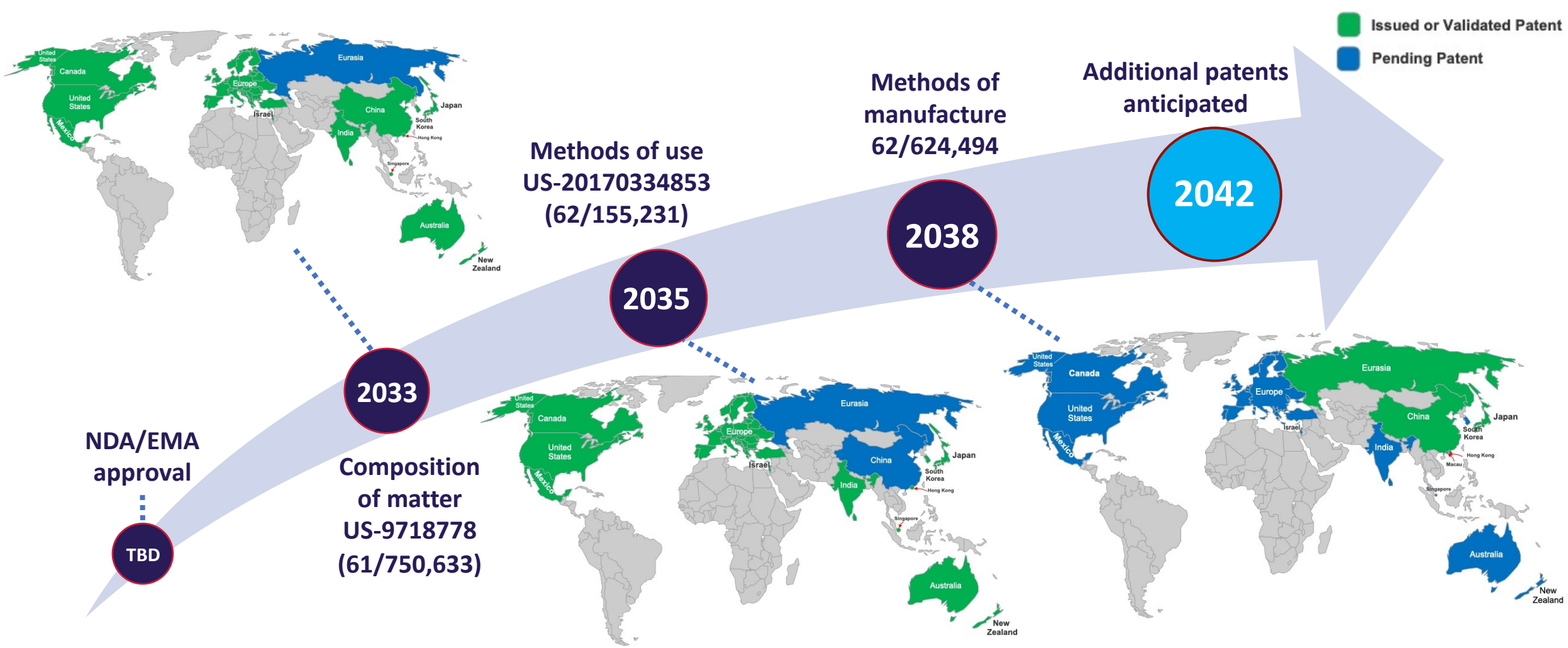
- Start of US BA study
- Completion of Phase 2 study in China
- Completion of US BA study
- File 505(b)(2) NDA submission

$7.5 Million to US NDA submission

* Timeline contingent on funding

DT678 Intellectual Property Portfolio

Anticipating long-term patent protection through 2042 – DT678



Intellectual Property Portfolio as of January 2025

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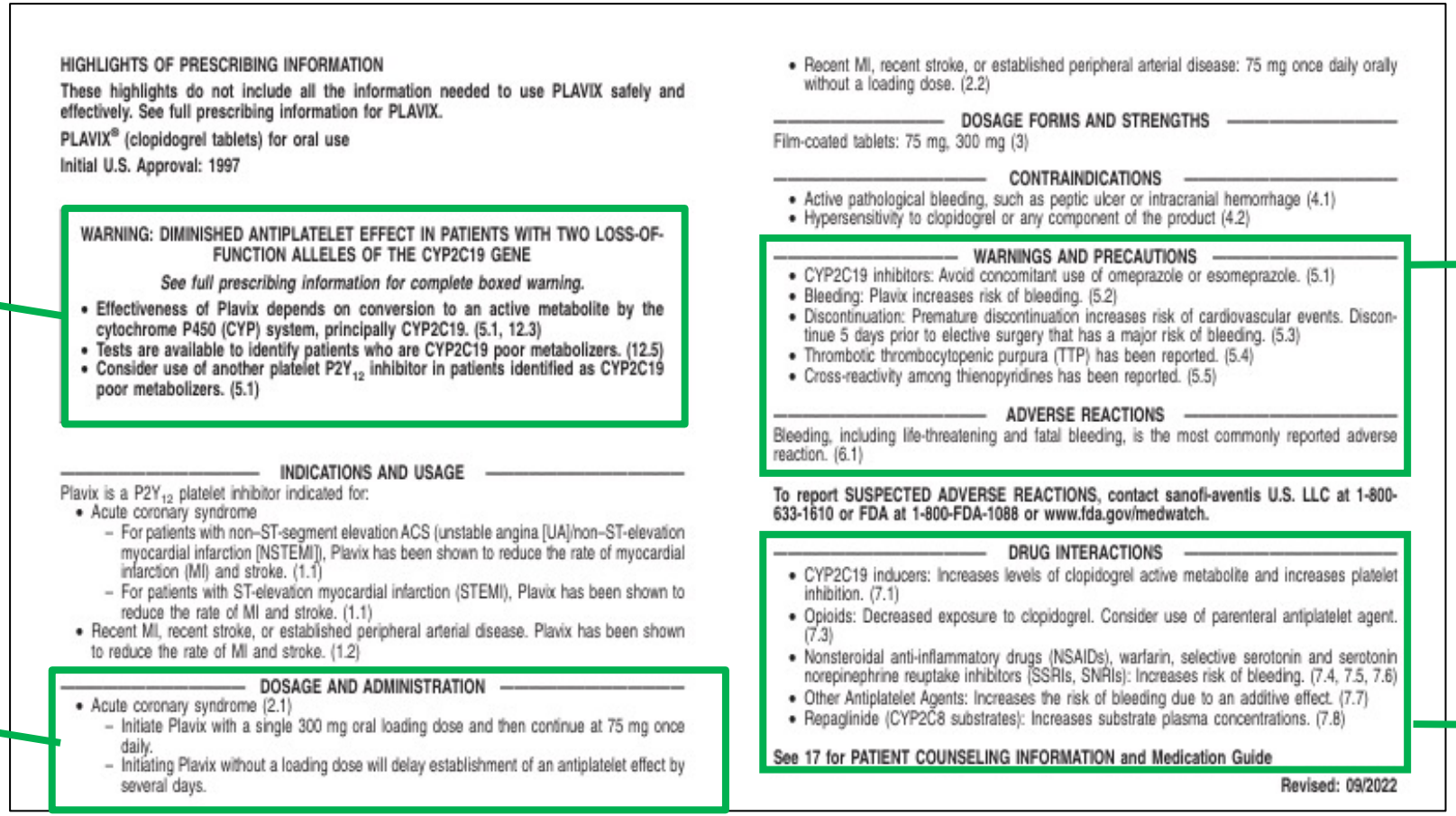
DT678 Label Differences versus Plavix

Target Patients with CYP2C19 LOF, Obesity, Diabetes, Age & Bleeding Risk

Removal of black box warning

May not require loading dose

No interaction with CYP2C19 inhibitors



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PLAVIX safely and effectively. See full prescribing information for PLAVIX.

PLAVIX® (clopidogrel tablets) for oral use

Initial U.S. Approval: 1997

WARNING: DIMINISHED ANTIPLATELET EFFECT IN PATIENTS WITH TWO LOSS-OF-FUNCTION ALLELES OF THE CYP2C19 GENE

See full prescribing information for complete boxed warning.

- **Effectiveness of Plavix depends on conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. (5.1, 12.3)**
- **Tests are available to identify patients who are CYP2C19 poor metabolizers. (12.5)**
- **Consider use of another platelet $P2Y_{12}$ inhibitor in patients identified as CYP2C19 poor metabolizers. (5.1)**

INDICATIONS AND USAGE

Plavix is a $P2Y_{12}$ platelet inhibitor indicated for:

- Acute coronary syndrome
  - For patients with non–ST-segment elevation ACS (unstable angina [UA]/non–ST-elevation myocardial infarction [NSTEMI]), Plavix has been shown to reduce the rate of myocardial infarction (MI) and stroke. (1.1)
  - For patients with ST-elevation myocardial infarction (STEMI), Plavix has been shown to reduce the rate of MI and stroke. (1.1)
- Recent MI, recent stroke, or established peripheral arterial disease. Plavix has been shown to reduce the rate of MI and stroke. (1.2)

DOSAGE AND ADMINISTRATION

- Acute coronary syndrome (2.1)
  - Initiate Plavix with a single 300 mg oral loading dose and then continue at 75 mg once daily.
  - Initiating Plavix without a loading dose will delay establishment of an antiplatelet effect by several days.
- Recent MI, recent stroke, or established peripheral arterial disease: 75 mg once daily orally without a loading dose. (2.2)

DOSAGE FORMS AND STRENGTHS

Film-coated tablets: 75 mg, 300 mg (3)

CONTRAINDICATIONS

- Active pathological bleeding, such as peptic ulcer or intracranial hemorrhage (4.1)
- Hypersensitivity to clopidogrel or any component of the product (4.2)

WARNINGS AND PRECAUTIONS

- CYP2C19 inhibitors: Avoid concomitant use of omeprazole or esomeprazole. (5.1)
- Bleeding: Plavix increases risk of bleeding. (5.2)
- Discontinuation: Premature discontinuation increases risk of cardiovascular events. Discontinue 5 days prior to elective surgery that has a major risk of bleeding. (5.3)
- Thrombotic thrombocytopenic purpura (TTP) has been reported. (5.4)
- Cross-reactivity among thienopyridines has been reported. (5.5)

ADVERSE REACTIONS

Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- CYP2C19 inducers: Increases levels of clopidogrel active metabolite and increases platelet inhibition. (7.1)
- Opioids: Decreased exposure to clopidogrel. Consider use of parenteral antiplatelet agent. (7.3)
- Nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, selective serotonin and serotonin norepinephrine reuptake inhibitors (SSRIs, SNRIs): Increases risk of bleeding. (7.4, 7.5, 7.6)
- Other Antiplatelet Agents: Increases the risk of bleeding due to an additive effect. (7.7)
- Repaglinide (CYP2C8 substrates): Increases substrate plasma concentrations. (7.8)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

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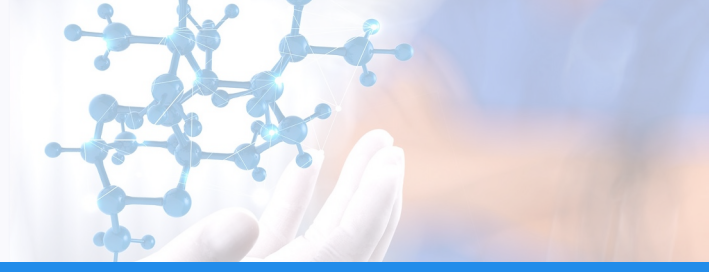
Thank You !



Raising seed round of $7.5 million to File US NDA for DT678

For more information please contact: jreed@diapin.com

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- ☑ Data room available