

Resverlogix Corp. Corporate Breakthroughs 公司突破

September 2020

2020年9月



Forward Looking Statement 前瞻性陈述

This presentation may contain certain forward-looking information as defined under applicable Canadian securities legislation, that are not based on historical fact, including without limitation statements containing the words "believes", "anticipates", "plans", "intends", "will", "should", "expects", "continue", "estimate", "forecasts" and other similar expressions. In particular, this presentation may include forward looking information relating to the Phase 3 BETonMACE2 clinical trial, Covid-19, vascular cognitive dementia, chronic kidney disease, fabry disease and pulmonary arterial hypertension clinical trials, and the potential role of apabetalone in the treatment of high-risk cardiovascular disease, diabetes mellitus, chronic kidney disease, end-stage renal disease treated with hemodialysis, neurodegenerative disease, Fabry disease, peripheral artery disease and other orphan diseases. Our actual results, events or developments could be materially different from those expressed or implied by these forward-looking statements. We can give no assurance that any of the events or expectations will occur or be realized. By their nature, forward-looking statements are subject to numerous assumptions and risk factors including those discussed in our Annual Information Form and most recent MD&A which are incorporated herein by reference and are available through SEDAR at www.sedar.com. The forward-looking statements contained in this news release are expressly qualified by this cautionary statement and are made as of the date hereof. The Company disclaims any intention and has no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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Resverlogix at a Glance

- Resverlogix Corp. is a Canadian public company developing an advanced cardiovascular drug called apabetalone. We are pioneering a technology that has the ability to turn multiple disease causing genes on or off. No actual change to the human DNA occurs. Our exciting breakthrough technology places Resverlogix as a world leader in utilizing “**epigenetics**” to regulate disease-causing genes.
- Apabetalone, was awarded **FDA Breakthrough Therapy Designation (BTD) in Feb. 2020**. This is the highest designations that a drug can receive from the FDA. BTD has only been awarded to 130 drugs previously and apabetalone is the first drug ever for mainstream cardiovascular development.
- Apabetalone’s unique approach has been tested in over **4,200 man years of treatment** and has demonstrated its positive biological effects on patients with diseases such as;
 - Cardiovascular disease (CVD),
 - Diabetes mellitus (DM)
 - Chronic kidney disease (CKD).
 - Non-Alcoholic Fatty Liver disease (NAFLD)
 - Vascular Dementia
- Apabetalone is the only drug of its kind in advanced human clinical trials. This drug is in the process of final approval in Europe and the USA as well as in a dozen other countries around the world with varying **patent life ranging from 2029 to 2040**.

Stock Symbol	TSX: RVX
Market Cap	\$180MM ¹
Shares Outstanding	217MM ¹

Resverlogix简介

- Resverlogix Corp.是一家加拿大上市公司，致力于开发一款名为apabetalone的先进心血管药物。我们正在开创一种能够打开或关闭多种致病基因的技术。人类DNA不会发生实际变化。我们令人兴奋的突破性技术使Resverlogix在利用“表观遗传学”调节致病基因方面处于世界前沿水平。
- Apabetalone于2020年2月被授予FDA突破疗法资格（BTD）。这是药物可以从FDA获得的最高认证。此前仅有130种药物获得突破疗法资格，而apabetalone是有史以来第一个用于主流心血管疾病、获得突破疗法资格的药物。
- 已在4200人中进行Apabetalone的独特方法的多年治疗测试，并证明了对以下疾病的患者具有积极的生物学作用：
 - 心血管疾病（CVD）
 - 糖尿病（DM）
 - 慢性肾脏病（CKD）
 - 非酒精性脂肪肝病（NAFLD）
 - 血管性痴呆
- 在高级的人类临床试验中，Apabetalone是同类药物中唯一的药物。该药物正在欧洲和美国以及世界上其他十几个国家处于最终批准过程中，专利期从2029年到2040年不等。

股票代码	TSX: RVX
市值	\$1.8亿 ¹
已发行股票	2.17亿 ¹

Near Term Development Points



- The US **FDA and Resverlogix** have now confirmed the final BETonMACE2 clinical plans.
 - Filing of a New Drug Application (NDA) with the FDA is possible following unequivocal efficacy at **an interim analysis** of BETonMACE2 - 2023
 - All or most BETonMACE2 patients to receive top standard of care, including **SGLT2 inhibitors**
 - BETonMACE2 to increase enrichment of chronic kidney disease (**CKD**) patients
 - Based on existing results, **the FDA encouraged the evaluation of a non-alcoholic fatty liver disease (NAFLD)** subgroup as well as related exploratory endpoints
- **Development, Option 1**, Resverlogix will now finalize it's ongoing negotiations with Major Pharmaceutical companies to determine a suitable partner for co-developing apabetalone. Co-development discussions include the following:
 - Resverlogix will receive a **significant** upfront payment H2, 2020.
 - The Phase 3b clinical trial will be funded by the partnering company - **\$120 to \$150 MM USD**.
 - Our new partner can supply their **SGLT2 diabetes drug as the co-medication**. Thus providing the pharma partner with valuable marketing material and the ability to launch a fixed dose combination product with **patent coverage until 2040**.
 - The deal will also include substantial milestone and royalty payments with an **M&A right of first refusal option**.
- **Option 2**, Resverlogix can finance the Phase 3b trial internally through the sale of 50% of the future royalty stream currently owned by Zenith Capital. Funds would be used to finance BETonMACE2.
- **Option 3**, Resverlogix can finance and launch the Phase 3b trial with internal insider investors.

近期发展点

- 美国FDA和Resverlogix现在已经确认了最终的BETonMACE2临床计划。
 - 在对BETonMACE2-2023的中期分析明确疗效后，可以向FDA提交新药申请（NDA）
 - 所有或大多数BETonMACE2患者都将接受最高标准的治疗，包括SGLT2抑制剂
 - BETonMACE2可增加慢性肾脏病（CKD）患者的营养
 - 根据现有结果，FDA鼓励对非酒精性脂肪肝疾病（NAFLD）亚组以及相关的研究终点进行评估
- 开发，选项1，Resverlogix现在将完成与主要制药公司的正在进行的谈判，以确定适合共同开发apabetalone的合作伙伴。共同开发讨论包括以下内容：
 - Resverlogix将在2020年下半年收到一笔可观的前期付款。
 - 3B期临床试验将由合作公司提供资金——1.2亿至1.5亿美元。
 - 我们的新合作伙伴可以提供SGLT2糖尿病药物作为联合用药。从而为制药合作伙伴提供有价值的营销材料，并有能力推出专利期到2040年的固定剂量组合产品。
 - 该交易还将包括重大里程碑和特许权使用费，以及并购优先购买权。
- 选项2，Resverlogix可以通过出售Zenith Capital目前拥有的未来特许权使用费的50%，在内部为3b期试验提供资金。资金将用于资助BETonMACE2。
- 选项3，Resverlogix内部投资者提供资金并启动3b期试验。

Required Drug Qualities for Successful Commercialization

- **Efficacy**, does the drug work? ✓
- **Safety**, is the drug safe in general populations? ✓
- **Regulatory Approvability**, will the FDA or EMA approve the drug based on safety and efficacy? ✓
- **Mechanism of Action (MOA)**, a deep understanding of how the drug works must be demonstrable. ✓
- **Publications**, a wide body of third party reviewed peer publications must be readily available. ✓
- **Strategic Commercial Pathway**, a clear commercial pathway with payer group support must be present. ✓

We have mountains of proof for all of the above, please see some examples in the following slides.

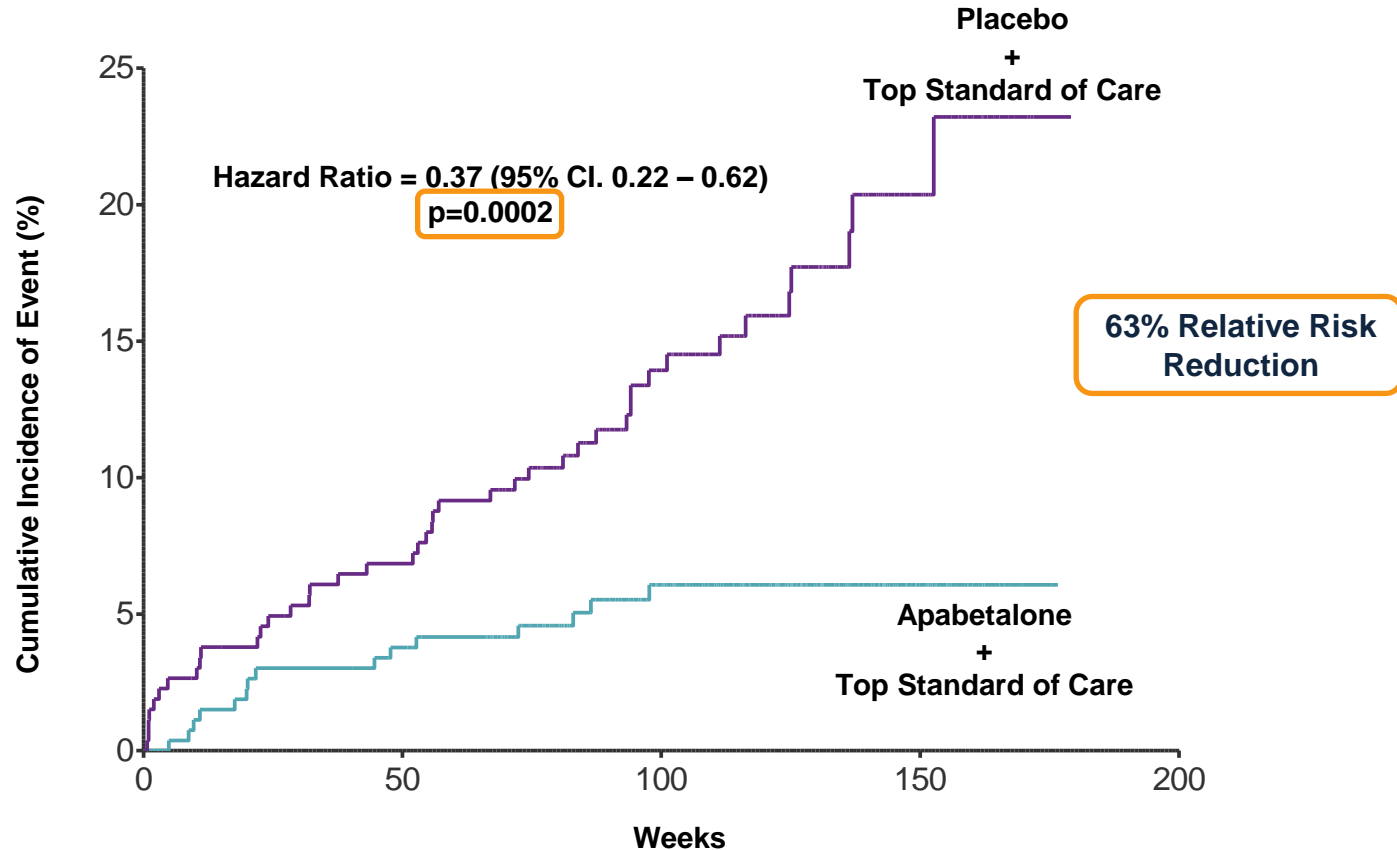
成功商业化所需的药物质量

- 功效，药物有效吗？ ✓
- 安全性，普通人群中用药安全吗？ ✓
- 法规批准，FDA或EMA是否会根据安全性和有效性批准药物？ ✓
- 作用机理（MOA），必须对药物的作用有深刻的了解。 ✓
- 出版物，必须经过大量第三方评审的同行出版物。 ✓
- 战略性商业途径，必须有一条得到付款人团体支持的清晰商业途径。 ✓

对于上述所有方面，我们都有很多证据，请在以下幻灯片中查看一些示例。



Efficacy - The Drug Works! Trials confirmed a highly significant reduction in Death, Heart Attacks and CHF.



- The effect of the co-administration of apabetalone and SGLT2 or DPP4 inhibitors – quantified by CV death, non-fatal MI, stroke and hospitalization for congestive heart failure (CHF) – illustrated a significant reduction of events compared to placebo and SGLT2 or DPP4 inhibitors
 - HR = 0.37 (95% CI, 0.22–0.62; p=0.0002)
- Apabetalone was well tolerated with similar rates of adverse events compared to placebo

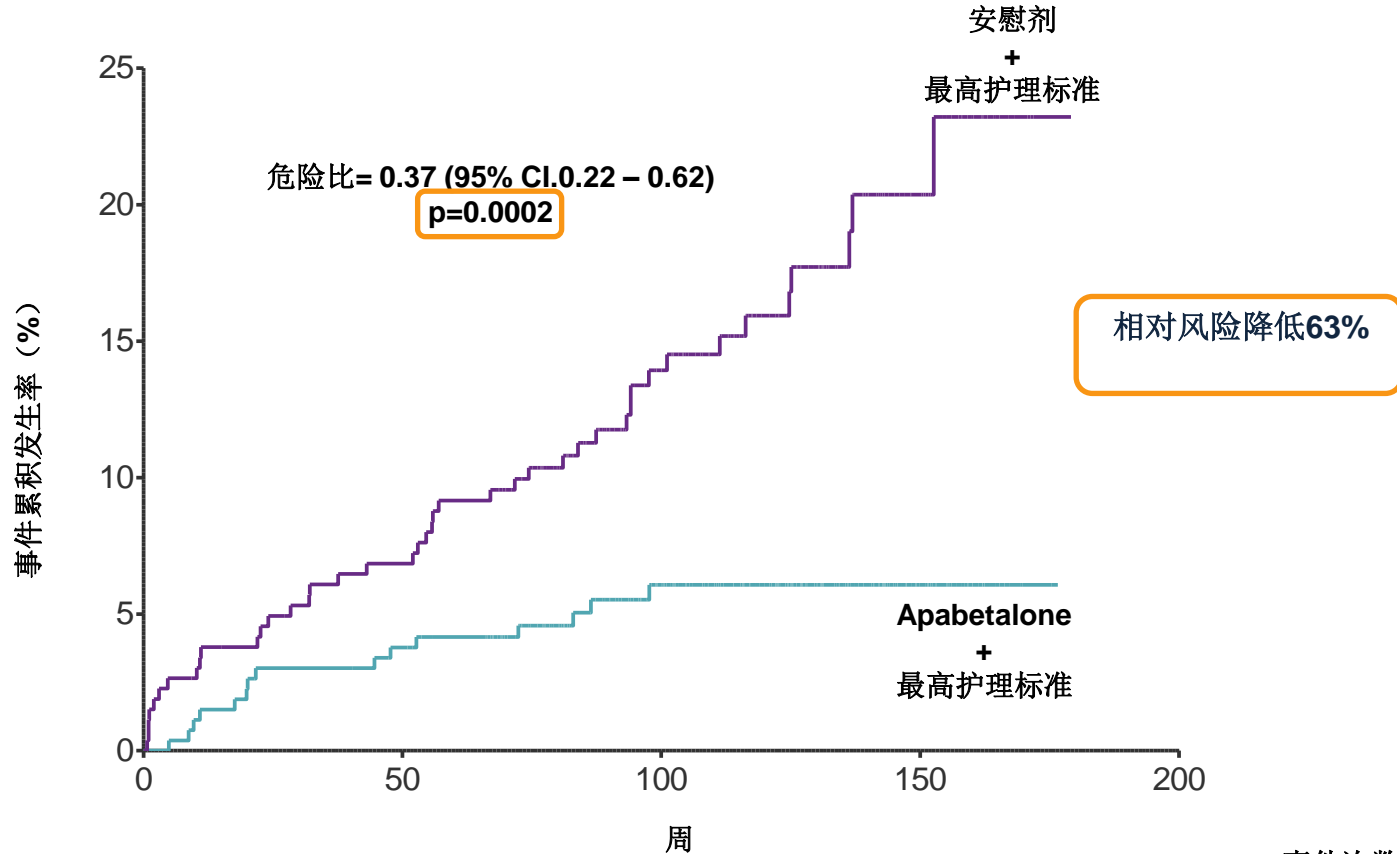
No. at Risk	Weeks				No. of Events
	0	50	100	150	
Placebo	264	244	151	36	42
Apabetalone	265	253	169	41	15

Top standard of care includes: high intensity statins, ACE inhibitors/angiotensin II blockers, beta blockers, antiplatelet agents

RVX Internal Analysis January 2020

Apabetalone treatment led to a significant 63% RRR of MACE and hospitalization for Congestive Heart Failure (CHF) compared to placebo in patients receiving SGLT2 or DPP4 Inhibitors

功效——药物有效！试验证实，死亡、心脏病发作和充血性心力衰竭（CHF）显著降低。



- apabetalone和SGLT2或DPP4抑制剂共同给药的效果——通过心血管死亡、非致死性心肌梗塞（MI）、中风和充血性心力衰竭（CHF）住院进行定量——说明与安慰剂和SGLT2或DPP4抑制剂相比，事件的发生率显著降低
 - HR = 0.37 (95% CI, 0.22–0.62; p=0.0002)
- 与安慰剂相比，Apabetalone对不良事件的耐受性良好

危险次数	周				事件次数
安慰剂	264	244	151	36	42
Apabetalone	265	253	169	41	15

最高护理标准包括：高强度他汀类药物、ACEI抑制剂/血管紧张素II受体阻滞剂、β受体阻滞剂、抗血小板药

RVX内部分析2020年1月

接受SGLT2或DPP4抑制剂的患者与安慰剂相比，使用Apabetalone治疗可使主要不良心血管事件（MACE）和充血性心力衰竭（CHF）住院率显著降低63%

FDA Approves Breakthrough Therapy Designation

FDA批准突破性疗法资格



“A breakthrough therapy designation is for a drug that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.”

FDA Website

“突破性疗法称号适用于治疗严重或危及生命的疾病的药物，并且初步临床证据表明，相比现有疗法，该药物可能在临床上具有重要意义。终点上有实质性改善。” **FDA官网**



IND 76487

**GRANT –
BREAKTHROUGH THERAPY DESIGNATION**

Resverlogix Corp.
Attention: Barry Calvarese
Consultant, Regulatory Affairs
44 Montgomery Street, Suite 4010
San Francisco, CA 94104

Dear Mr. Calvarese:

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for apabetalone (RVX000222).

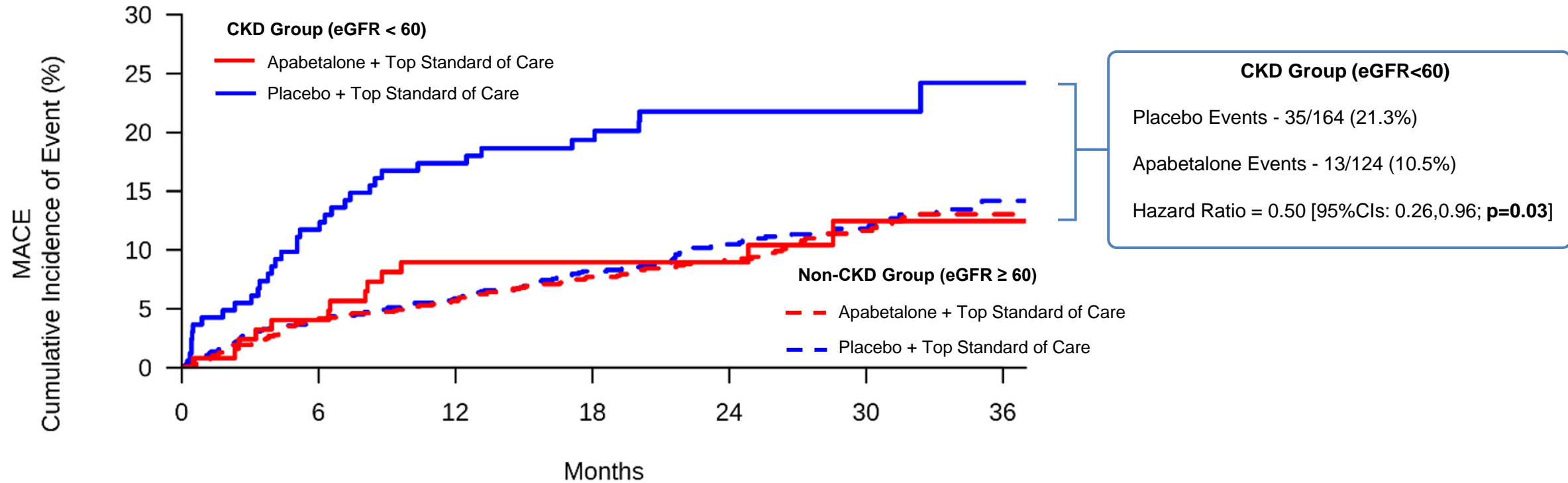
We also refer to your December 4, 2019, request for Breakthrough Therapy designation. We have reviewed your request and have determined that apabetalone, in

As the result of very safe and promising data the FDA granted Resverlogix the coveted Breakthrough Therapy Designation.

由于获得了非常安全和有希望的数据，FDA授予Resverlogix梦寐以求的突破性疗法资格。

Kaplan-Meier Estimates by CKD/Non-CKD for MACE Apabetalone Compared to Placebo

A



No. at Risk

eGFR < 60	288	259	240	207	146	85	20
eGFR ≥ 60	2125	2022	1971	1675	1163	691	192

Source: Kalantar-Zadeh et al 2020; Apabetalone in CKD and MACE; publication pending

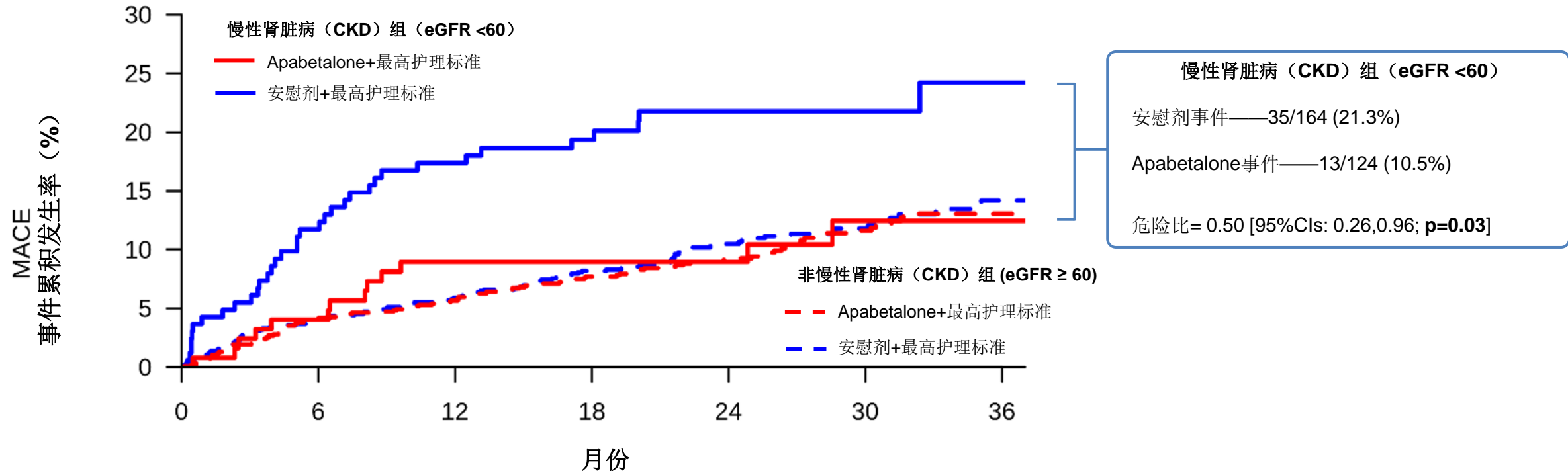
Apabetalone treatment led to a significant 50% relative risk reduction of MACE compared to placebo in patients with CKD



与安慰剂比较，Apabetalone治疗严重的不良心血管事件（MACE）的慢性肾脏病（CKD）和非慢性肾脏病（CKD）的卡普兰-梅尔估计量



A



危险次数

eGFR < 60	288	259	240	207	146	85	20
eGFR ≥ 60	2125	2022	1971	1675	1163	691	192

来源: Kalantar-Zadeh等 2020; Apabetalone治疗慢性肾脏病（CKD）和严重的不良心血管事件（MACE）；出版待定

与安慰剂相比，慢性肾脏病（CKD）患者接受Apabetalone治疗后，使严重的不良心血管事件（MACE）相对风险显著降低**50%**



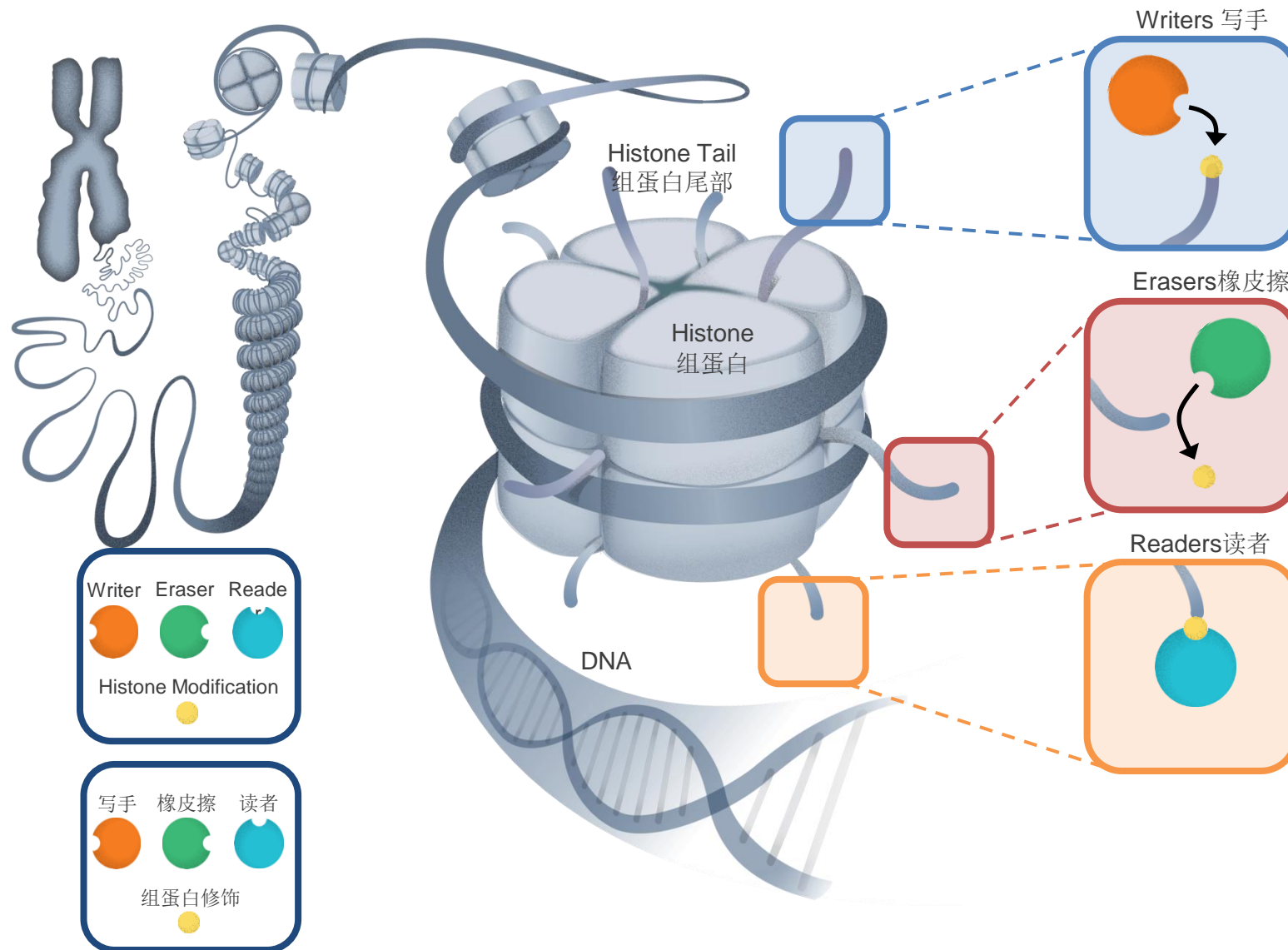
Mechanism of Action –Understood at a Granular Level

作用机理——深入了解

Chromosome
染色体

Chromatin Fiber
染色质纤维

Nucleosome
核小体



- Epigenetics refers to **modifications** to chromatin that regulate its activity 表观遗传学是指对染色质进行修饰，以此来调节活性
- Transcription is regulated by **addition, removal, or recognition** of these modification 通过添加、删除或识别这些修饰来调节转录
- **Acetylation** is associated with **active transcription** regions of chromatin 乙酰化与染色质的活性转录区相关
- **Bromodomain and Extraterminal Domain (BET)** proteins bind to acetylated histones and recruit additional transcription factors to drive gene expression 溴结构域及超末端结构域(BET)蛋白与乙酰化组蛋白结合并接收额外的转录因子来驱动基因表达

Mechanism of Action - Unique, Effective, Highly Advanced!

How Does Drug Development Work?

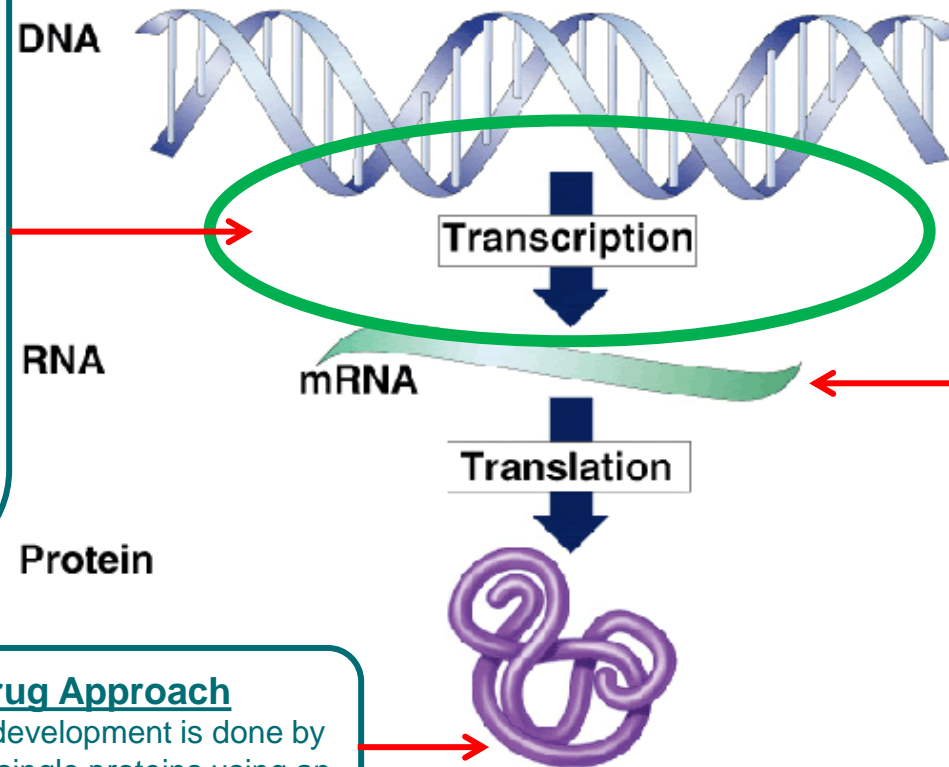
Epigenetic Regulation - New

Due to disease, environment or diet a patients original DNA messages can be corrupted before it is replicated into mRNA. Our epigenetic approach has demonstrated the ability to impact hundreds of compromised proteins in a safe manor. **No competitors.**

Apabetalone – basically resets the original DNA message and reduces numerous metabolic disease mediators , potentially including Covid-19 factors.

Protein Targeting – Standard Drug Approach

Approximately 95% of standard drug development is done by either down regulating or up regulating single proteins using an inhibitor or antibody. **Tens of thousands of competitors**



Genome Editing

The mechanism is based on cutting and pasting undesired/desired sequences into or out of the DNA, thereby altering the gene sequence and then re-introducing the modified DNA into the body. **Dozens of competitors.**

Messenger RNA

This new approach of altering mRNA has recently made some advances as significant improvements in oligonucleotide delivery have been realized. A promising approach in vaccinations but still only deals with one protein issue at a time. **Dozens of competitors.**

行动机制——独特、有效、高度先进！

药物开发如何进行？

表观遗传调控——新的

由于疾病、环境或饮食的原因，患者原始的DNA信息在复制到mRNA中之前可能会被破坏。我们的表观遗传学方法已证明能够在安全的区域中影响数百种受损蛋白质。**没有竞争对手。**

Apabetalone——基本上重设了原始的DNA信息并减少了许多代谢性疾病的介质，可能包括**Covid-19**因子。

蛋白质靶向——标准药物方法

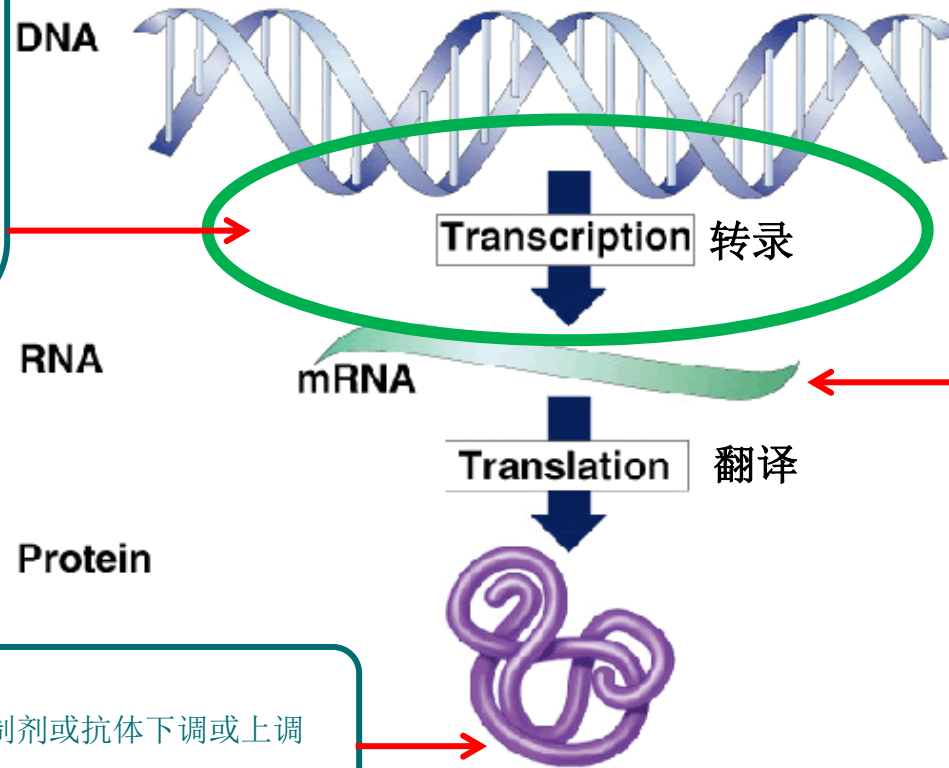
约**95%**的标准药物开发乃是通过使用抑制剂或抗体下调或上调单个蛋白来完成。**数以万计的竞争对手**

基因组编辑

该机制是基于将不需要的/不需要的序列切割并粘贴到DNA中或从DNA粘贴出来，从而改变基因序列，然后将修饰的DNA重新引入体内。**数十个竞争对手。**

信使RNA

随着寡核苷酸递送得到显著改善，这种改变mRNA的新方法最近取得了一些进展。一种有希望的疫苗接种方法，但一次只能处理一种蛋白质。**数十个竞争对手。**

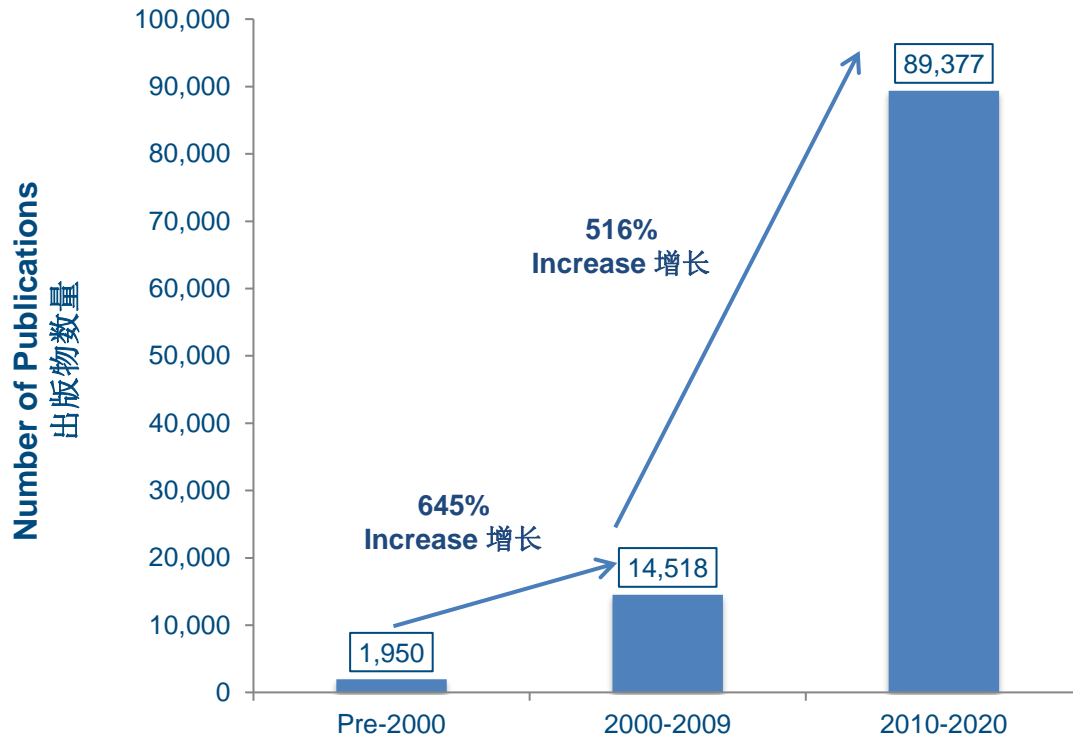


Publications on Epigenetics and RVX 表观遗传学和RVX的出版物

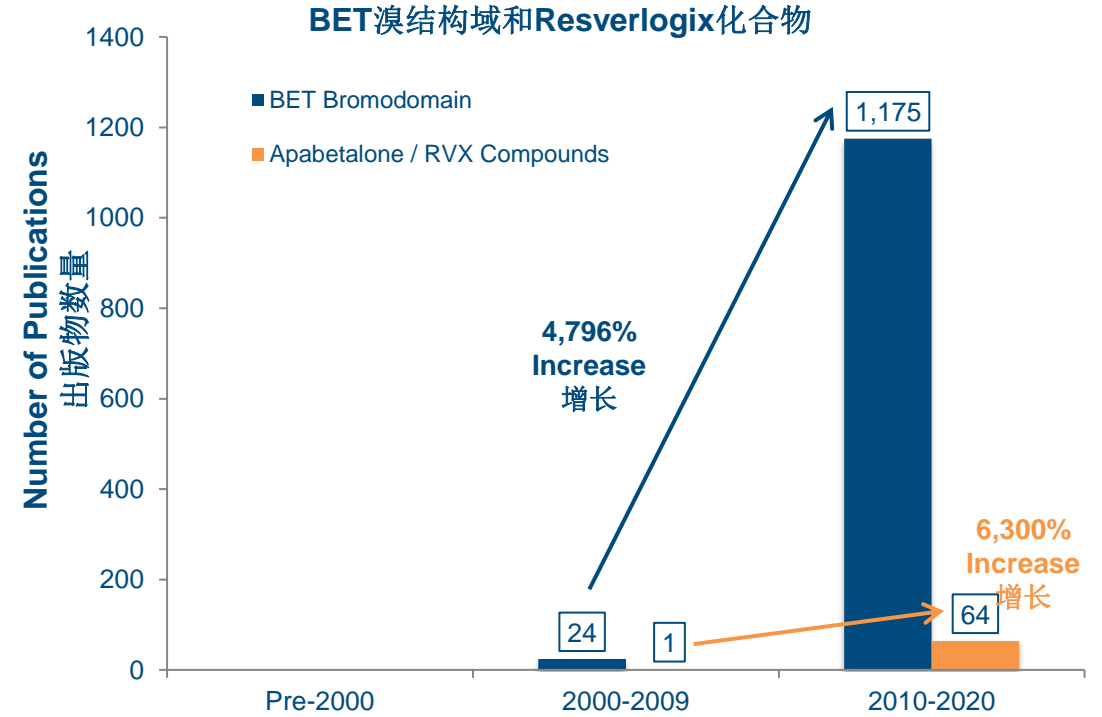


Dramatic growth of publications over the past decade in Epigenetics and BET Inhibition
在过去十年中，表观遗传学和BET抑制的出版物急剧增长

Publications on Epigenetics 表观遗传学出版物



Publications on BET Bromodomain and Resverlogix Compounds



Safety- BETonMACE Nov. 2015 to Sept. 2019

安全——2015年11月至2019年9月的BETonMACE



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As the result of very safe and promising data the FDA granted Resverlogix the coveted **Breakthrough Therapy Designation**. Apabetalone has already been tested in over 1,900 patients in 18 countries around the world, 14 countries have approved Phase 3 usage. 由于获得了非常安全和有希望的数据，FDA授予Resverlogix梦寐以求的突破性疗法资格。Apabetalone已经在全球18个国家/地区的1,900多名患者中进行了测试，其中14个国家/地区已批准三期使用。

Business Development Strategy 业务发展策略





- Partnered Apabetalone in Greater China (China, Hong Kong, Taiwan and Macau) with Shenzhen Hepalink Pharmaceutical, a ~US\$4 billion market cap company listed in Hong Kong & China 与市值约40亿美元的香港和中国上市公司深圳市海普瑞药业股份有限公司展开Apabetalone在大中华区（中国、香港、台湾和澳门）的合作
 - US\$35M initial equity investments in Resverlogix (total now exceeds US\$130M) Resverlogix 获得3500万美元初始股权投资（目前总金额超过1.3亿美元）
- Exclusive licensing agreement with Medison Pharma Ltd. for Apabetalone in Israel 与Medison Pharma Ltd. 达成Apabetalone的以色列独家许可协议
- Discussing additional global or regional licensing or co-development opportunities with major pharmaceutical companies 与大型制药公司讨论其他全球或地区许可或共同开发的机会



Strategic Commercial Pathway - Global Vascular Opportunity



Apabetalone is a first-in-class, small molecule that is a selective BET inhibitor that produces a specific set of biological effects with important benefits while maintaining a well described safety profile.
It is currently being evaluated for the following indications:

- | | | | |
|----------|--|---|--------------------------------|
| 1 | High Risk Acute Coronary Syndrome (ACS) Patients with a Type II Diabetes Mellitus (DM) Comorbidity and Low High-Density Lipoprotein Cholesterol (HDL-C) |  | 1.5 M+ Patients by 2032 |
| 2 | High Risk Chronic Kidney Disease (CKD) Patients (Stages 3-5, Pre-Dialysis) with a Diabetes Mellitus Comorbidity and a History of Cardiovascular Disease (CVD) |  | 4.0 M+ Patients by 2032 |
| 3 | High Risk End Stage Renal Disease (ESRD) Patients with Elevated Alkaline Phosphatase (ALP) (>80 U/L) |  | 1.0 M+ Patients by 2032 |
| 3 | Vascular Cognitive Dementia (MoCA score < 26) in Elderly (>65 years) Patients with Diabetes Mellitus Comorbidity and a History of CVD |  | 1.5 M+ Patients by 2032 |

战略性商业途径——全球血管机会



Apabetalone是一类小分子选择性BET抑制剂，可产生一组具有重要益处的特定生物学效应，同时保持良好安全性。目前正在评估以下适应症：

1

伴有II型糖尿病（DM）合并症和低高密度脂蛋白胆固醇（HDL-C）的高危急性冠状动脉综合征（ACS）患者



到2032年将有超过150万患者

2

伴有糖尿病合并症和心血管疾病史（CVD）的高危慢性肾脏病（CKD）患者（3-5阶段，透析前）



到2032年将有超过400万患者

3

伴有高碱性磷酸酶（ALP）（>80 U/L）的高危末期肾病（ESRD）患者

到2032年将有超过100万患者

3

伴有糖尿病合并症和心血管疾病史（CVD）的血管性认知痴呆（MoCA得分<26）的老年患者（> 65岁）



到2032年将有超过150万患者

Additional Indication Targets 其他适应症目标

- Complement Mediated Disease: orphan indication 补体介导疾病：孤儿药适应症
- Neurofibromatosis – Malignant Peripheral Nerve Sheath Tumors (MPNST): orphan indication 神经纤维瘤病——恶性周围神经鞘瘤（MPNST）：孤儿药适应症
- Pulmonary Arterial Hypertension (PAH): orphan indication – **In progress now** 肺动脉高压（PAH）：孤儿药适应症——目前正在进行中
- Muscular Dystrophy/Facio Scapulo Humeral Dystrophy: orphan indication 肌肉萎缩症/面肩胛肱型肌营养不良症：孤儿药适应症
- Fabry Disease: orphan indication 法布里病：孤儿药适应症
- Vascular Cognitive Dementia 血管性认知痴呆
- HIV eradication 消除艾滋病毒
- Covid -19, interruption of replicating mechanisms such as BRD4 and ACE2 - **In progress now** / Covid -19, 复制机制（例如BRD4和ACE2）中断——目前正在进行中



Management Team



Donald McCaffrey
President & Chief Executive Officer

- Co-founded Resverlogix in 2001 with Dr. Norman Wong
- Has over 40 years of corporate management experience, including over 20 years in drug discovery & development



Dr. Norman C.W. Wong, M.D., FRCP,
Chief Scientific Officer & Co Founder

- Co-founded Resverlogix in 2001 with Donald McCaffrey
- Researches molecular actions of hormones related to the regulation of gene expression and pathogenesis of diabetes mellitus



A. Brad Cann, CA, Chief Financial Officer

- Has over 20 years of experience in a variety of financial and business roles
- Leads the Company's expanding financial activities supporting advancing scientific and clinical development



Dr. Ewelina Kulikowski,
PH.D., SVP, Research & Development

- Joined in 2005 as Director of Research and Development
- Has been Involved in the development of lead drug RVX-208 from its discovery through to Phase 3 clinical development



Dr. Michael Sweeney, M.D., SVP,
Clinical Development

- Cardiologist with extensive experience in pharmaceutical product development and marketing
- Has over 30 years in the pharmaceutical industry, including 11 years at Pfizer



Kenneth Lebioda, BA, SVP, Business & Corporate Development

- Has over 30 years of experience in the innovative pharmaceutical industry with leading global companies such as Bristol-Myers Squibb, Hoechst Marion Roussel and Marion Merrell Dow



Dr. Jan O. Johansson, M.D., PH.D.,
SVP, Medical Affairs

- Has had a distinguished 35 year career in academia and in the pharmaceutical industry of which including various companies with expertise in the cardio-metabolic and neurological disease therapeutic area



Dr. Henrik C. Hansen, PH.D., VP,
Intellectual Property

- Has 20 years in drug discovery & development experience.
- Areas of expertise also include medicinal chemistry, process development and manufacturing of drug substances and products for clinical use



Paul Moon, CPIR
VP, Investor Relations and Communications

- Has over 25 years of public company experience working in multiple industries, including: technology, financial services, real estate, international mining, and oil and gas



Donald McCaffrey
总裁兼首席执行官

- 与Norman Wong博士于2001年共同创立了Resverlogix
- 拥有40多年的企业管理经验，包括20多年的药物发现与开发经验



Norman C.W. Wong博士、医学博士、皇家内科医学院荣誉院士、首席科学官兼联合创始人

- 与Donald McCaffrey于2001年共同创立了Resverlogix
- 研究激素的分子作用与糖尿病的基因表达调控和发病机制



A. Brad Cann，注册会计师、首席财务官

- 有20多年担任财务和商务职位的经验
- 领导公司不断扩展的金融活动，以支持科学和临床发展



Ewelina Kulikowski博士、研发高级副总裁

- 2005年加入，担任研发总监
- 一直参与先导RVX-208药物的发现到3期临床开发



Michael Sweeney博士、医学博士、临床开发高级副总裁

- 拥有丰富药品开发和市场营销经验的心脏病专家
- 在制药行业拥有30多年的经验，其中在辉瑞公司工作了11年



Kenneth Lebioda，文学士、业务与企业发展高级副总裁

- 在创新制药行业拥有超过30年的经验，曾就职于百时美施贵宝、赫斯特公司和Marion Merrell Dow等全球领先公司



Jan O. Johansson博士、医学博士、医学事务高级副总裁

- 在学术界和制药行业拥有杰出的35年职业生涯，在多家公司任职，具有心脏代谢和神经疾病治疗的专业知识



Henrik C. Hansen，博士、知识产权副总裁

- 拥有20年的药物研发经验。
- 擅长药物化学、工艺开发以及用于临床的原料药和产品的制造等



Paul Moon，CPIR
投资者关系与公关副总裁

- 拥有超过25年的上市公司经验，涉及多个行业，包括：技术、金融服务、房地产、国际矿业以及石油和天然气