

CANFITE

BioPharma Ltd

Small Molecules for Big Clinical Needs / 满足巨大临床需求的小分子药物™

Investor Presentation / 投资者报告

NYSE:CANF | June 2023 / 2023年6月

Forward Looking Statement / 前瞻性陈述

This presentation contains forward-looking statements, about Can-Fite's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. All statements in this communication, other than those relating to historical facts, are "forward looking statements". Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause Can-Fite's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause actual results, performance or achievements to differ materially from those anticipated in these forward-looking statements include, among other things, our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all; uncertainties of cash flows and inability to meet working capital needs; the initiation, timing, progress and results of our preclinical studies, clinical trials and other product candidate development efforts; our ability to advance our product candidates into clinical trials or to successfully complete our preclinical studies or clinical trials; our receipt of regulatory approvals for our product candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of our product candidates; our ability to establish and maintain strategic partnerships and other corporate collaborations; the implementation of our business model and strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our ability to operate our business without infringing the intellectual property rights of others; competitive companies, technologies and our industry; risks related to the COVID-19 pandemic and the Russian invasion of Ukraine; risks related to not satisfying the continued listing requirements of NYSE American; and statements as to the impact of the political and security situation in Israel on our business. More information on these risks, uncertainties and other factors is included from time to time in the "Risk Factors" section of Can-Fite's Annual Report on Form 20-F filed with the SEC on March 30, 2023 and other public reports filed with the SEC and in its periodic filings with the TASE. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Can-Fite undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

Company Overview / 公司概况

1

Advanced clinical stage company / 高级临床阶段药物开发公司

Small molecule drug products for treatment of inflammatory and cancer indications / 拥有治疗炎症和癌症适应症的小分子药物产品

2

Robust clinical proof of concept / 强大的临床概念证明

Phase 2 and Phase 3 clinical studies; Technology is covered by 15 patent families / 二期和三期临床研究；15个专利家族所覆盖其技术

3

Successful out-licensing deals / 成功的对外许可交易

~\$20 M received to date and an additional ~\$130M in potential milestone payments plus double-digit royalties on net sales following regulatory approval / 迄今已收到约\$2,000万，另外还有约\$1.3亿的潜在里程碑付款，以及监管部门批准后净销售额的两位数权利金。

4

Financial Summary / 财务状况

(Ticker: CANF) Listed on NYSE American and Tel-Aviv Stock Exchange / 在美国证券交易所和特拉维夫证券交易所上市，交易代码为CANF

~4 M ADRs outstanding; ~1,225 M ordinary shares outstanding; (1 ADR = 300 Ordinary Shares) / 发行在外ADR约400万份，发行在外普通股 12.25亿股；（1 ADR=300普通股）

Cash: ~\$12.4 M as of 3/31/23 / 现金：截止2023年3月31日约为\$1240万

Unique Platform Technology / 独特的平台技术

Specific oral therapy aimed at diseased cells / 针对病变细胞的特定口服疗法

Therapeutic Target / 治疗靶点

- Global leader in discovering and developing drugs that target the A3 adenosine receptor (A3AR) / 发现和开发针对A3腺苷受体 (A3AR) 的药物的全球领导者

Pipeline Drugs / 管线药物

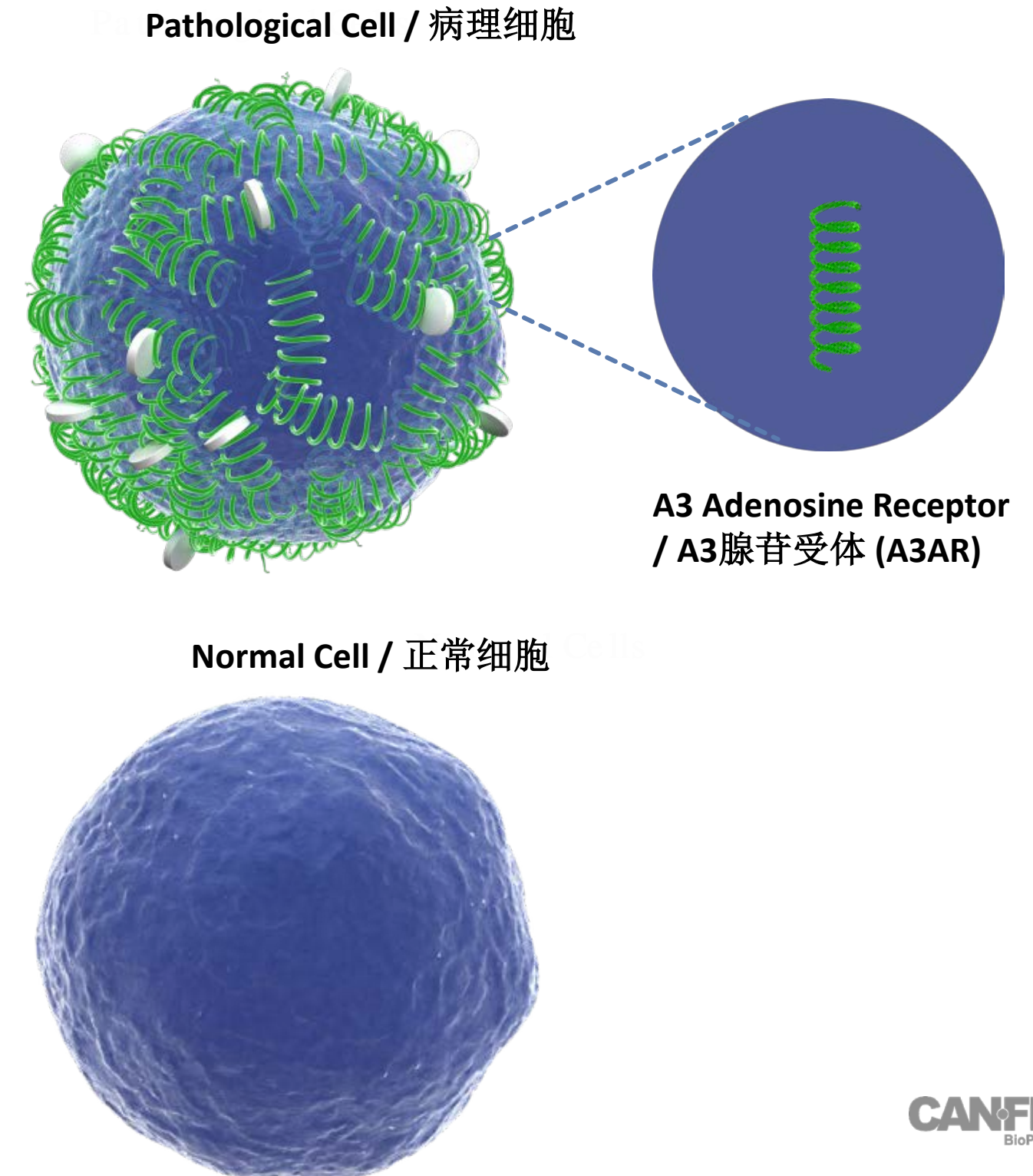
- Bind only to pathological cells, not normal cells / 只与病理细胞结合，不与正常细胞结合
- Small molecule, orally bioavailable drugs / 小分子、口服生物药物

Proven Therapeutic Effect / 经过验证的治疗效果

- High efficacy and good safety with anti-inflammatory and anti-cancer effects shown in Phase 2 and Phase 3 studies / 在II期和III期研究中显示出高疗效和良好的安全性，具有消炎和抗癌作用

Excellent Safety Profile / 出色的安全性能

- Demonstrated in >1500 patients / 在超过1500名患者中得到证明



Pipeline Drugs / 管线药物

Drug/Indication 药物/适应症	Pre-Clinical / 临床前	Phase 1 / 一期	Phase 2 / 二期	Phase 3 / 三期
Piclidenoson Psoriasis / 银屑病	Headed into Pivotal Phase 3: Cleared by EMA / 进入关键三期试验, EMA已批准			
Namodenoson Liver Cancer / 肝癌	Pivotal Phase 3 Open for Enrollment / 关键三期试验开始患者招募			
Pancreatic Cancer / 胰腺癌	Preparatory Work for a Phase 2a / 正在进行2a期试验的准备工作			
NASH / 非酒精性脂肪性 肝炎	Phase 2b Enrollment Ongoing / 2b期试验的患者招募正在进行			
CF602 Erectile Dysfunction / 勃起功能障碍	Ongoing / 正在进行			
Cannabinoids / 大麻素	Ongoing / 正在进行			

Corporate Partnerships: Current Out-Licensing Deals / 公司合作伙伴- 对外许可交易



\$20M / \$2000万

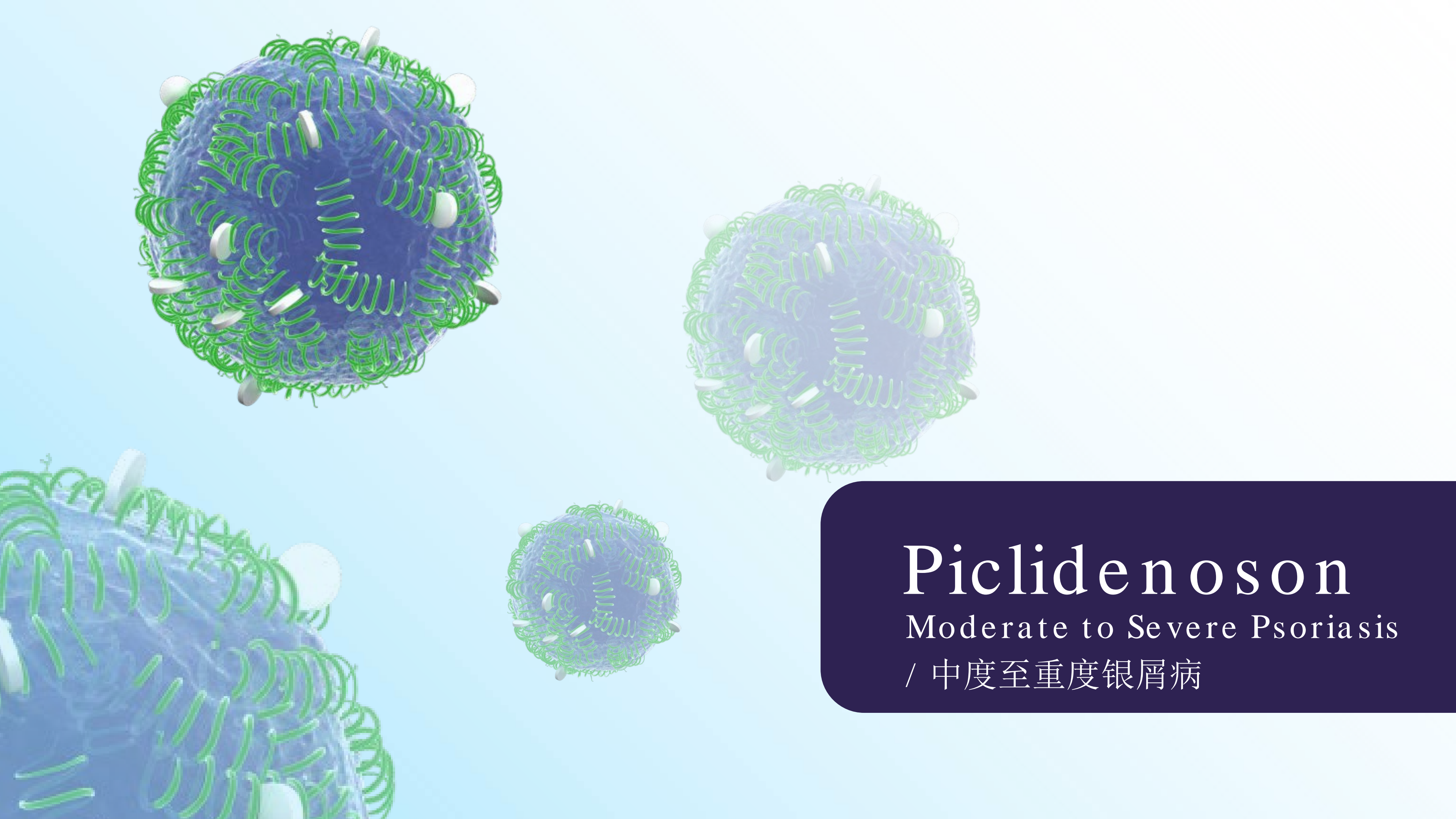
received in upfront and milestone payments / 已收到首付款和里程碑付款

\$130M / \$1.3亿

potential based on regulatory and sales milestones / 基于监管批准和销售里程碑，有望再获得\$1.3亿付款

Typical Deal Structure / 典型的交易结构

- Up-front money upon signing a distribution deal / 签署分销协议后首付款
- Regulatory milestone payments / 监管机构批准里程碑付款
- Royalties (double-digits) / 权利金 (两位数)
- Sales milestone payments / 销售里程碑付款



Piclidenoson

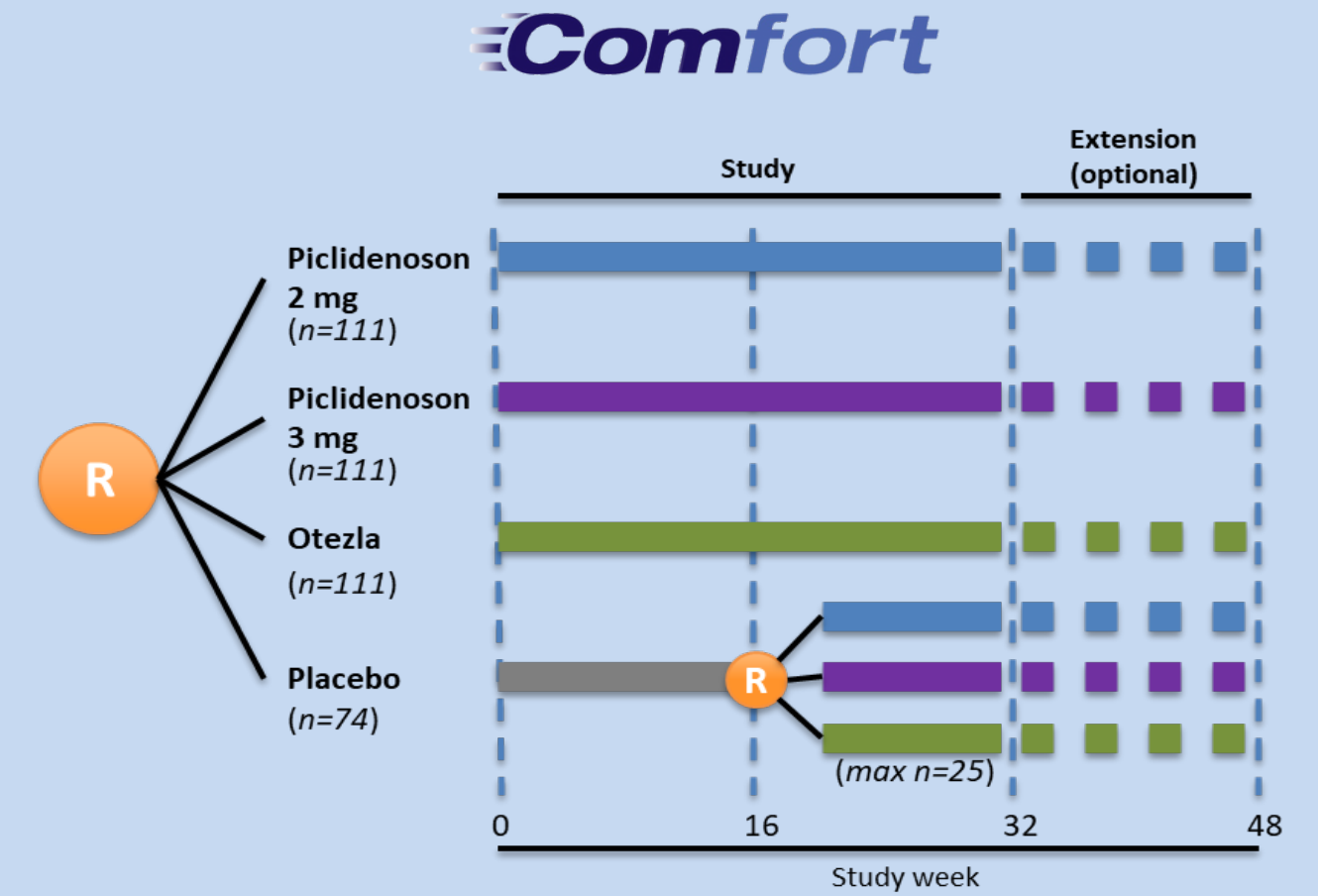
Moderate to Severe Psoriasis

/ 中度至重度银屑病

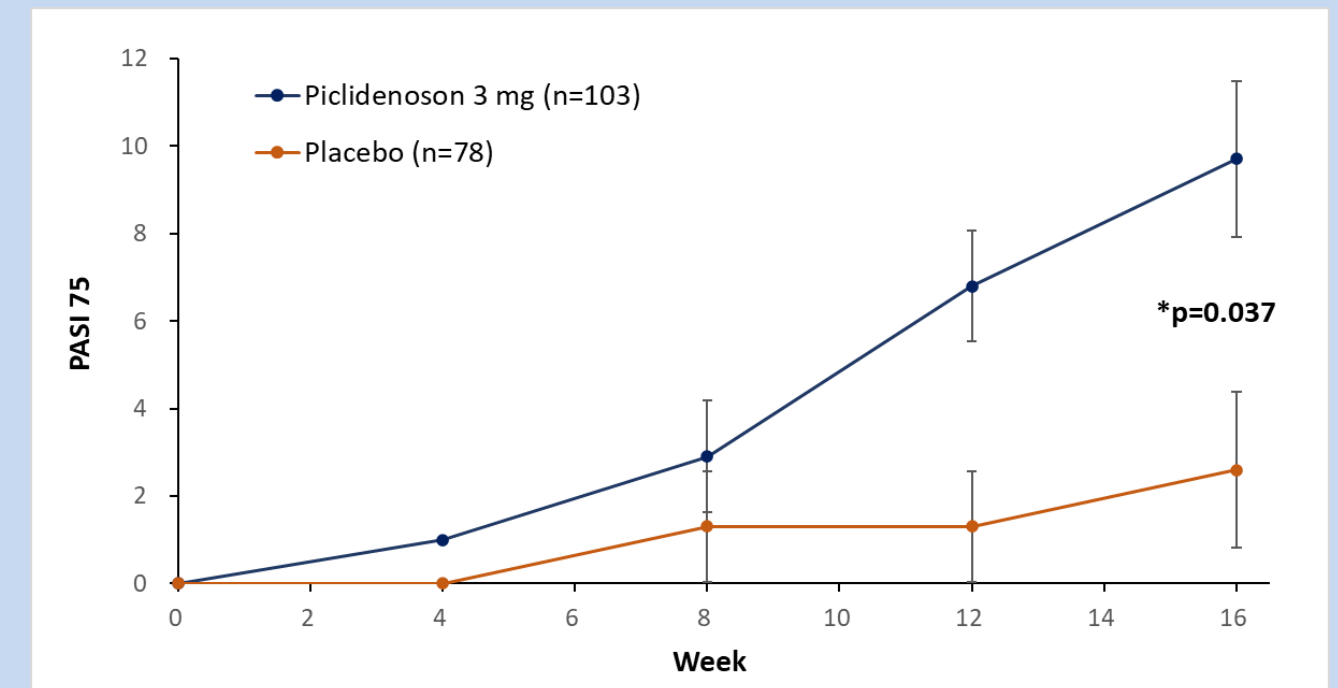
Psoriasis Phase 3 Positive Data / 银屑病三期临床试验获得积极数据

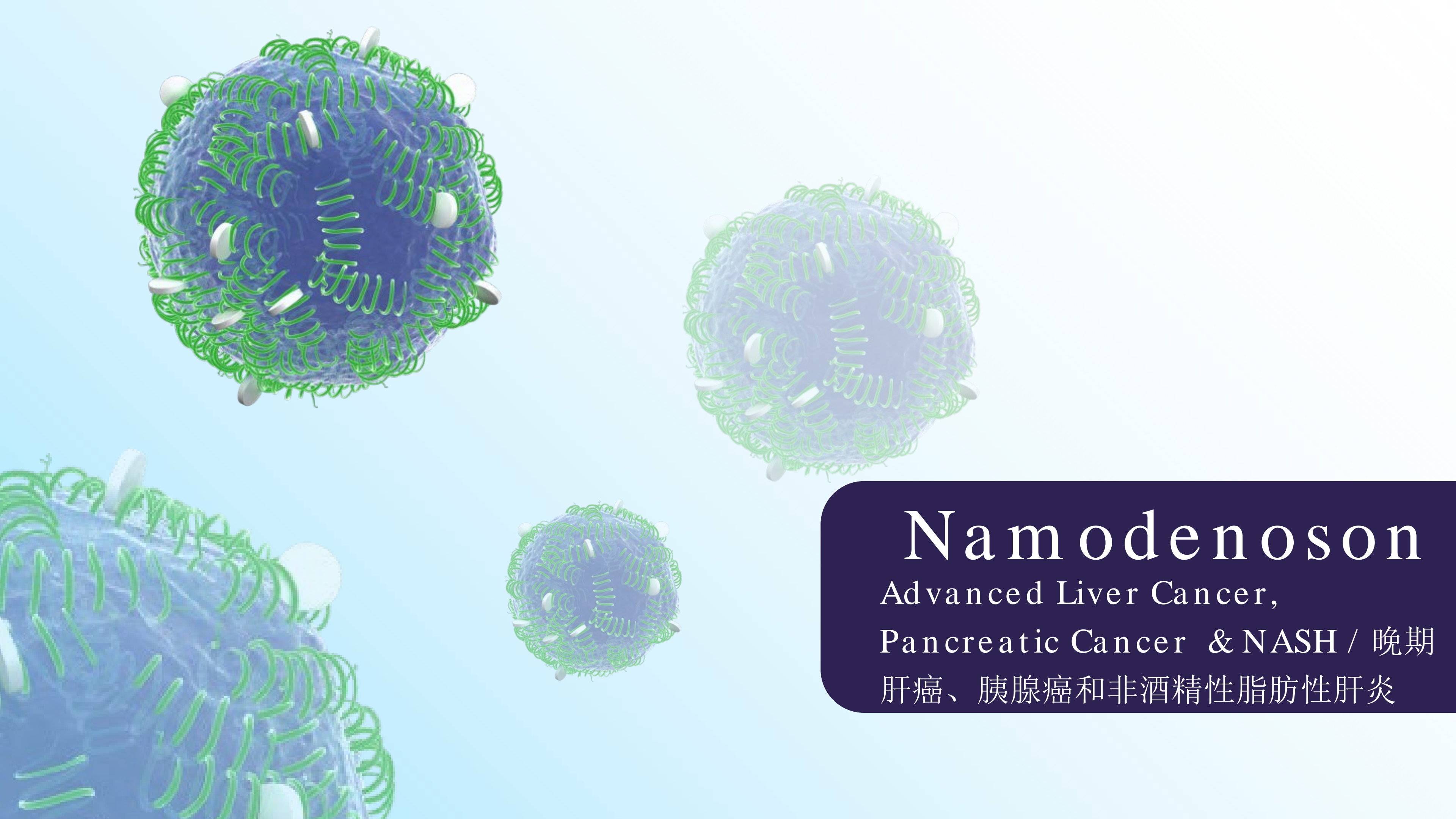
Headed into Pivotal Market Registration Study / 进入关键的市场注册研究

- The Comfort™ Phase 3 study met the **primary endpoint** which was superiority vs. placebo on week 16 / Comfort™三期研究达到了主要终点，即在第16周与安慰剂相比具有优势。
- Phase 3 shows patients see improving **progressive response** over time / 三期试验显示患者看到了随着时间推移不断改善的渐进式反应
- Piclidenoson demonstrated **excellent safety profile**, overlapping that of the placebo treated group / Piclidenoson表现出良好的安全性，与安慰剂治疗组的安全性相重合。
- Better **safety profile than Otezla (apremilast)** / 比Otezla (apremilast)的安全性更好
- Can-Fite submitted market registration plans to **FDA and EMA** for Piclidenoson in the oral treatment of moderate to severe psoriasis including a pivotal Phase 3 study / Can-Fite向FDA和EMA提交了Piclidenoson口服治疗中度至重度银屑病的市场注册计划，包括一项关键的三期研究。
 - EMA has agreed with plan / EMA已经同意该计划
 - FDA response expected soon / 预计FDA很快作出回应



Primary Endpoint / 主要终点





Namodenoson

Advanced Liver Cancer,
Pancreatic Cancer & NASH / 晚期
肝癌、胰腺癌和非酒精性脂肪性肝炎

Hepatocellular Carcinoma (HCC) Phase 2 Study:

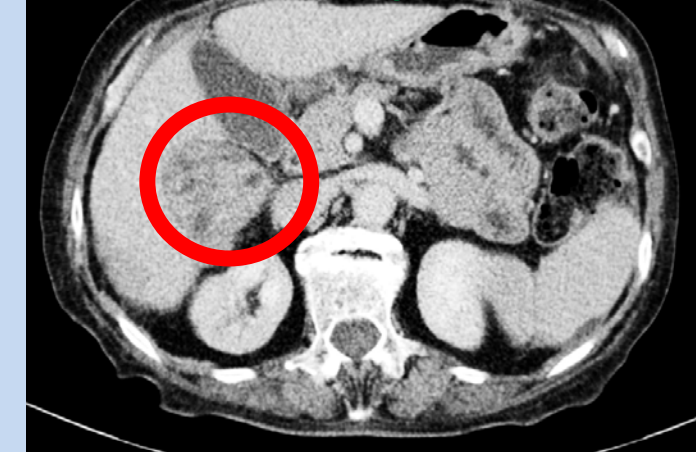
/ 肝细胞癌(HCC)二期研究:

Complete Response in Treated Patient / 接受治疗的患者完全反应

- Patient was enrolled in Can-Fite's Phase 2 liver cancer study / Can-Fite的二期肝癌研究招募患者
- Continued treatment with Namodenoson for 5 years under Open Label Extension Program in Europe/ 在欧洲的开放标签扩展计划下，继续使用Namodenoson治疗5年
- Patient had Complete Response: Completely cleared all cancer lesions / 病人有完全反应：完全清除了所有的癌症病灶
- Over the course of 5 years, clinical benefits included: / 在5年的时间里，临床效益包括：
 - ✓ Disappearance of ascites / 腹水消失
 - ✓ Return to normal liver function / 恢复正常的肝功能
 - ✓ Disappearance of peritoneal carcinomatosis / 腹膜癌变消失

Complete disappearance of tumor lesion / 肿瘤病变完全消失

28-Nov-2016 / 2016年11月28日



16-Jan-2017 / 2017年1月16日



25-Oct-2021 / 2021年10月25日



Liver Cancer

Pivotal Phase 3 / 肝癌

- 关键的三期临床试验

Orphan Drug Designation in US & EU / 美国和欧盟的孤儿药资格

Fast Track Designation in US / 美国的快速通道资格

Open for Enrollment / 开始招募患者

- **FDA and EMA** agreed on Pivotal Phase 3 study protocol / **FDA和EMA**就批准关键的三期研究方案
- **Interim analysis** to be conducted by Independent Data Monitoring Committee (IDMC) after 50% of planned 450 patients are enrolled and treated / 独立数据监测委员会 (IDMC) 将在计划的450名患者中的50%入组和治疗后进行**中期分析**。
- **Namodenoson evaluated as a 2nd- or 3rd-line** treatment for advanced liver cancer patients in whom other approved therapies have not been or are no longer effective / **Namodenoson** 将被评估为晚期肝癌患者的**二线或三线疗法**，其他获批的治疗方法对这些患者无效或不再有效。
- **Primary endpoint** - overall survival / **主要终点**是总生存期
- **Orphan Drug Status** - granted by FDA and EMA/ **孤儿药资格** -由FDA和EMA授予
- **Fast Track Status** - granted by FDA / **快速通道资格** -由FDA授予
- **Compassionate Use Program** - currently treating liver cancer patients in Israel and Romania / **关怀使用计划** - 目前在以色列和罗马尼亚治疗肝癌患者

Pancreatic Cancer / 胰腺癌

Robust Inhibitory Effect on
Growth of Pancreatic Cancer
Cells / 对胰腺癌细胞的生长有强大
抑制作用

Currently Preparing for Phase 2a
Clinical Study / 目前正在准备2a
期临床研究

Pre-clinical Studies: / 临床前研究

- Significant growth inhibition of pancreatic carcinoma cell lines / 对胰腺癌细胞系有明显的生长抑制作用
- Molecular mechanism of action: / 分子的作用机制:
 - De-regulation of the Wnt signaling pathway / 解除对Wnt信号传导通路的控制
 - Inhibition of the NF-kB signaling pathway / 抑制NF-kB信号通路

Phase 2a Study Under Preparation: / 正在准备2a期研究

- Second line therapy / 二线疗法
- Open label / 开放标签
- Oral doses of Namodenoson 25 mg every 12 hours / Namodenoson的口服剂量是每12小时25毫克
- Efficacy endpoints will include: objective response, progression-free survival, duration of response, disease control (defined as an objective response or stable disease), and overall survival / 疗效终点将包括: 客观反应、无进展生存期、反应持续时间、疾病控制(定义为客观反应或疾病稳定)和总生存期。
- Safety will be assessed / 将评估安全性

NASH / 非酒精 性脂肪性肝炎

Addressing Severe Unmet Need
No FDA-Approved Treatment / 解决严重的未满足的需求，无FDA批准的治疗方法

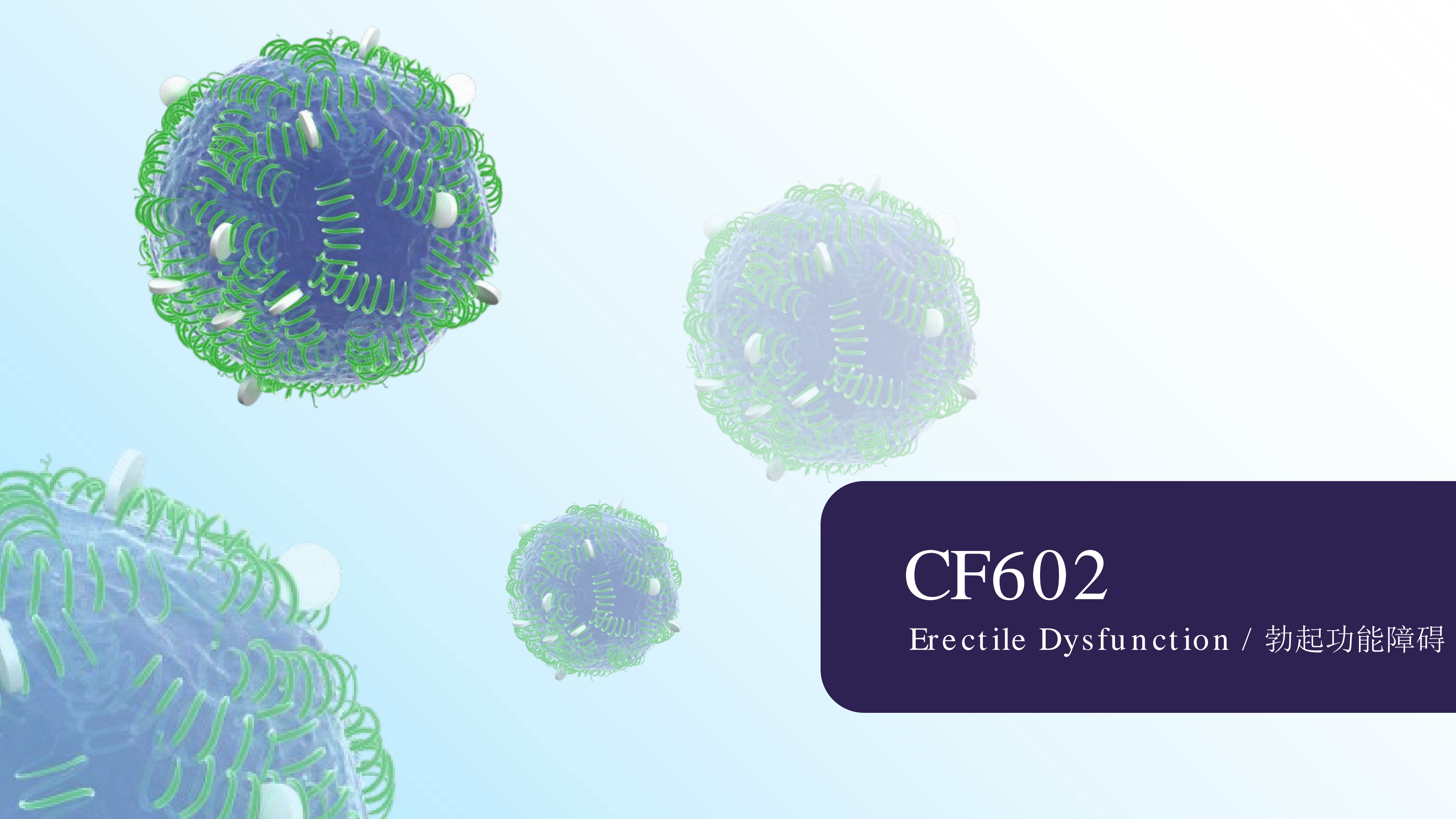
Currently Enrolling Patients for
a Phase 2b Study / 正在招募2b期研究的患者

Phase 2a Study Successfully Concluded: / 成功完成2a期研究

- Reduced liver fat content (LFC) / 减少了肝脏脂肪含量(LFC)
- Anti-Inflammatory effect / 消炎作用
- Dose selection for Phase 2b determined / 2b期研究的剂量选择已经确定
- Decrease in body weight / 体重下降
- Excellent safety / 优秀的安全性

Phase 2b Study: / 2b期研究

- Multicenter, randomized, double-blind, placebo-controlled study in 140 subjects with biopsy-confirmed NASH / 在140名活检证实为NASH的受试者中进行的多中心、随机、双盲、安慰剂对照研究
- Subjects are randomly assigned in a 2:1 ratio to oral doses of Namodenoson 25 mg every 12 hours or a matching placebo for 36 weeks / 受试者按2:1的比例随机分配到每12小时口服25毫克的Namodenoson或相应的安慰剂，持续36周。
- Regular evaluation for safety and efficacy biomarkers baseline measurements at weeks 6, 12, 24, and 36 / 在第6、12、24和36周对安全性和疗效生物标志物基线指标进行定期评估
- Primary efficacy endpoint will be determined by liver biopsy at week 36 / 主要疗效终点将在第36周通过肝脏活检确定。



CF602

Erectile Dysfunction / 勃起功能障礙

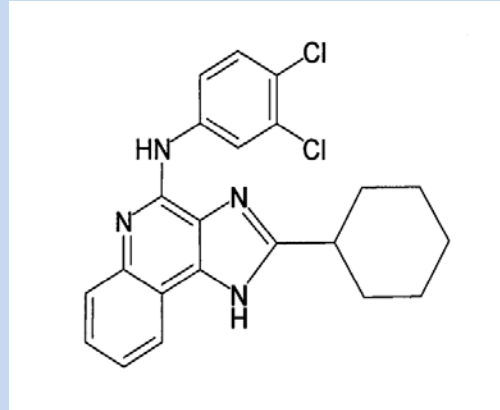
CF602

Erectile Dysfunction (ED) / CF602治疗勃起功能障碍

Rationale:/ 作用原理:

anecdotal reports from patients treated with Can-Fite's drugs, both women and men, testifying that the drugs reversed their sexual dysfunction / 使用Can-Fite药物治疗的病人的轶事报告, 包括女性和男性。证实这些药物扭转了他们的性功能障碍。

Chemical Formula: / 化学式



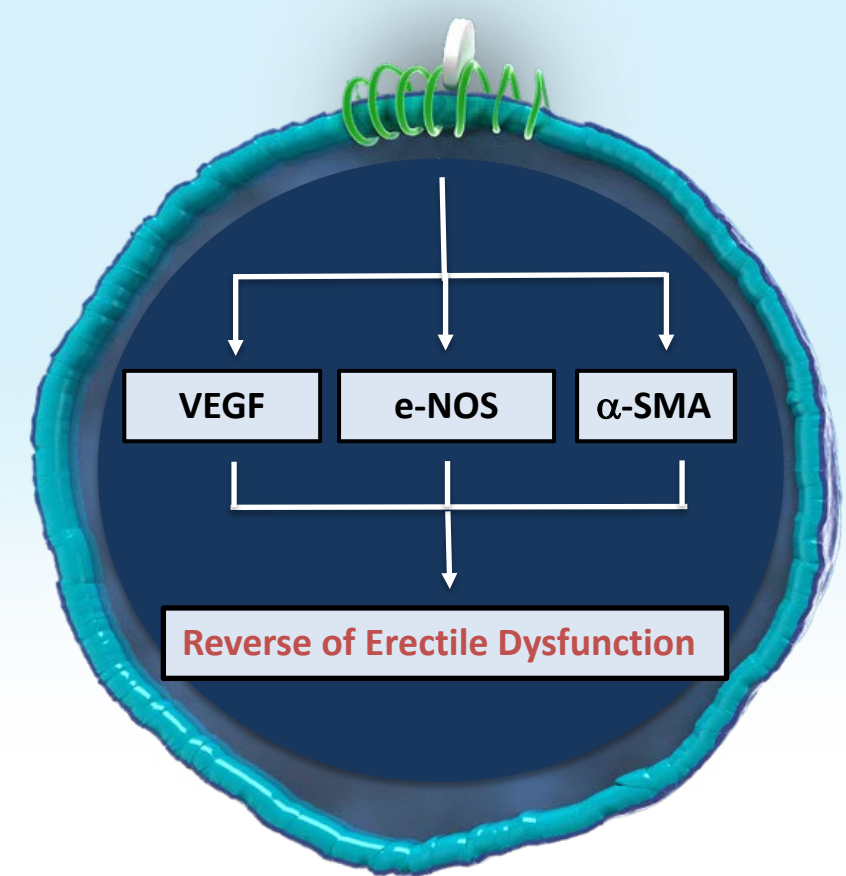
Properties: / 特性

- A3AR allosteric modulator/ A3AR别构调节酶
- Molecular weight – 411.34 / 分子量 – 411.34
- Water insoluble / 不溶于水
- Orally bioavailable / 口服生物制剂

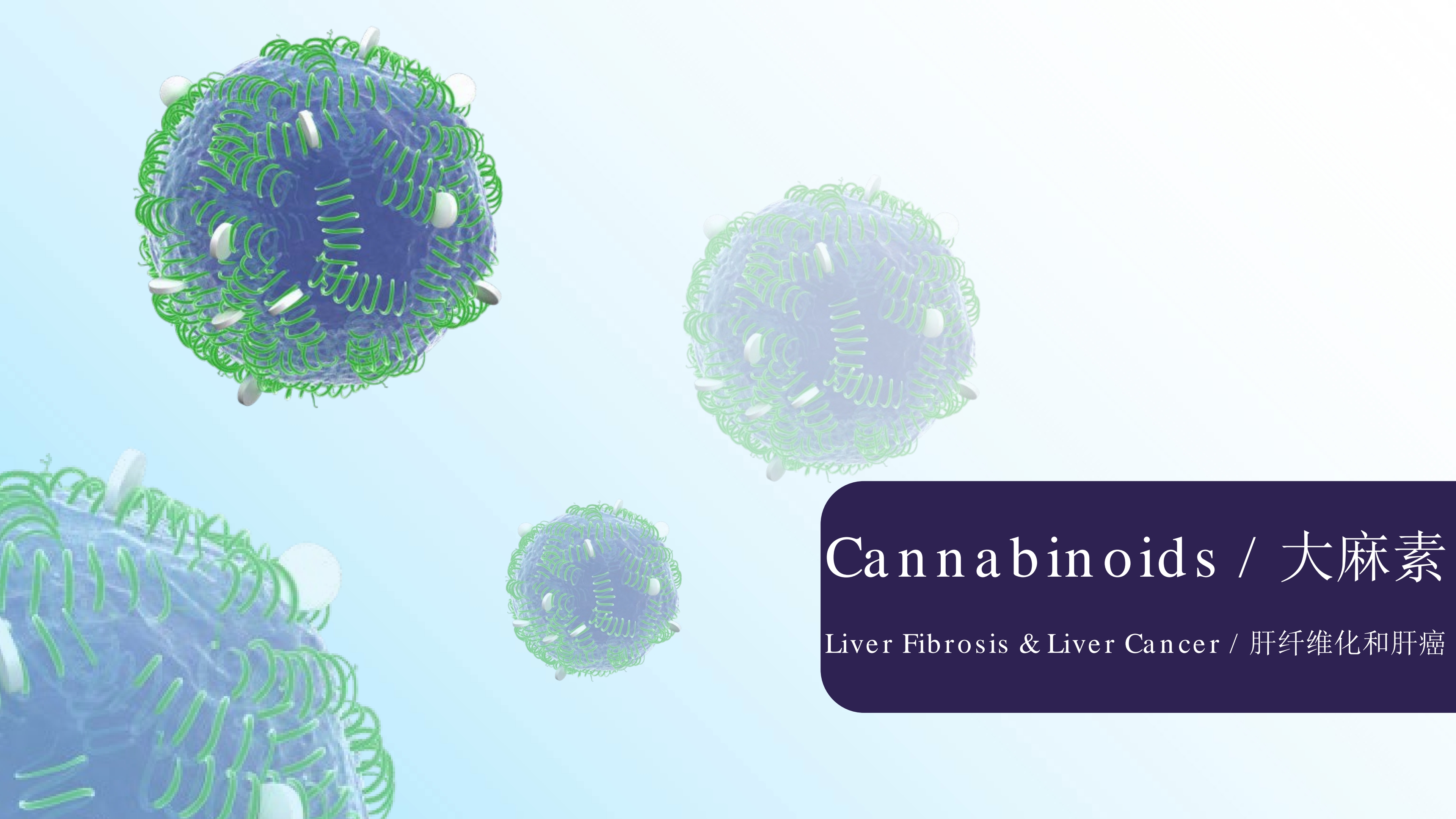
Activity: / 活性

- Significant full recovery from erectile dysfunction in a diabetic rat model / 糖尿病大鼠模型的勃起功能障碍得到明显的完全恢复
- Topically & Systemic / 局部和全身用药
- Dose-dependent, linear effect / 剂量依赖性, 线性效应
- Response after single dose of CF602 / 单剂量CF602后的反应

Mechanism of Action / 作用机理



- Up-regulation of eNOS and VEGF / 上调eNOS和VEGF
- Improves vasodilation and smooth muscle relaxation / 改善血管扩张和平滑肌的放松



Cannabinoids / 大麻素

Liver Fibrosis & Liver Cancer / 肝纤维化和肝癌

Cannabinoids /大麻素

Rationale: / 基本原理:

Cannabinoids are known to bind to A3 adenosine receptor (A3AR) and mediate clinical effects / 已知大麻素能与A3腺苷受体 (A3AR) 结合并发挥临床作用。

Assay to Identify Clinically Active Cannabinoids / 鉴别临床活性大麻素的检测方法

Can-Fite developed a biological assay that identifies clinically active cannabinoids based on the binding to A3AR / Can-Fite公司开发了一种生物检测方法，根据与A3AR的结合情况来识别具有临床活性的大麻素。

Pre-clinical Data in Liver Cancer and Fibrosis / 肝癌和肝纤维化的临床前数据

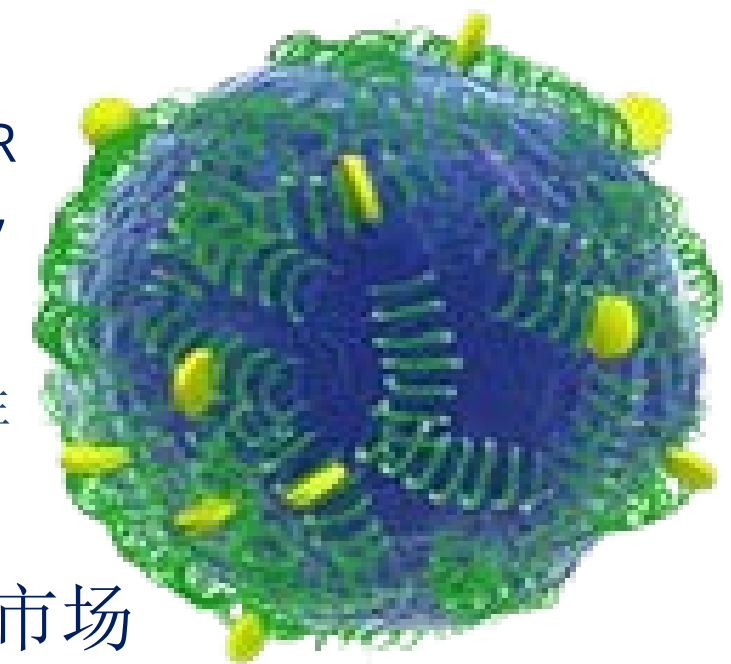
Based on this assay, Can Fite has demonstrated how CBD-rich T3/C15 binds to A3AR to inhibit the growth of hepatocellular carcinoma and liver stellate via de-regulation of the Wnt/ β -catenin pathway / 基于这一检测，Can Fite证明了富含CBD的T3/C15如何与A3AR结合，通过解除控制Wnt/ β -catenin通路来抑制肝细胞癌和肝星状细胞的生长。

Intellectual Property / 知识产权

Can-Fite filed a patent protecting the discovery of cannabinoid-based treatment of diseases where A3AR is overexpressed including liver cancer, other cancers, autoimmune inflammatory and metabolic diseases / Can-Fite申请了一项专利，保护基于大麻素治疗A3AR过度表达的疾病的发现，包括肝癌、其他癌症、自身免疫性炎症和代谢性疾病。

Medical Cannabis Market / 医用大麻市场

Projected to grow at CAGR of 29% to \$56.7B by 2026* / 预计将以29%的年复合增长率增长，到2026年达到\$567亿 *



mmmm A3AR

● CBD

Closing Highlights / 亮点

1

Oral drugs with proven safety and efficacy in Phase 2 & 3 — Piclidenoson and Namodenoson are Phase 3 assets in psoriasis and liver cancer; Namodenoson showed strong efficacy in a Phase 2 NASH study and is headed into an exploratory Phase 2a study in pancreatic cancer / **安全性和疗效在二期和三期试验中得到证实的口服药物** - Piclidenoson和Namodenoson是治疗银屑病和肝癌的三期临床阶段资产；Namodenoson在NASH二期临床研究中显示出强大的疗效，进入到治疗胰腺癌的探索性2a期试验

2

Monetizing advanced portfolio through corporate partnerships — Piclidenoson and Namodenoson have been out-licensed in select territories with ~\$20 million received to date and potentially up an additional \$130 million plus royalties / **通过企业伙伴关系将高级阶段项目组合变现** - 已经在选定的地区对外许可Piclidenoson和Namodenoson，迄今已收到约\$2000万，并有可能获得另外的\$1.3亿多权利金。

3

Novel therapeutic approach — Unique technology for the treatment of cancer, liver and inflammatory diseases; addressing multi-billion dollar markets / **新的治疗方法** - 治疗癌症、肝脏和炎症疾病的独特技术；解决数十亿美元市场规模的问题。

4

Intellectual property portfolio — Consists of 15 patent families issued and pending to protect the different indications / **知识产权组合** - 包括15个已颁发和正在申请的专利系列，以保护不同的适应症。

5

Financially well positioned — To conduct all clinical development programs and G&A for > 1 year / **财务状况良好** - 公司有能力进行所有的临床开发项目和支付一年以上的一般及行政费用。