

CANFITE

BioPharma Ltd

Small Molecules for **Big** Clinical Needs™

July 2025

<https://www.canfite.com/>

NYSE American:CANF

Forward Looking Statement

This presentation may contain 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 any resurgence of the COVID-19 pandemic and the war between Israel and Hamas; 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 28, 2024 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

1

**Safe Drugs for the Treatment of
Oncological and Inflammatory Diseases**

2

**Advanced Clinical Stage Pipeline;
Short Regulatory Approval Pathway
(FDA & EMA)**

3

Successful Out-licensing Deals

4

Financial Summary

(Ticker: CANF) Listed on NYSE American and Tel-Aviv Stock Exchange
~13.2M ADRs outstanding; ~3.900M ordinary shares outstanding
(1 ADR = 300 Ordinary Shares)

Cash: ~\$8M as of December 31, 2024; Raised \$3M in April 2025

Unique Platform Technology

Specific oral therapy aimed at diseased cells

Therapeutic Target

- Global leader in discovering and developing drugs that target the A3 adenosine receptor (A3AR)

Pipeline Drugs

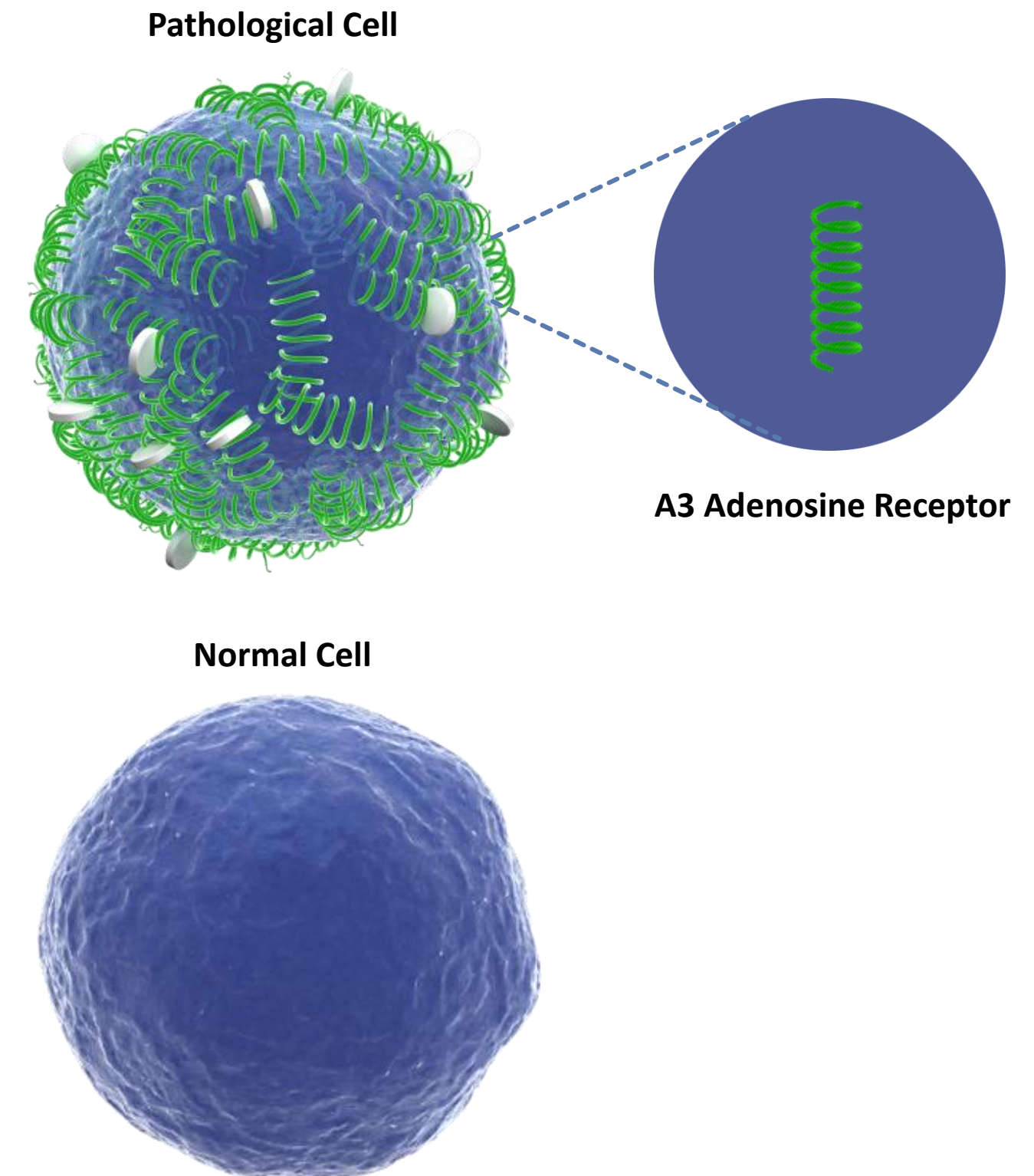
- Small molecule, orally bioavailable drugs
- Bind only to pathological cells, not normal cells

Proven Therapeutic Effect

- Good efficacy and safety with anti-inflammatory and anti-cancer effects shown in Phase 2 and Phase 3 studies

Excellent Safety Profile








- Demonstrated in >1600 patients



Pipeline Drugs

Drug/Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
Piclidenoson				
Psoriasis	Pivotal Phase III agreed with FDA & EMA; Ongoing			
Lowe syndrome	Phase II to be initiated			
Pets Osteoarthritis	Positive Phase II data; Out licensed to Vetbiolix			
Namodenoson				
Liver Cancer	Pivotal Phase III agreed with FDA & EMA; Ongoing			
Pancreatic Cancer	Phase IIa Ongoing			
MASH	Phase IIb Ongoing			

Corporate Partnerships: Current Out-Licensing Deals

	Eastern Europe	<i>Psoriasis, Liver Cancer, MASH</i> <i>Pancreatic cancer</i>
	Spain, Switzerland, Austria	<i>Psoriasis</i>
	China, Taiwan, Hong Kong, Macao	<i>Psoriasis, Liver Cancer, MASH</i>
	South Korea	<i>Liver Cancer, MASH</i>
	South Korea	<i>Psoriasis</i>
	Canada	<i>Psoriasis</i>
	Global	<i>Piclidenoson</i> <i>- Pets' Osteoarthritis</i>

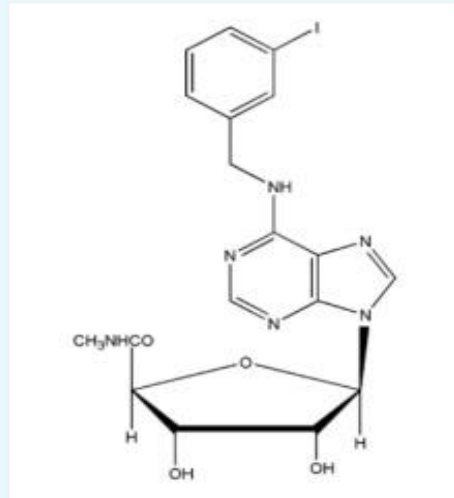
\$20M received in upfront and milestone payments

\$130M potential based on regulatory and sales milestones

Typical Deal Structure

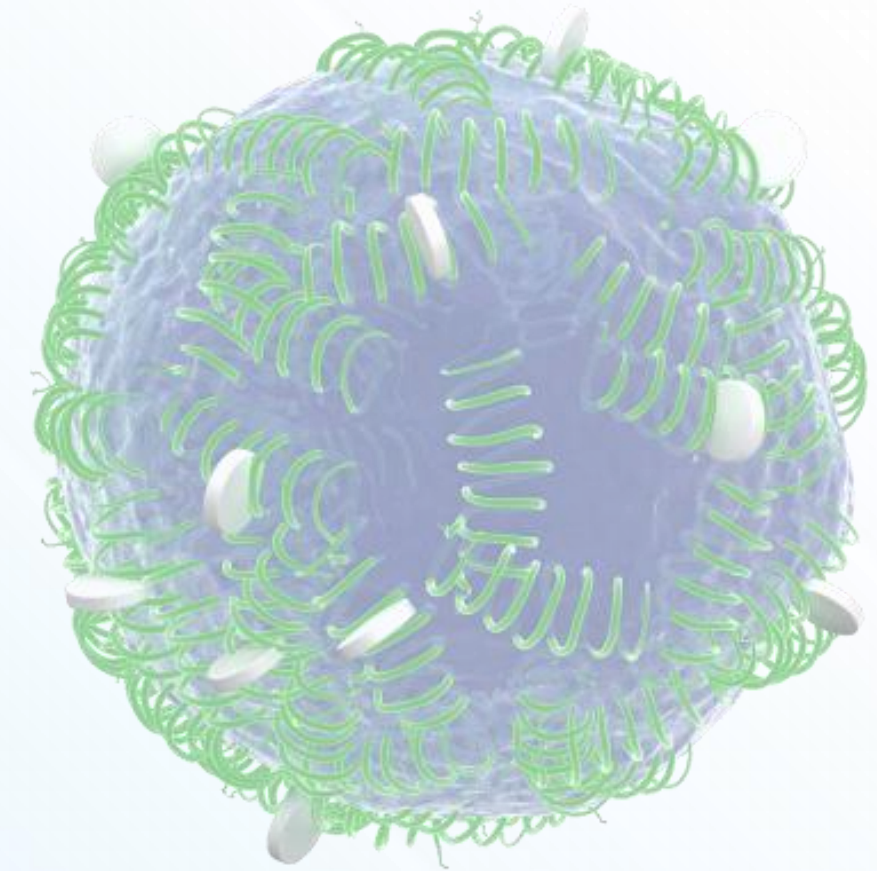
- Up-front money upon signing a distribution deal
- Regulatory milestone payments
- **Royalties (double-digits)**
- Sales milestone payments

Piclidenoson Drug Candidate



Chemical Properties

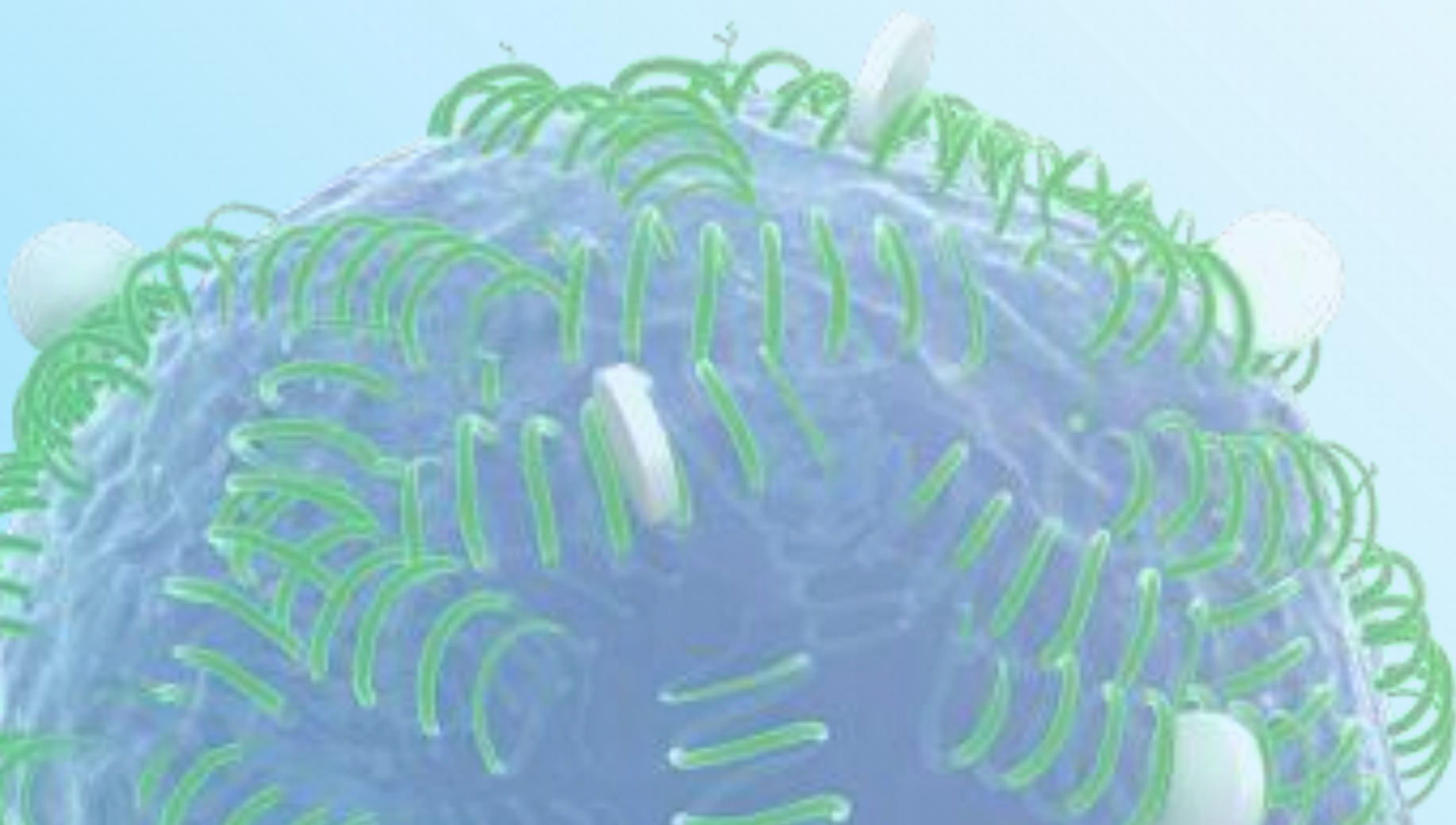
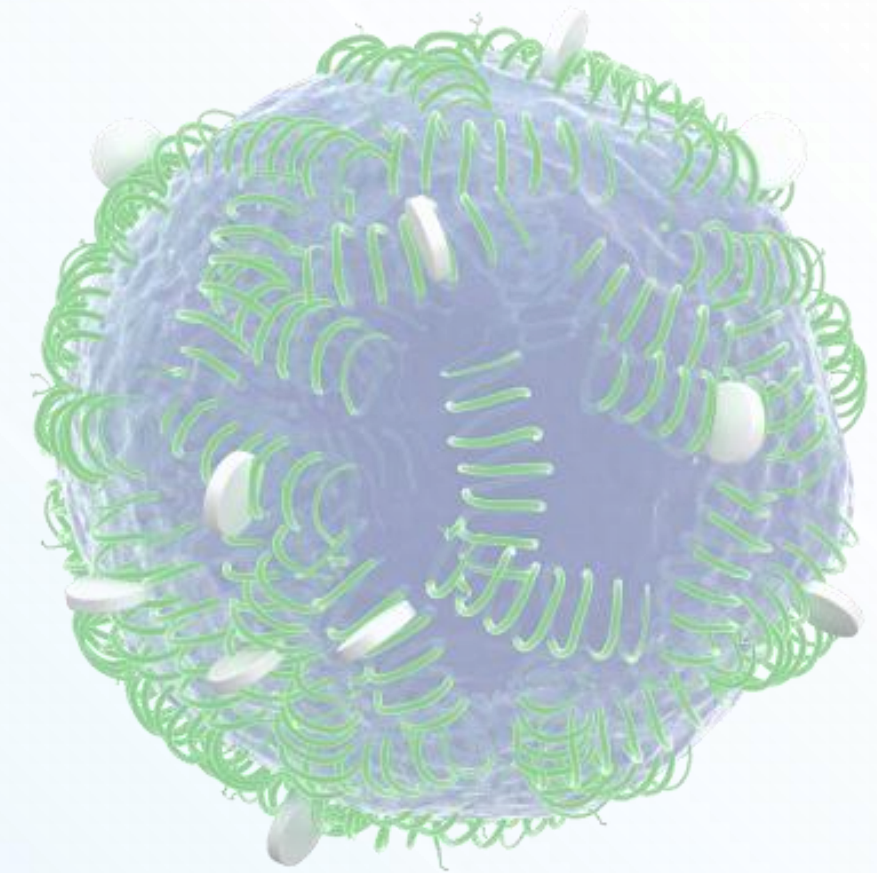
- Nucleoside derivative
- Highly Selective A3AR Agonist
- Molecular weight - 510.29
- Water insoluble
- Half lifetime in blood – 8-9 hours



Piclidenoson
Inflammatory Indications

Piclidenoson

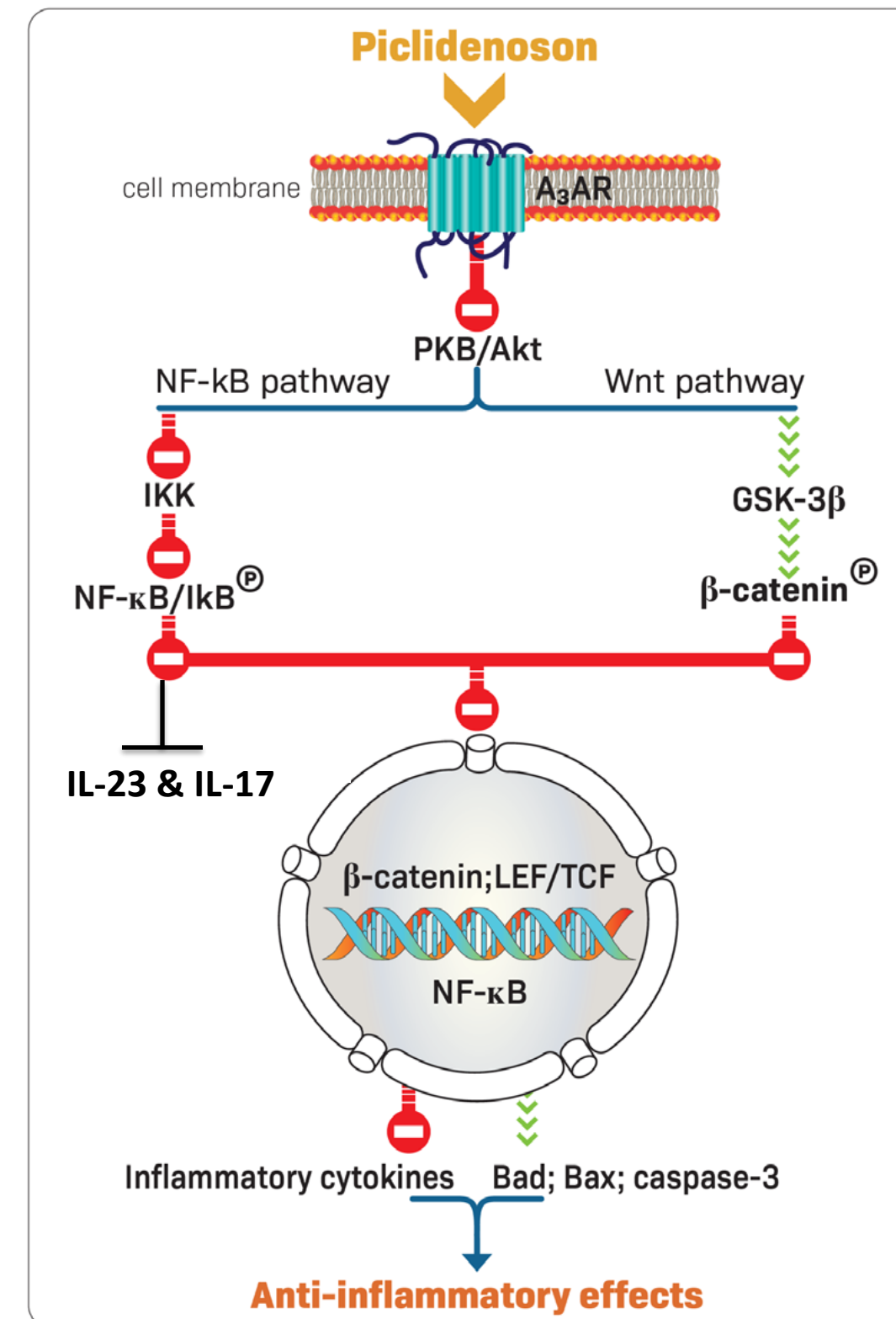
Moderate to Severe Psoriasis



Piclidenoson for the Treatment of Plaque Psoriasis

Rational for Development

- Overexpression of the A3AR target in Keratinocytes of psoriasis patients
- Robust anti-inflammatory effect manifested by specific apoptosis of inflammatory cells
- Piclidenoson inhibits **IL-17 & IL-23** production in keratinocytes
- Piclidenoson had significant anti-psoriatic effects and promising safety profile in a Phase 3 trial in patients with moderate-to-severe plaque psoriasis.

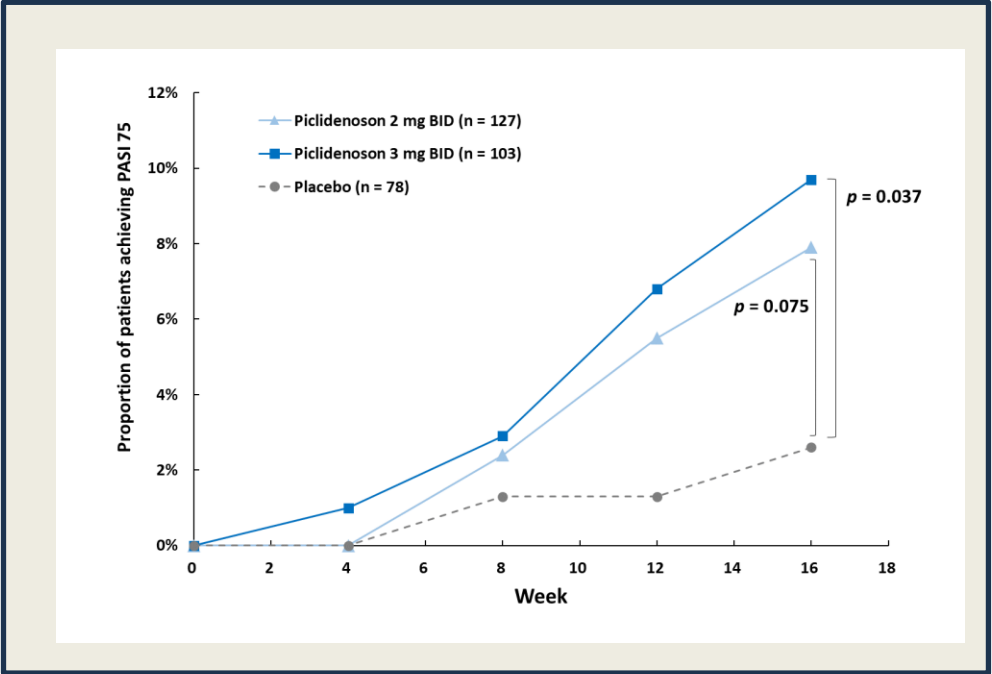


Phase III Study Endpoints - Achieved



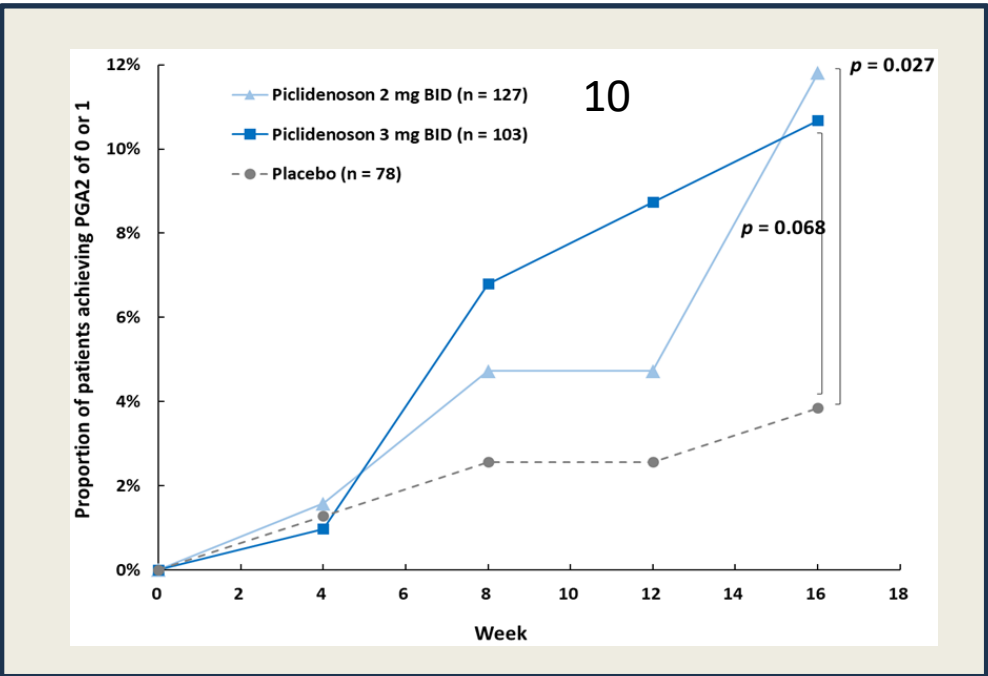
Primary Endpoint

PASI 75 Significant Superiority of Piclidenoson 3 mg vs. Placebo

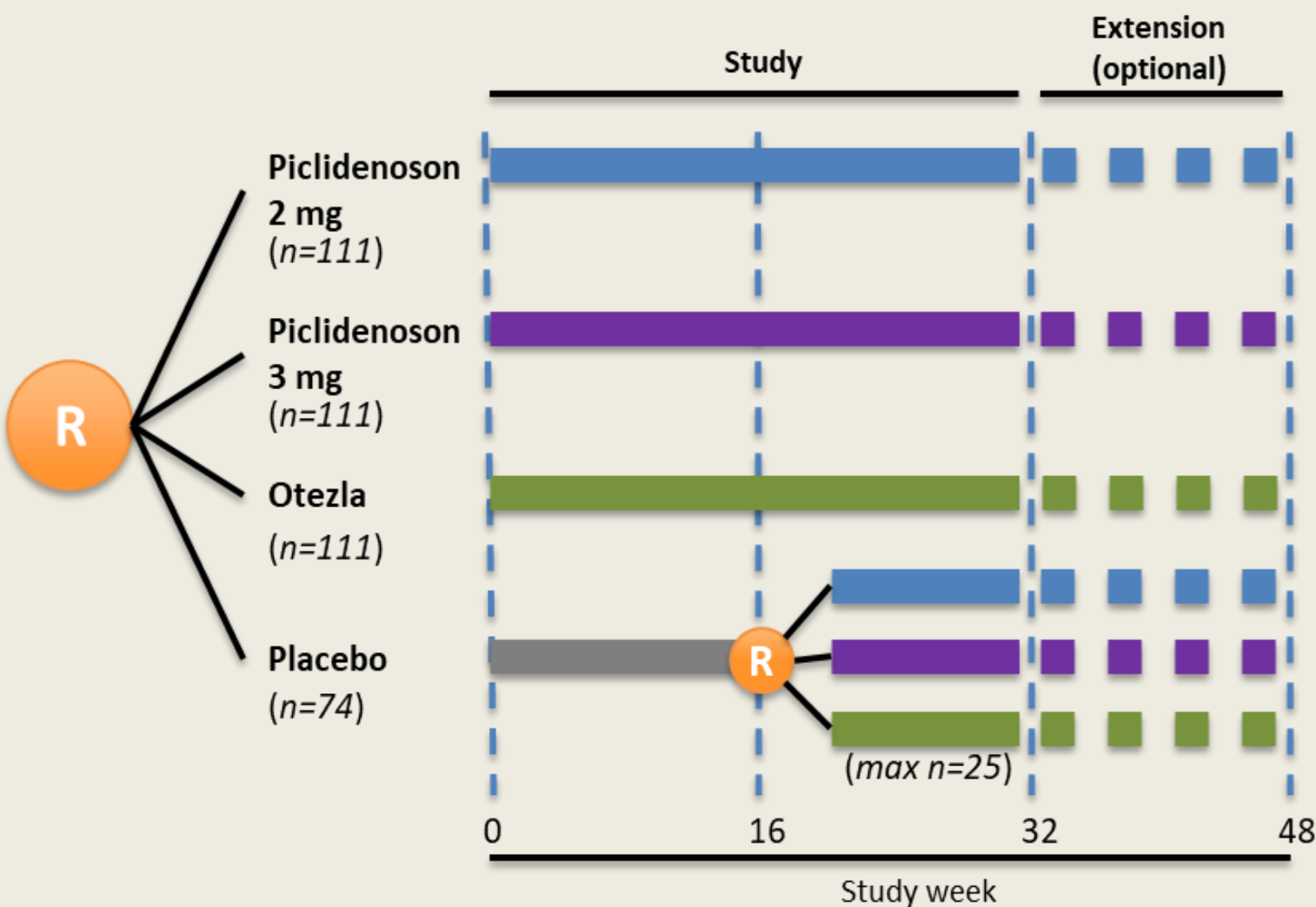


Secondary Endpoint

Subjects Achieving PGA2 for Piclidenoson vs Placebo



Study Design

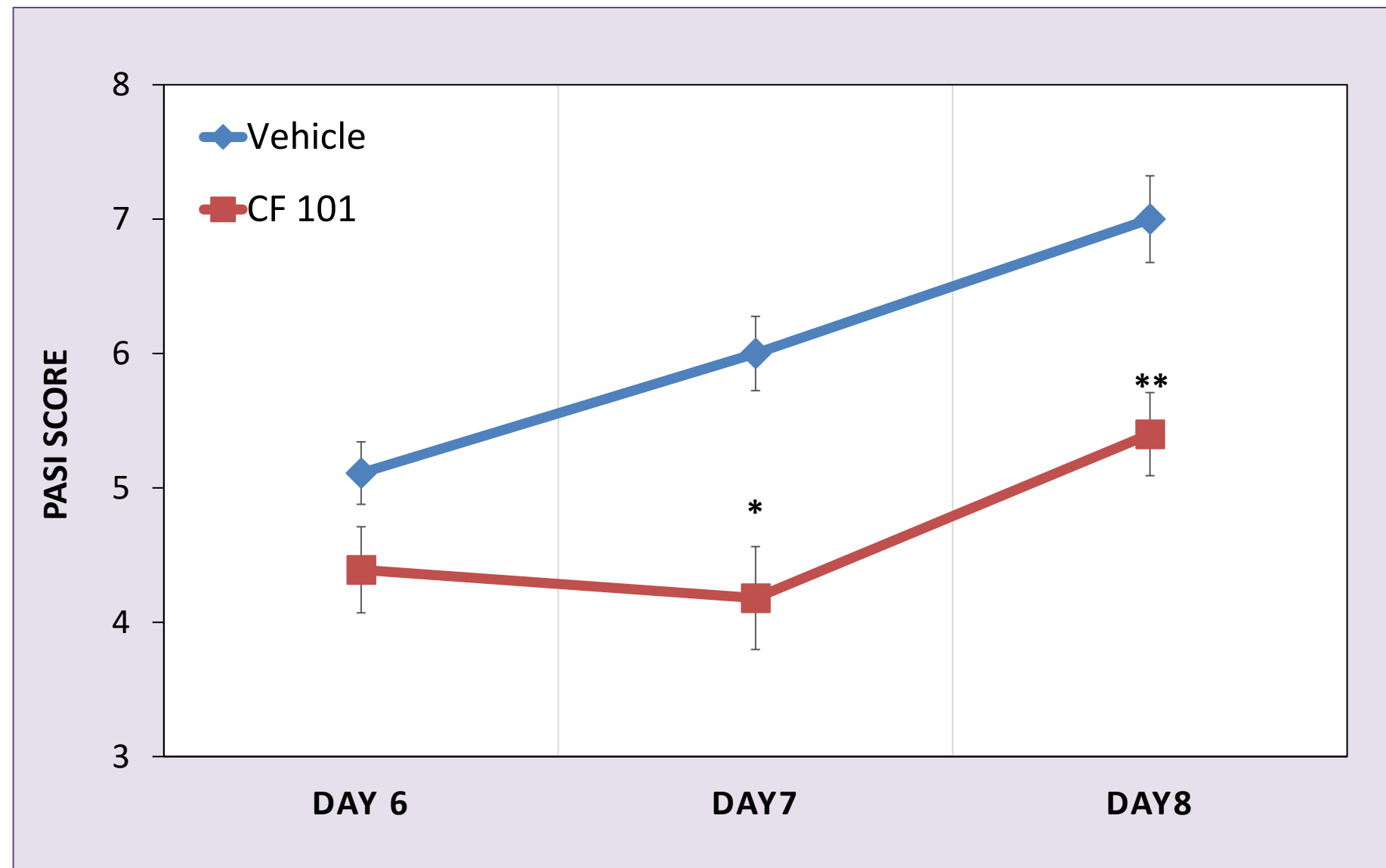


Pivotal Phase III



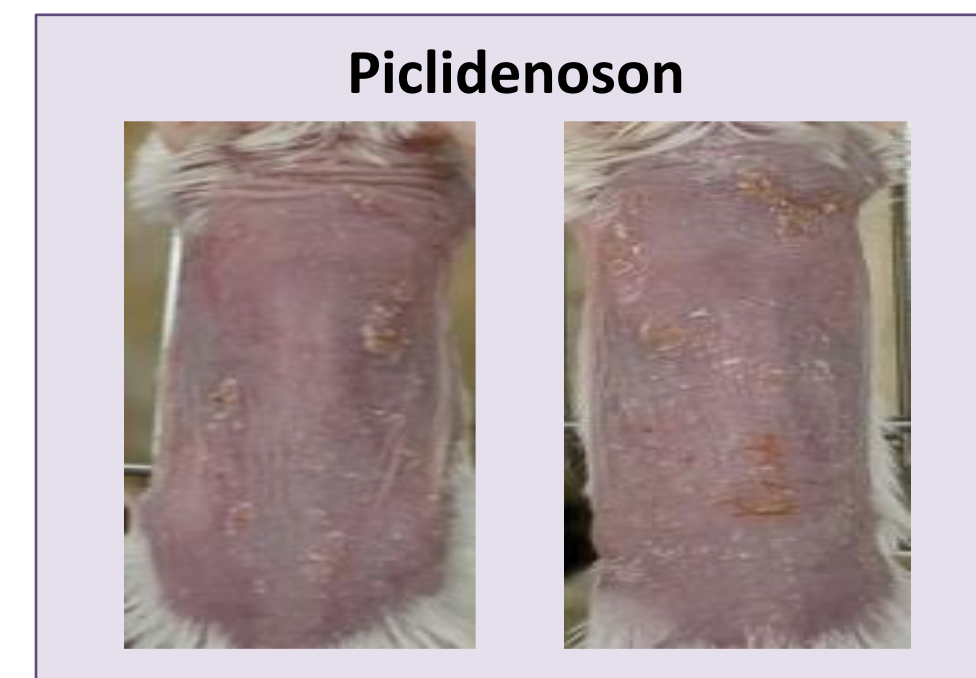
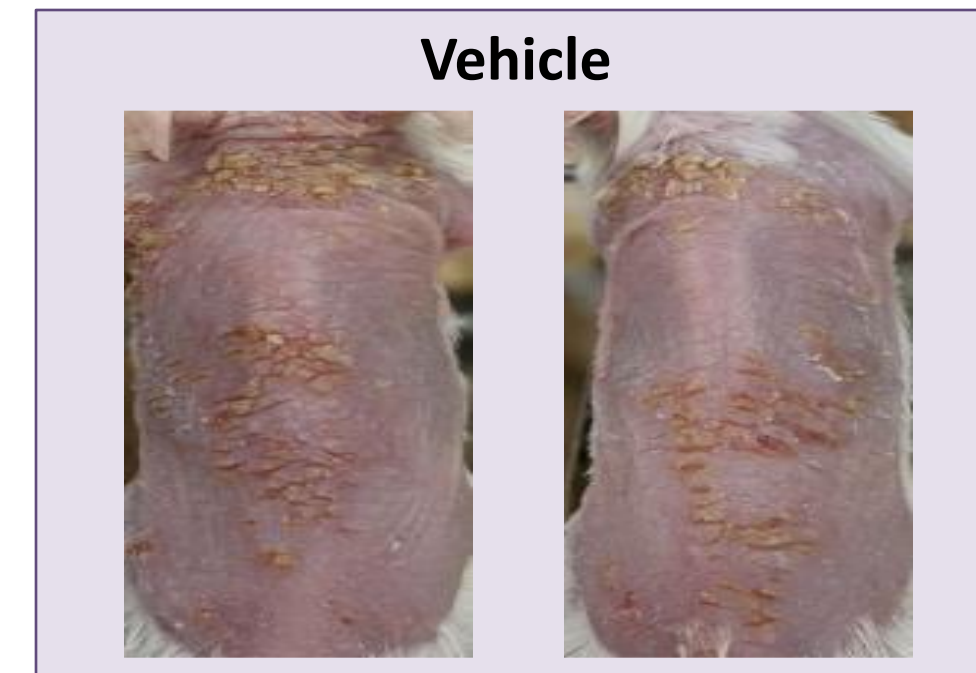
- Pivotal Phase III study that has been approved by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
- Oral piclidenoson 3 mg twice daily (BID) in subjects with moderate-to-severe plaque psoriasis, compared with placebo
- The co-primary Primary Objectives of this study:
 - Proportion of subjects who achieve a Psoriasis Area and Severity Index (PASI) score response at Week 16 of $\geq 75\%$ (PASI 75); and
 - Proportion of subjects who achieve a Static Physician's Global Assessment (sPGA) at Week 16 of 0 or 1 with at least a 2-point improvement from Baseline.
- The primary safety objective of this - Evaluate the safety of oral piclidenoson in this population.

Topical Piclidenoson Treatment Inhibits Psoriasis in an Imiquimod-induced Model



Psoriasis Area and Severity Index (PASI): cumulative score ,erythema thickness and scaling, served as an assessment of the severity of psoriasis

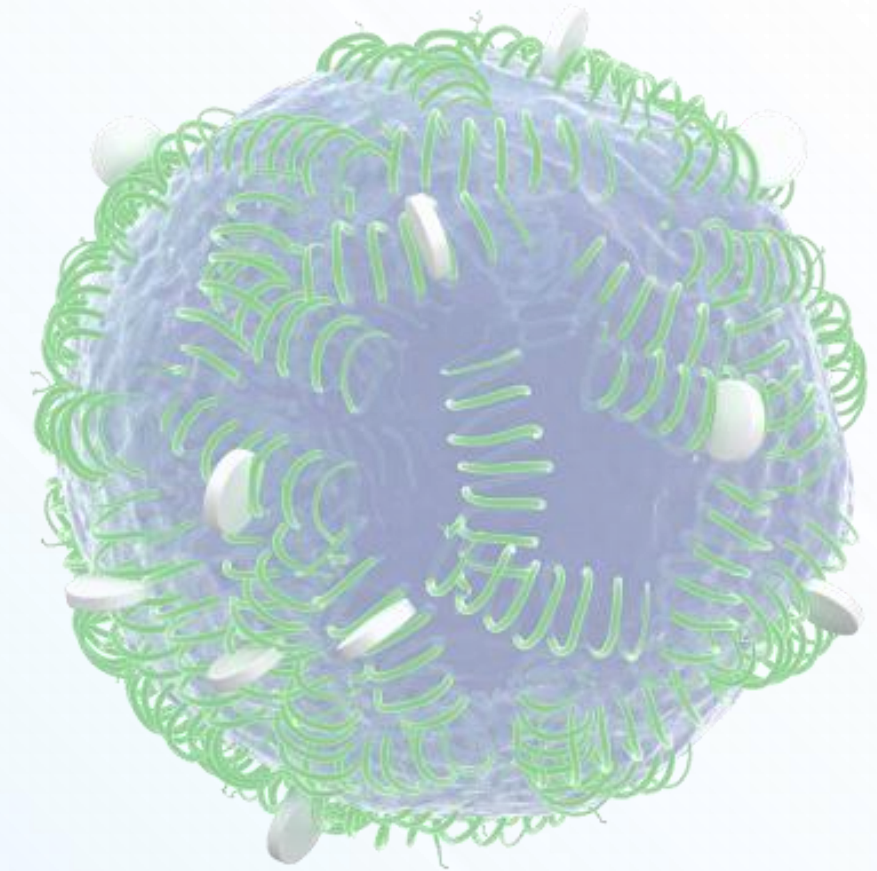
*p value<0.05, **p value<0.005: each group Vs. Vehicle group, using T-Test analysis



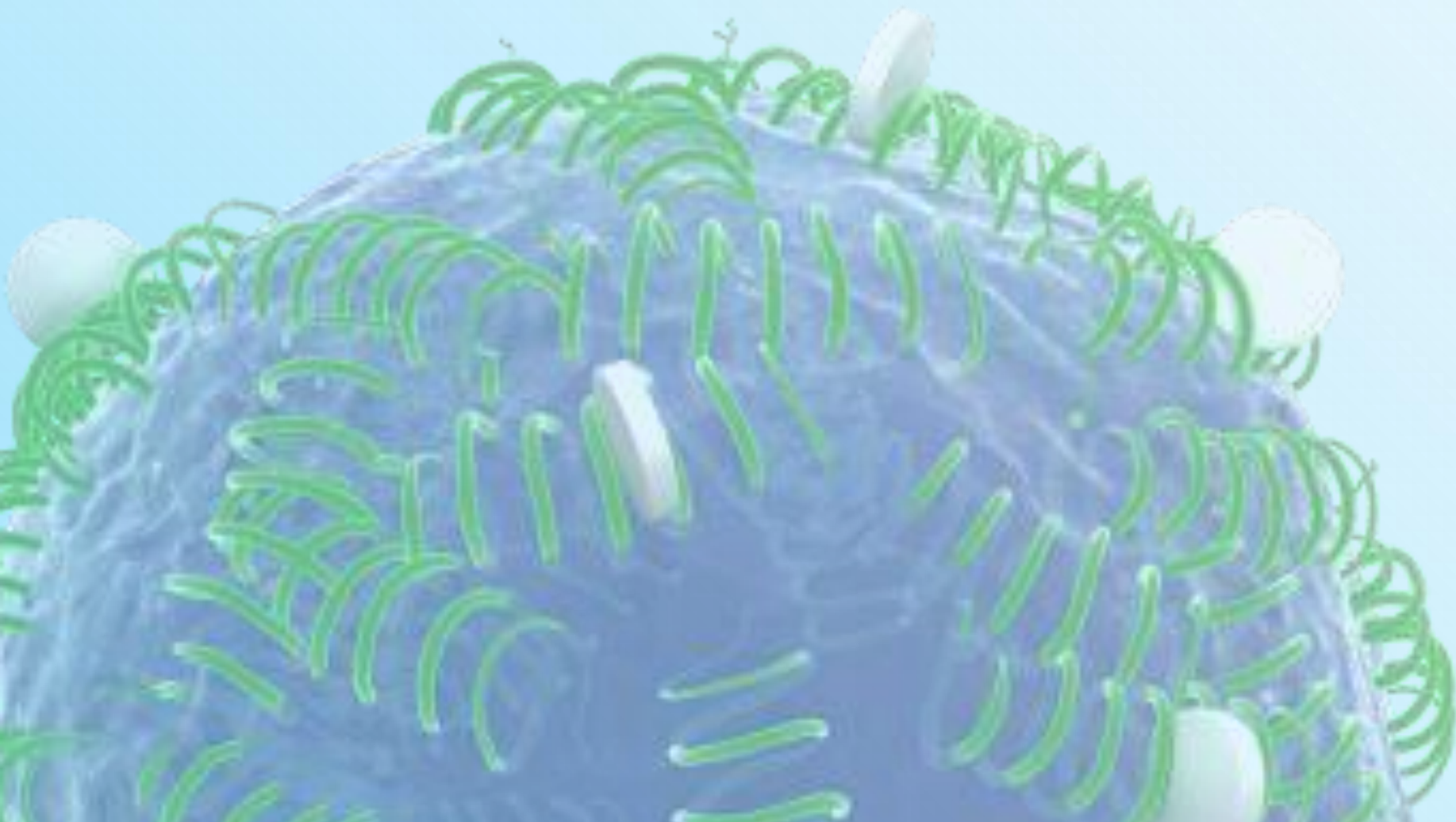
Day 8: BALB/c mice

Piclidenoson

Osteoarthritis in Pets



**Partnership with
Veterinarian Company
Vetbiolix**



Osteoarthritis in Pets

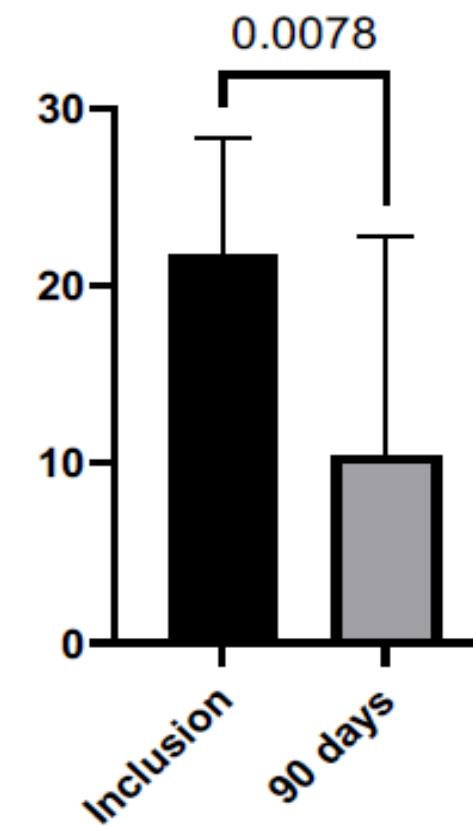
- The canine osteoarthritis market is projected to reach \$3 billion by 2028
- Vetbiolix exercised the option to enter into a full in license agreement with Can-Fite
- Projected Income of \$325M¹ to Can-Fite Over the Next 10 Years After Vetbiolix Exercised its Option

Rational for Development

- A3AR is over-expressed in inflamed synovial cells
- Piclidenoson has robust anti-inflammatory effect manifested by inhibition of osteoarthritis in murine models
- Clinical study in beagles has been successfully concluded reaching primary and secondary endpoints
- Primary objective was LOAD (Liverpool Osteoarthritis in Dogs)

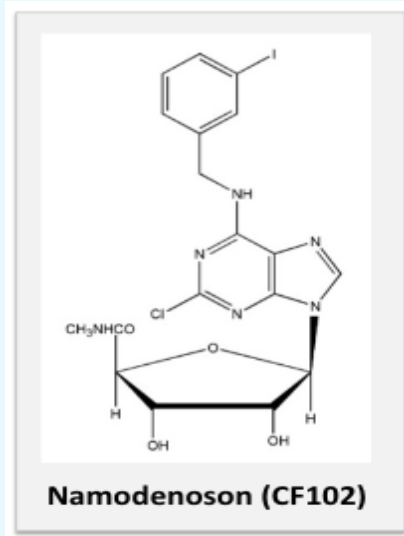
Inhibition of Osteoarthritis in Dogs

LOAD before and after treatment in 500 µg/kg group
(Primary Endpoint; geometric mean \pm 95% CI)



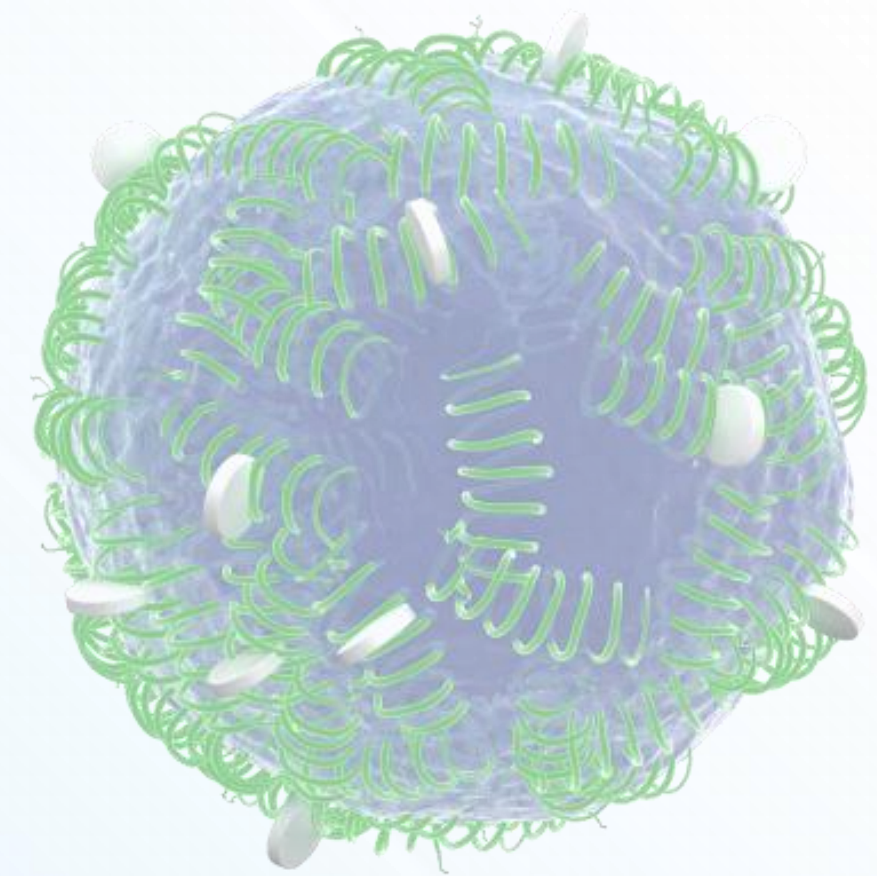
¹The arthritis market for companion animals is estimated by [Coherent Market Insights](#) to be \$3.8 Billion in 2023 and is expected to grow to \$6.3 Billion by 2030. Can-Fite and Vetbiolix model that Piclidenoson has the potential to capture up to 6% of this opportunity, with peak worldwide sales of \$445 Million by 2034. Under the agreement, Can-Fite is entitled to receive a 15% royalty on worldwide sales in this indication. This means that Can-Fite's upfront and royalties on sales upon regulatory approval for veterinary use, is projected to be \$325 million in the aggregate over the next decade assuming a 2027 launch.

Namodenoson Drug Candidate



Chemical Properties

- MW: 544.73 g/mol
- Water Insoluble
- Half life: 12 hours
- Nucleoside Derivative
- Orally Bioavailable
- High Stability in the Liver

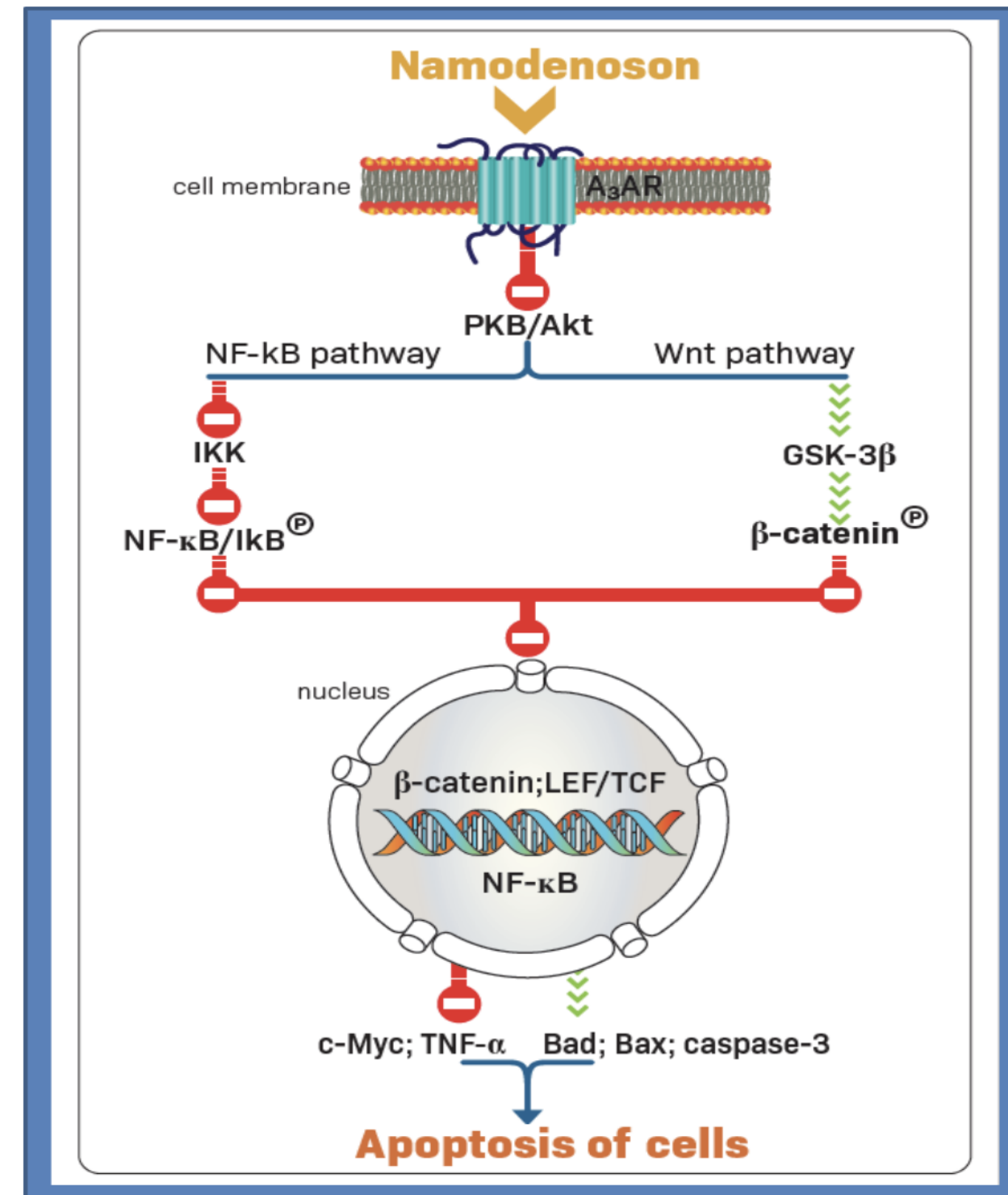


Namodenoson
Oncology & MASH (NASH)

Advanced Liver Cancer

Rational for Development

- A3AR is over-expressed in human hepatocellular carcinoma (HCC) cells.
- Namodenoson, induces de-regulation of the Wnt and NF- κ B signalling pathways resulting in apoptosis of HCC cells.
- In Phase II study in patients with advanced HCC, Namodenoson was safe and well tolerated. Evidence of antitumor activity was observed.



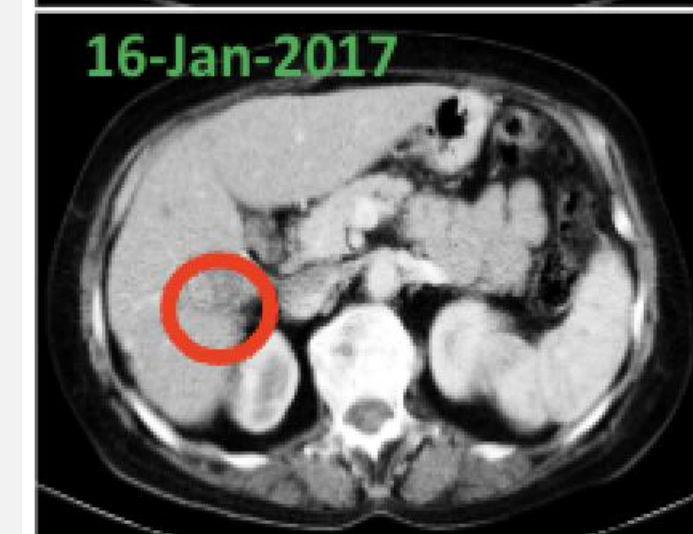
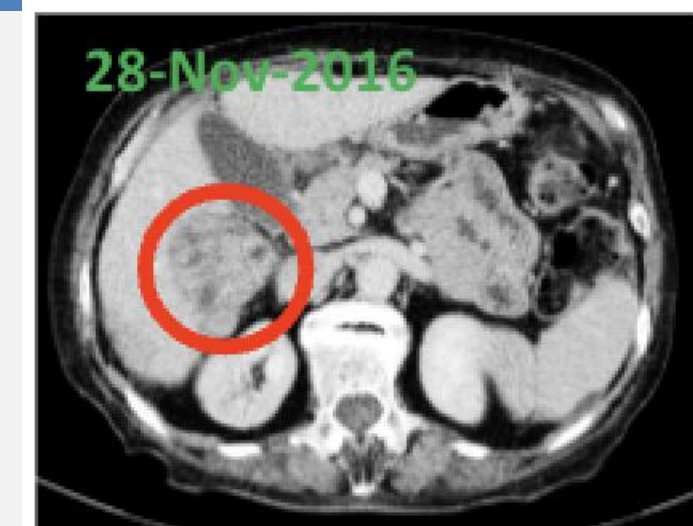
HCC Phase II Study – Recent Data

Presented at the AASLD 2022 & ASCO-Breakthrough 2023 Meeting

Complete Response in a Namodenoson Treated Patient

- Patient was enrolled in Phase II liver cancer study
- Continued treatment with Namodenoson for >8 years under Open Label Extension Program in Europe
- Patient had Complete Response: Completely cleared all cancer lesions
- Over the course of 8 years, clinical benefits included:
 - Disappearance of ascites
 - Return to normal liver function
 - Disappearance of peritoneal carcinomatosis

Complete disappearance
of tumor lesions



Liver Cancer

Pivotal Phase III Ongoing

*Orphan Drug Designation
with FDA&EMA*

*Fast Track Designation with
FDA*

Interim Analysis

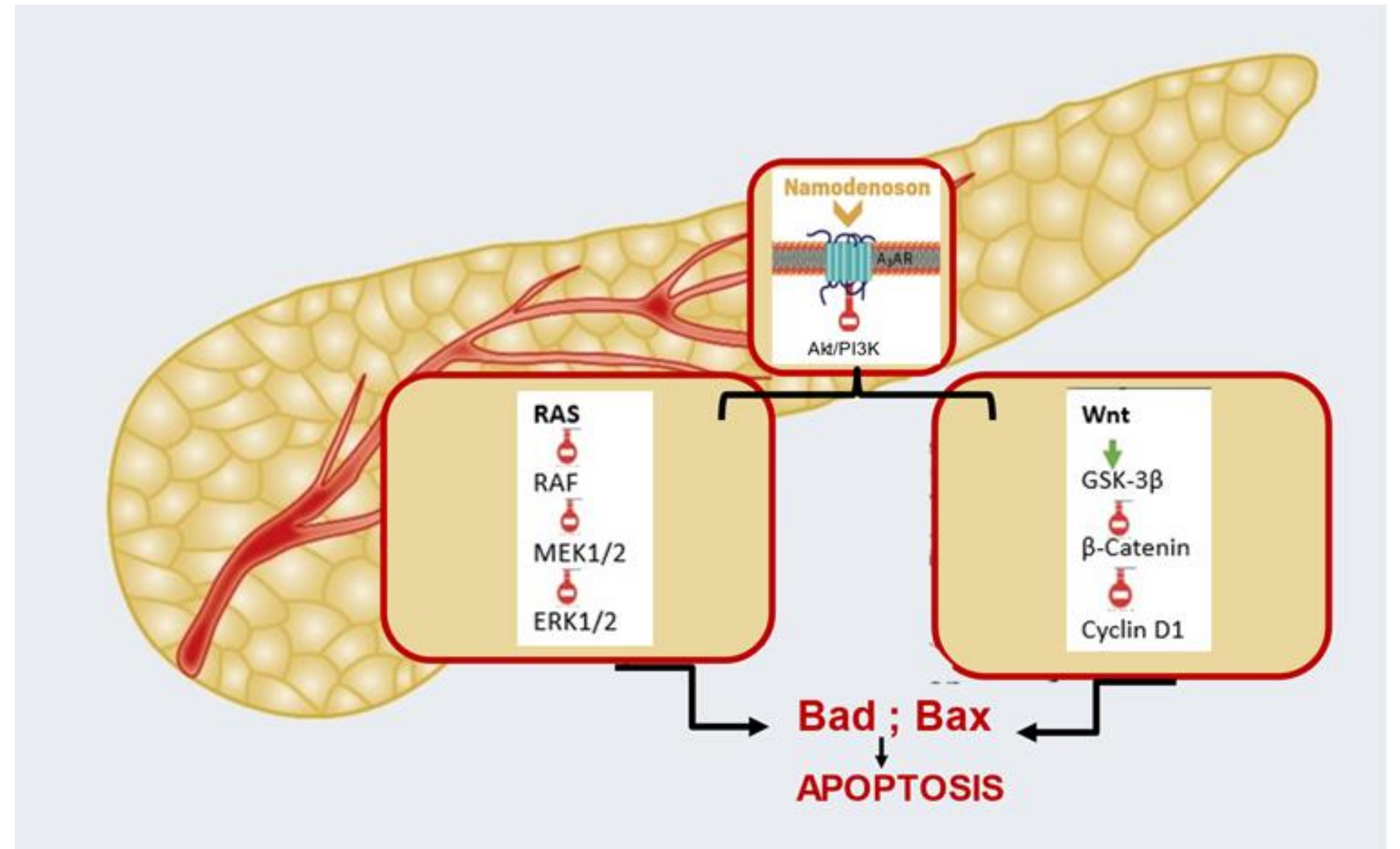


- **FDA and EMA** agreed on Pivotal Phase 3 study protocol
- **Interim analysis** to be conducted by Independent Data Monitoring Committee (IDMC) after 50% of planned 450 patients are enrolled and treated
- **Namodenoson evaluated as a 2nd- or 3rd-line** treatment for advanced liver cancer patients in whom other approved therapies have not been or are no longer effective
- **Primary endpoint** - overall survival
- **Orphan Drug Status** - granted by FDA and EMA
- **Fast Track Status** - granted by FDA
- **Compassionate Use Program** - currently treating liver cancer patients in Israel and Romania

Pancreatic Cancer

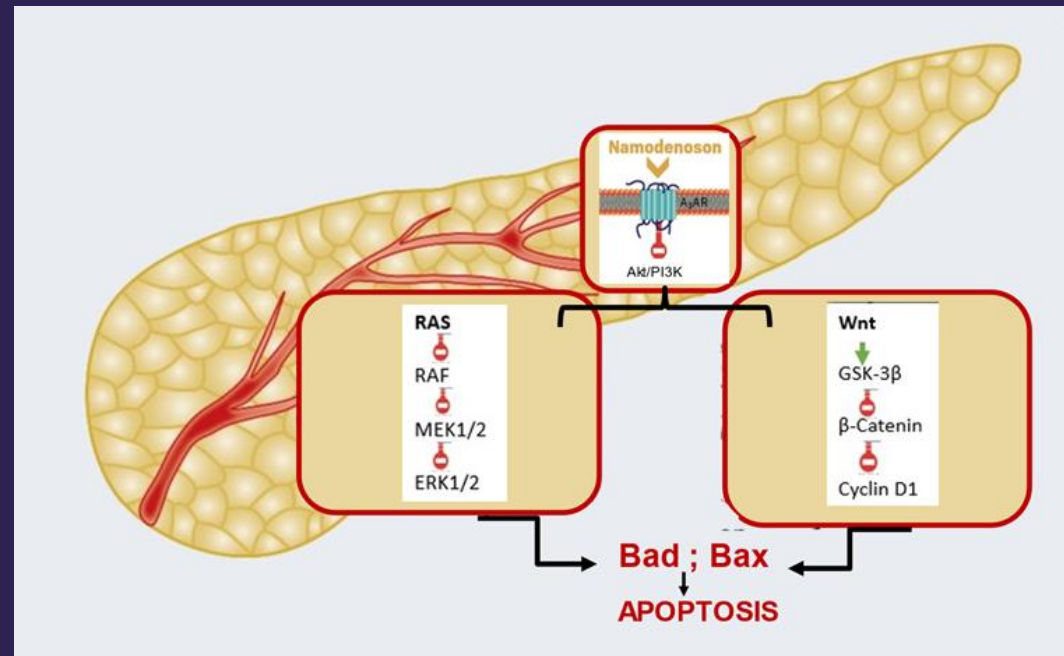
Rationale for Development

- Namodenoson induces 90% growth inhibition of pancreatic cancer cells
- The molecular mechanism of action includes de-regulation of the Wnt and the Ras signaling pathways
- *In vivo* studies showed robust inhibition of pancreatic tumor size



Pancreatic Cancer

Currently Enrolling Patients for a Phase IIa Study



Exploratory Phase IIa Study

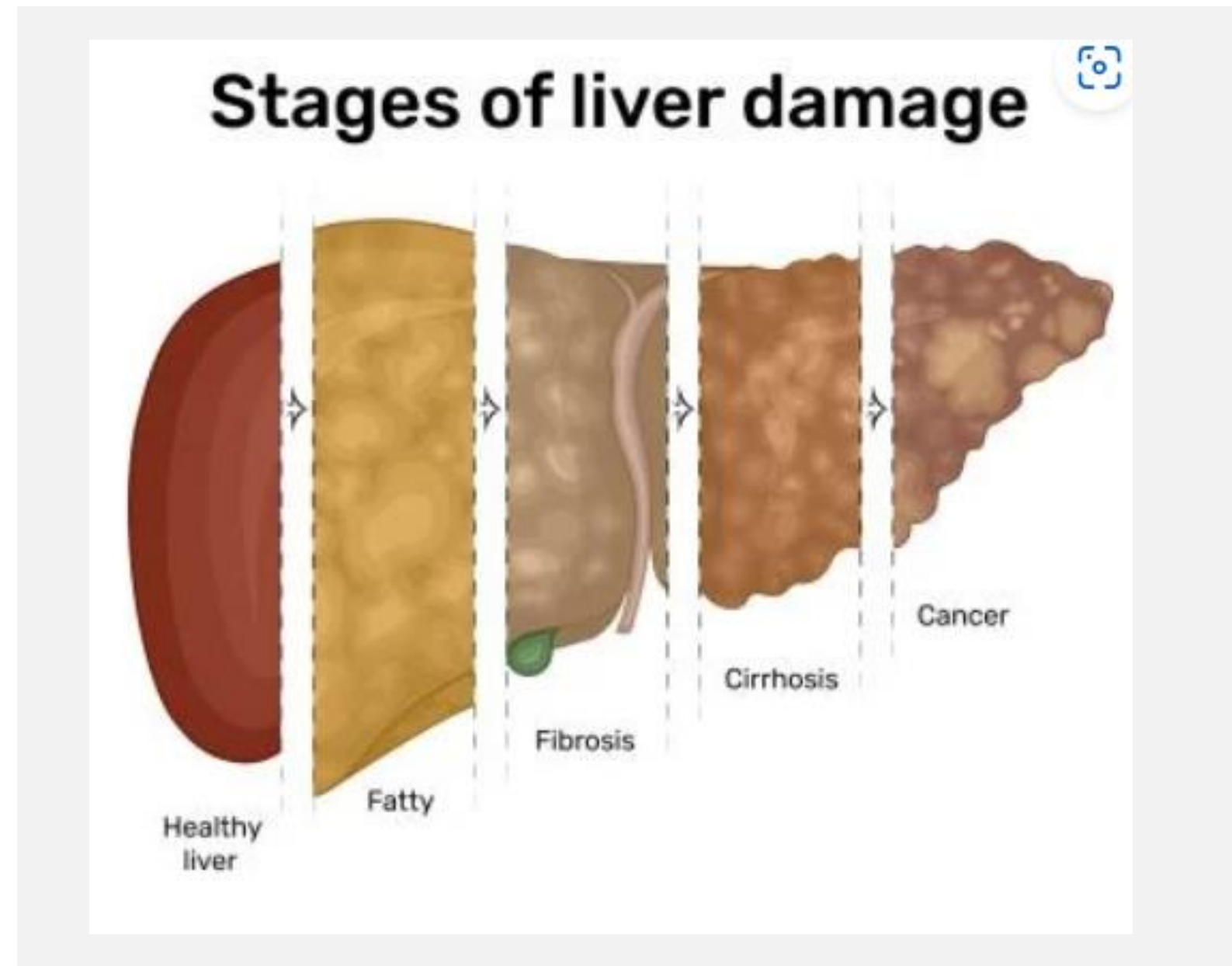
Second line therapy

- **Open label**
- **Oral dose of Namodenoson:** 25 mg twice daily
- **Primary End point:** Safety
- **Secondary Endpoints:** Objective response, progression-free survival, duration of response, disease control (defined as an objective response or stable disease), overall survival

MASH - Metabolic Associated Steatohepatitis

Rational for Development: Liver protective Effect

- Induction of anti - inflammatory effect manifested by reduction of NAFLD Activity Score (NAS)
- Anti-fibrotic effect
- Anti-steatotic effect: significant decrease in steatosis, ballooning and lobular inflammation
- Decrease in ALT, AST, Triglyceride levels
- Namodenoson protects the liver against Ischemia/Reperfusion injury



MASH (NASH)

Addressing Severe Unmet Need

Currently Enrolling Patients for a Phase IIb Study

*US Patent Office Granted
Can-Fite Namodenoson Patent
for Use as anti-Obesity Drug*

Phase IIa Study Successfully Concluded:

- Reduced liver fat content (LFC)
- Anti-Inflammatory effect
- Dose selection for Phase IIb determined
- **Decrease in body weight**
- Excellent safety profile

Phase IIb Study

- Multicenter, randomized, double-blind, placebo-controlled study in 130 subjects with biopsy-confirmed MASH
- 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
- Regular evaluation for safety and efficacy biomarkers baseline measurements at weeks 6, 12, 24, and 36
- Primary efficacy endpoint will be determined by liver biopsy at week 36

Closing Highlights

- 1 Oral drugs with proven safety and efficacy in Pivotal Phase III studies**
Piclidenoson and Namodenoson are Phase III assets in psoriasis and liver cancer; Namodenoson showed strong efficacy in a Phase II SLD study and is headed into an exploratory Phase IIa study in pancreatic cancer
- 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
- 3 Novel therapeutic approach –** Unique technology for the treatment of cancer, liver and inflammatory diseases; addressing multi-billion dollar markets
- 4 Intellectual property portfolio –** Consists of 15 patent families issued and pending to protect the different indications
- 5 Financially well positioned –** To conduct all clinical development programs and G&A for > 1 year