

Empowering Immuno-Oncology Therapies By Stimulating the Immune System: **A Novel 1-2 Punch Against Cancer**

April 2024

CSE: SONA | OTCQB: SNANF

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Forward Looking Statement

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Such forward-looking statements include, but are not limited to, statements regarding the benefits to accrue to Sona from the future development of Targeted Hyperthermia Therapy and the development of diagnostic devices.

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Using Proprietary, Uniquely Biocompatible Nanotechnology for a More Effective <u>and</u> Gentler Cancer Therapy That Enables Immunology

Sona's Proprietary Technology

 Patented^{*}, biocompatible, proprietary *gold nanorod* manufacturing technology

Used to Develop:

Therapies

 Developing 'Targeted Hyperthermia Therapy' to eliminate tumors with minimal systemic toxicity

Diagnostics

 Developer of novel lateral flow assay rapid tests for concussions and animal disease

Sona's Gold Nanorod Advantages

Uniquely Biocompatible:

- Sona surfactant uses no toxic CTAB **
- Equally as effective at heat transfer as CTAB-based GNRs
- Potentially more suitable for use in the body: stable, inert and biocompatible

Functional:

- Gold nanorods provide the most efficient thermal conversion
- · Variety of lengths and widths to optimize surface area
- Aspect ratio control permits tuning to specific wave lengths
- Long shelf life and stable surface properties

Validated :

- NCL was established by the FDA & NCI to accelerate the progress of nanomedicine by providing testing and characterization of nanoparticles.
 - Neither endotoxins nor microbial contamination were detected in seven rounds of NCL analysis

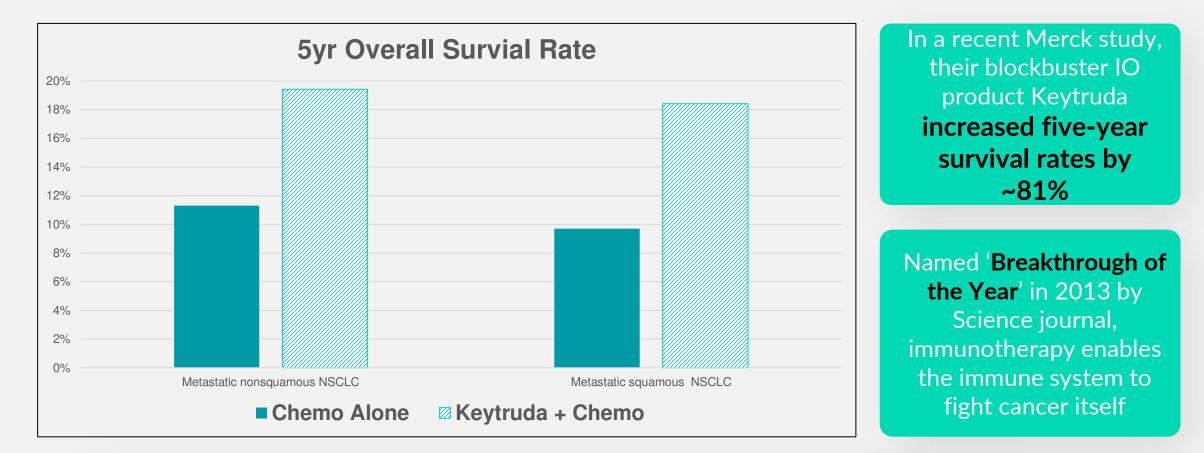


 NCL joined as part of Sona's team in its recent FDA 'Pre-sub' meeting

Which then would be licensed to commercialization partners



Immuno-Oncology ("IO") Therapies With Chemo Can *Vastly* Improve Survival Rates Vs. Chemo Alone



IO therapy, however, only works in ~21% of tumors/patients



Sources: CA A Cancer J Clinicians, Volume: 73, Issue: 1, Pages: 17-48, First published: 12 January 2023, DOI: (10.3322/caac.21763) Response Rates to Anti–PD-1 Immunotherapy in Microsatellite-Stable Solid Tumors With 10 or More Mutations per Megabase <u>Cristina Valero</u>, MD, PhD,¹ et al

IO Success Can Be Constrained If The Tumor Antigens Presented Are Too Weak To Elicit A Strong Immune Response

Sources of Immunotherapy Resistance

- 1. Weak tumor antigen or loss of tumor-antigen expression
- 2. Upregulation of immune-checkpoint molecules (immune fatigue)
- 3. Activation of alternative signaling pathways
- 4. Immunoediting

More of a good thing isn't necessarily better:

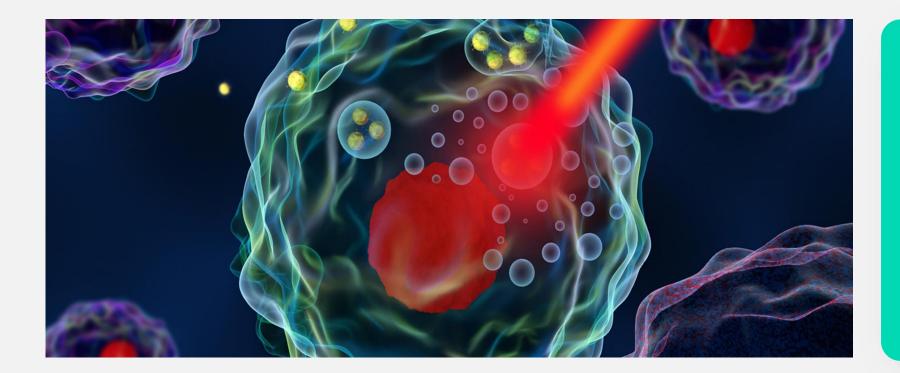
Addressing a weak antigen tumor microenvironment with stronger/more IO drugs risks triggering autoimmunity and toxicity

Revealing fresh tumor antigens would spark and activate the innate immune system



Source: Cancer Resistance to Immunotherapy: Comprehensive Insights with Future Perspectives Sawsan Sudqi Said and Wisam Nabeel Ibrahim, in Pharmaceutics, April 2023

Many Unexposed Antigens Exist in Tumors But How Can We Cause Them to be Presented to the Immune System?

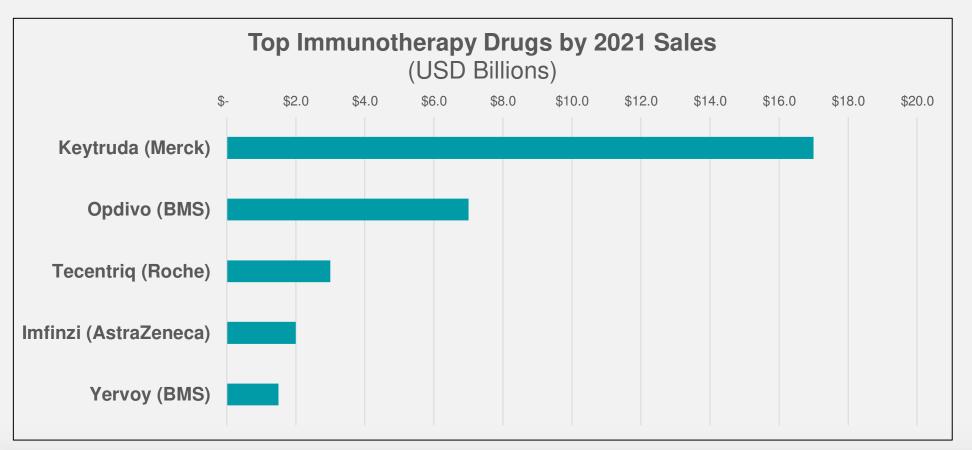


Heating cancer cells gently causes them to die by apoptosis which causes the release of neo-antigens

Sona's therapy primes the tumor microenvironment to present neo-antigens, thereby enabling immunotherapy to work better



The U.S. Market for Immuno-Oncology Therapy Drugs For Solid Cancers Is Worth \$31 Billion



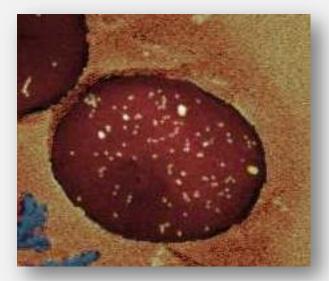
Raising response rates, even marginally, could result in billions in market share for the partner

Sources:

https://www.statista.com/statistics/1269401/revenues-of-keytruda/ https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-opdivo-1127420/ https://www.globaldata.com/data-insights/healthcare/the-global-drug-sales-of-tecentriq-1127456/ https://www.astrazeneca.com/content/dam/az/PDF/2021/full-year/Evilts-announcement.pdf https://www.precisionmedicineonline.com/business-news/bms-posts-strong-o4-precision-oncology-products-sales#:~:text=Opdivo%20revenues%20in%202022%20were.from%20%242.03%20billion%20in%202021 Sona's Targeted Hyperthermia Therapy (THT) Applies NIR Light to Nanorod-Saturated Tumors To Heat Them From the Inside Out, Gently

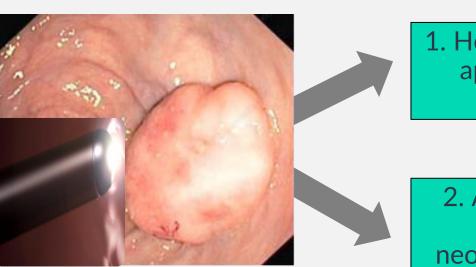
A Two Device System

1. Inject Biocompatible Gold Nanorods Intratumorally



Nanoparticles shown in a red blood cell to show relative scale

2. Shine NIR Light Tuned to 850nm on Tumor



Near infrared light applied to GNR saturated tumor

Delivering a 1-2 Punch:

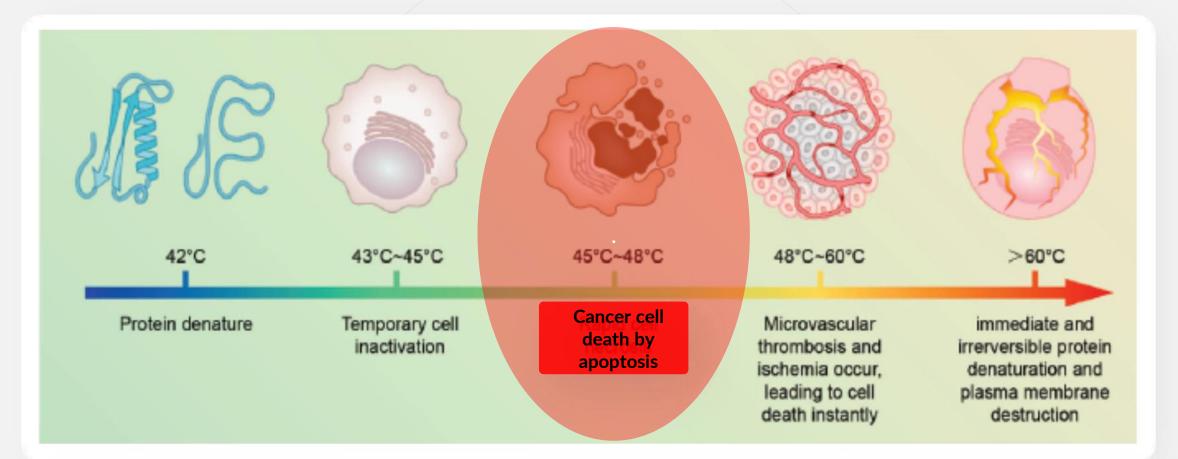
1. Heat causes cancer cell apoptosis, shrinking tumors

2. Apoptotic cell death releases intact neoantigens, awakening the innate immune system

THT heats the tumor cells gently, shrinking it and causes the exposure of intact tumor-specific neo-antigens



THT's 'Hyperthermia' Approach Heats Tumors to 41-48 °C – Enough to Kill Cancer Cells, But Not Enough to Harm Healthy Cells



Apoptosis: A type of cell death in which a series of molecular steps in a cell lead to its death. This is one method the body uses to get rid of unneeded or abnormal cells. The process of apoptosis may be blocked in cancer cells. Also called *programmed cell death*.



While Cancer Cell Death by Apoptosis Can Be Stimulated In a Variety of Ways, Sona's THT Therapy is Efficient and Selective in its Treatment

Rationale for Sona's Targeted Hyperthermia Therapy (THT)

- Gold nanorods (GNRs) are the most efficient gold nanoparticles at converting light energy into heat potentially minimizing therapy times
- Sona's GNRs are uniquely manufactured without toxins, making them an inherently safe and therefore desirable heat generating agent, in vivo
- THT limits healthy cell damage and promotes apoptosis, rather than necrosis by generating moderate hyperthermia instead of high-temperature ablation

Leverages the innate immune system without 'cutting, burning or poisoning'



Sona's THT Therapy is Proprietary And Will Benefit From IP Protection

Sona's Four Sources of IP Advantage

Patents:

- Method for Manufacture of Biocompatible Gold Nanorods
 - Issued: South Korea; Pending: PCT, USA, Canada, EU, China.
- Photothermal NIR LED Light Device
 - Issued on Dec. 11, 2014, as US patent #10,064,940
- Photothermal Near-Infrared Laser Light Device
 - U.S. Provisional Patent Application No. 63/562461, filed Mar. 7, 2024
- Gold Nanoparticle Conjugates and Uses Thereof
 - US patent #9,175,015 filed Aug. 22, 2008
- Further provisional patent work underway

Time Advantage:

 Moving quickly to maintain Sona's lead to be the first to be approved by regulators

Two Device System:

- Once approved by regulators, Sona's light device may not be used with 3rd party GNPs
- Once approved by regulators, Sona's GNRs may not be used with 3rd party light device
- Use of one with a substitute for the other would also void warranties

All restrict off-label use

Trade Secrets:

- Techniques for delivery of GNRs in vivo and application of the non-thermal energy
- Protocols for immunotherapy agent combinations



THT Concept is Backed By Science; Now Relies On Preclinical Development Work to Advance

Previously Done/Approved:

- Heat used to kill cancer cells
- Photothermal treatment using infrared light devices
- FDA has approved nano particles for injection into humans⁽¹⁾
- THT efficacy and safety in small animals demonstrated in peer reviewed scientific journal

Sona To Do:

- 1. Deliver infrared light device that can monitor temperature in real time
- 2. Preclinical studies to demonstrate safety and efficacy, optimal dosage and treatment duration
- 3. Develop THT-IO combination therapy protocols
- 4. Enhance production to meet regulatory requirements
- 5. Develop intellectual property protection
- 6. Secure first-in-human efficacy trial

Sona's development plan leverages significant prior third-party research

Sona's Development of THT Has Benefited From The Guidance Of A Panel Of Leading Physicians In The U.S. And Multiple FDA Interactions

Stakeholder Engagement

EXCITE International Panel Members:

- Three surgical oncologists from leading U.S. cancer centres
- Four physicians representing different U.S. payer organizations

FDA Pre-IDE Submission Correspondence and Meeting #1:

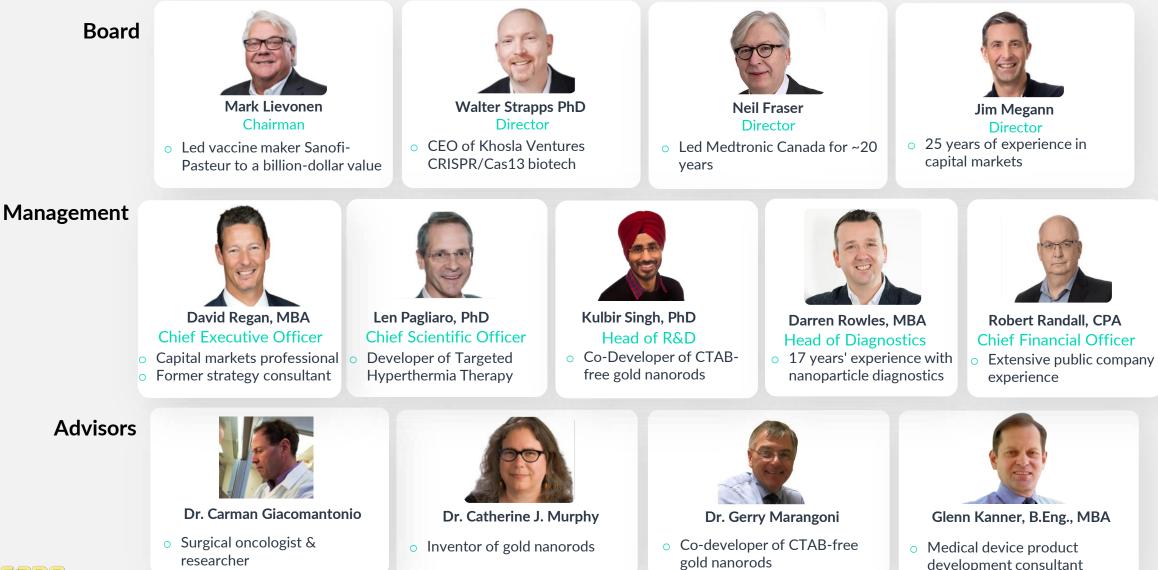
- Commented on THT pre-clinical development plan
- Responded to questions on target Indications of Use and safety considerations







Sona Has Engineered the Right 'Gene Pool' to Develop Its Cancer Therapy



Building the Safety and Efficacy Data Required by Regulators for a 'First in Human' Pivotal Phase 1 Clinical Study

Current Efficacy Study at Dalhousie University:

Evaluation of Sona Nanotech's Gold Nanoparticle-Mediated Photothermal Therapy in Combination with Intralesional Immune Modulation as a Novel Immuno-Oncology Combination Strategy for Colorectal, Skin and Breast Cancers

<u>Principal Investigator:</u> Dr. Carman Giacomantonio MD, MSc., FRCSC (Cav.)

Professor, Faculty of Medicine, Dalhousie University **Surgical Oncologist / General Surgeon**, QEII HSC







Research Study Background – Premises

Cancer cells are inherently susceptible to therapeutic hyperthermic therapy (THT) stress Sona's GNRs can be activated in precise anatomic locations to cause THT induced damage to cancer cells

Immunotherapy is the leading-edge in cancer treatment, but alone has demonstrated a limited response rate

Can THT cause a synergistic effect as part of an immunomodulation strategy?



Research Study

Research Study Background – Metrics of Success

Research Study

Success Will Be Assessed By The Extent To Which:

Tumor Shrinkage

- THT causes tumor volume reduction in mouse models of:
 - Melanoma
 - Breast cancer
 - Rectal cancer

Enhanced Immune Response

 Use of THT with certain immunotherapies is additive or even synergistic

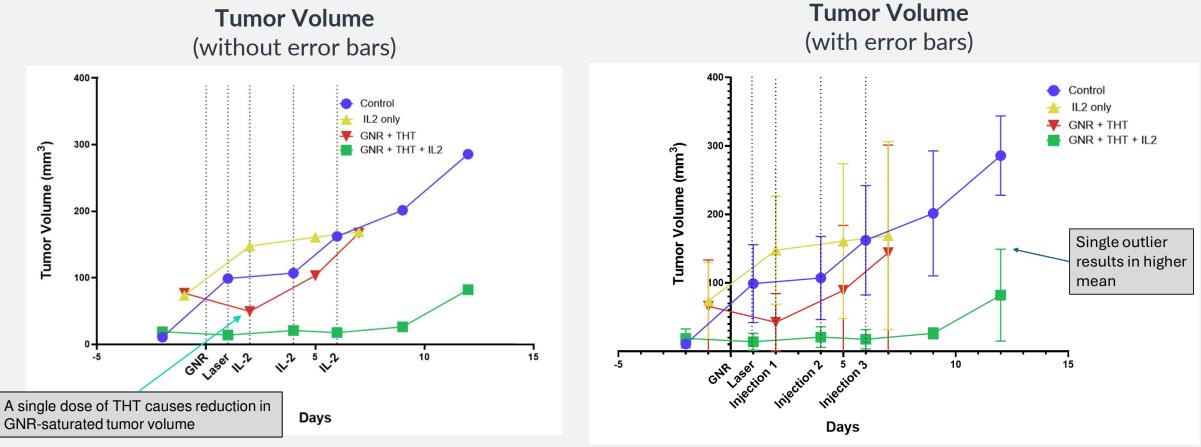
Abscopal Effects are Observed

 Immune responses created in remote tumors without directly treating them



Data Shows Synergistic Effect of Combining Sona's THT and Standard Immunotherapy Agent IL-2

Research Study Background – Initial Results (Triple Negative Breast Cancer Mouse Tumor Model, n=6)



Research

Study

Moving Quickly Towards Pre-clinical Studies and Regulatory Filings

- 1. Selection of pre-clinical study partners, plans and initial safety study results
 - Utilizing pre-existing research & advisory groups to conduct studies in the most cost-effective ways
- 2. Panel of leading EXCITE International expert advisors from top U.S. institutions and 'payors' to provide guidance
 - To ensure that Sona's product development is in line with what surgical oncologists are looking for, prior to FDA submission
- 3. First FDA pre-submission meeting
 - Received written and verbal feedback from FDA in February, validating Sona's current approach
- 4. Gold nanorod GMP manufacturing partner selection
- 5. Efficacy study results
 - Currently measuring Sona's technology effectiveness in mice for melanoma, colorectal and breast cancer
- 6. Initiate Safety Feasibility and Biocompatibility non-GLP studies
- 7. Initiate regulator required GMP manufacture of gold nanorods
- 8. First-in-human studies (subject to regulatory approval)
 - Company exploring opportunities to accelerate human efficacy studies, once safety established



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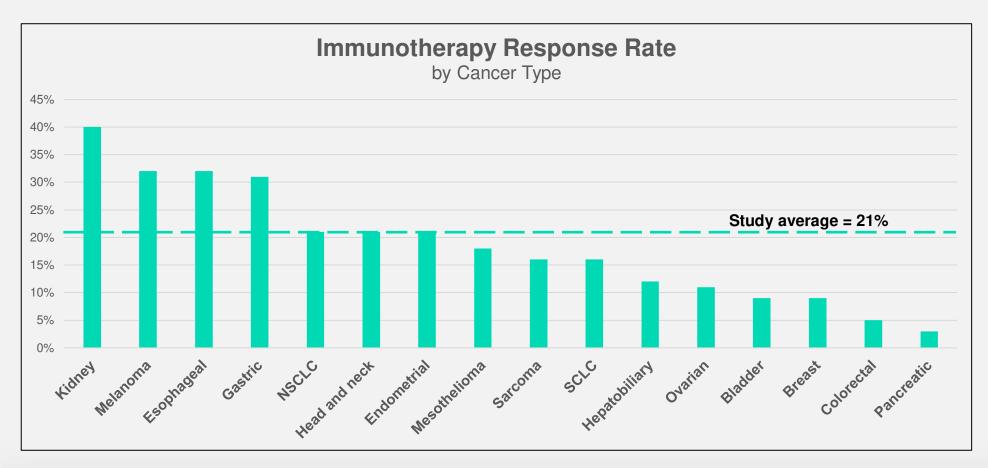
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In progress

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Improving Immuno-Oncology Drug Response Rates Could Substantially Decrease Mortality Rates



...And offer greater hope to the two million people expected to be diagnosed with cancer each year



Sources: CA A Cancer J Clinicians, Volume: 73, Issue: 1, Pages: 17-48, First published: 12 January 2023, DOI: (10.3322/caac.21763) Response Rates to Anti–PD-1 Immunotherapy in Microsatellite-Stable Solid Tumors With 10 or More Mutations per Megabase <u>Cristina Valero</u>, MD, PhD,¹ <u>et al</u>



Thank you

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GNR

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