# TORAGEN

TREATING THE ROOT CAUSE OF HPV INDUCED HEAD AND NECK CANCER

JANUARY 2021

## WORLDWIDE INCIDENCE THE UNMET NEED

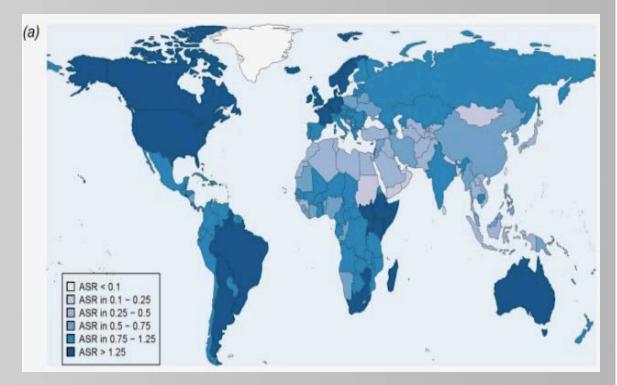


80% of us are exposed to the Human papillomavirus (HPV) in our lifetime

HPV is the leading cause of viral associated cancers (5% of all Cancers Worldwide)

Over 640,000 Head and Neck Cancers Annually

330,000 Deaths Each Year



JNCI Cancer Spectrum, Volume 2, Issue 4, October 2018, pky045

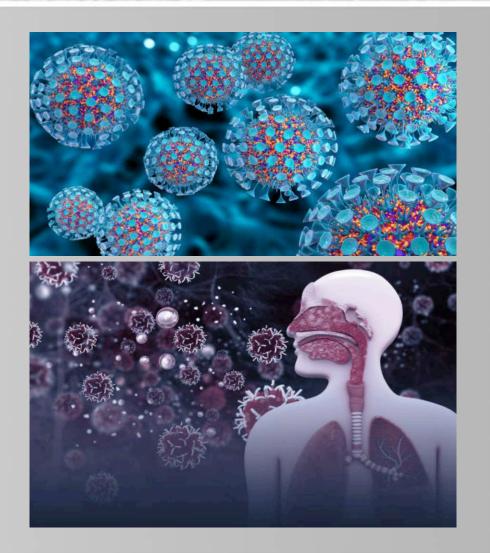
# HEAD AND NECK CANCER TREATMENT 30-50% will recur



Chemotherapy

Cetuximab is used upon recurrence (\$82,000 for 18-week treatment)

Immunotherapy – PD/PDL-1 Inhibitors





# MARKET SIZE – SECOND LINE INDICATION



## Approximately \$2 Billion Worldwide

Toragen opportunity could approach \$200 Million Annually

In the U.S. – Orphan Drug Designation

# TREATING THE ROOT CAUSE BY TARGETING HPV ONCOGENES

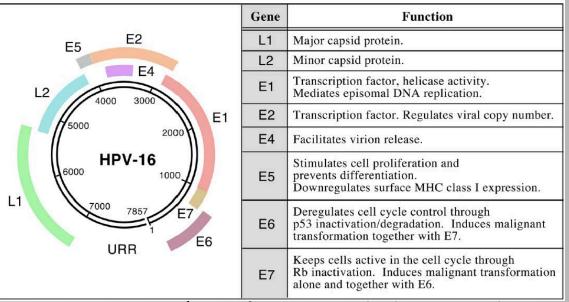


TGN-S11 Selectively Targets HPV Oncogenes

Reformulating an already FDA-approved Drug

Enter market in half the time

**IP-protected Pipeline** 



Human Papillomavirus (HPV 16) Oncogenes

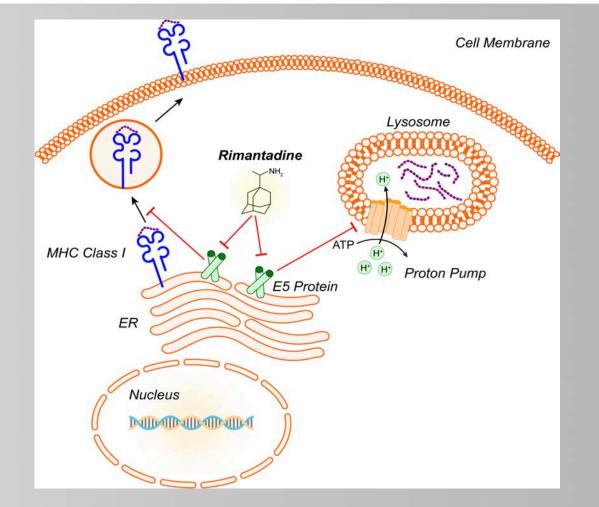
**IORAGE** BIOTECHNOLOGI

<sup>&</sup>lt;sup>1</sup>Centers for Disease Control and Prevention., July 8, 2016

# HPV-ASSOCIATED CANCERS - TARGETING E5 WITH TGN-S11



- □ HPV E5 directly binds to MHC Class I and downregulates surface expression of MHC.
- □ HPV E5 also inhibits antigen processing and tumor antigen presentation.
- □ This directly limits the ability of T-cells to detect and kill HPV+ tumor cells.
- Potential to enhance activity of existing approved immunotherapy agents including PD-1 blockade

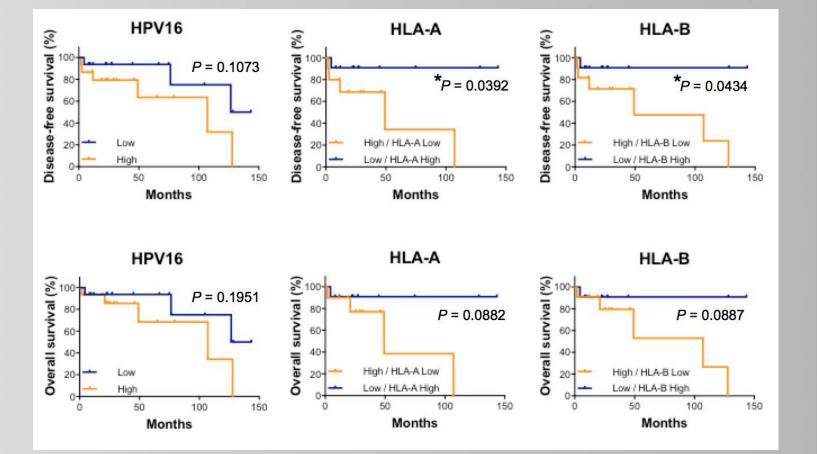


**IORAG** 

# TORAGEN RESEARCH DATA



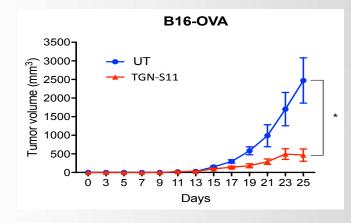
High expression of the HPV E5 oncogene confers worse Overall Survival in Head and Neck Cancer Patients

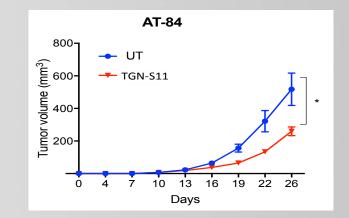


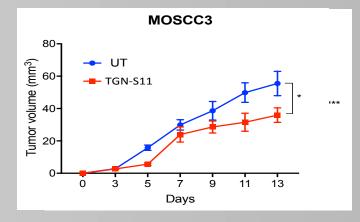
Miyauchi et al., Cancer Res. 2020 Feb 15

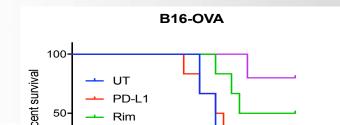
# TORAGEN LEAD COMPOUND – TGN-S11 TORAGEN BIOTECHNOLOGIES

#### Single agent anti-tumor activity of TGN-S11 in multiple murine head and neck models









Toragen Inc. Confidential

Miyauchi et al., Cancer Res. 2020 Feb 15

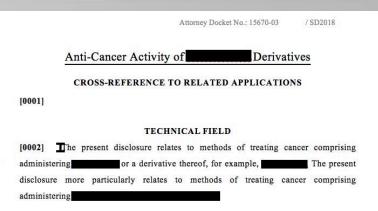
# ACCOMPLISHMENTS - WE ARE EXECUTING

#### \$450,000 of Angel Capital raised

#### Licensed Drug from UCSD & Filed PCT Patent

#### **Developed our Fast to Market Regulatory Strategy**

FDA agreed to our 505(b)(2) Strategy

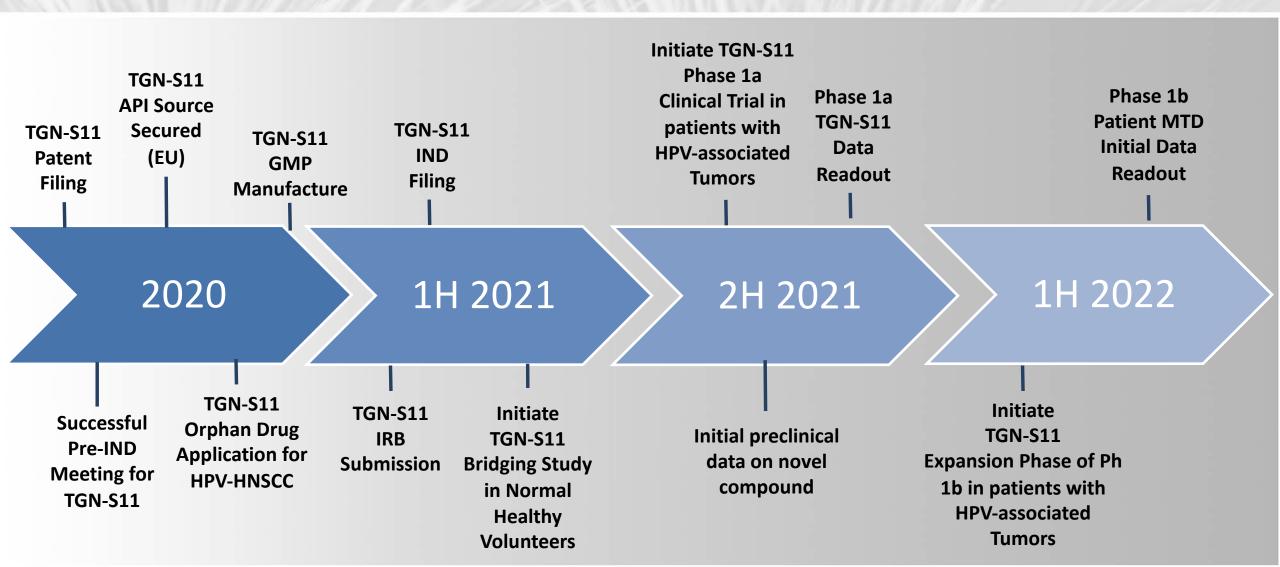


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#### BACKGROUND

- Cancer is the second most common cause of death in the United States. In 2018, approximately 1.7 million new cases were expected to be diagnosed and about 610,000 deaths due to cancer were expected to occur in the United States. There are more than 100 types of cancer including head and neck cancer, skin cancer (e.g., melanoma), cervical cancer, lung cancer, and breast cancer. Head and neck cancer accounts for approximately 4% of all cancers in the United States, and while melanoma accounts for
- 15 only 1% of skin cancers, it causes the majority of deaths due to skin cancer. Additionally, about 1 in 8 women in the United States will develop breast cancer over the course of her lifetime, and death rates due to breast cancer are higher for women than any other cancer, excluding lung cancer. Additionally, about 5% of overall cancer worldwide is associated with human papillomavirus (HPV), including cervical cancer and head and neck
- 20 squamous cell carcinoma (HNSCC), and the percentage of HPV-associated cancer has been increasing. Anti-PD-1 checkpoint blockade immunotherapy for recurrent or metastatic HNSCC after platinum-based chemotherapy was approved by the FDA due to overall survival benefits in patients receiving these anti-PD-1 agents, but the objective response rate to single agent checkpoint blockade immunotherapy in remains low (see
- 25 e.g., Ferris et al. N Engl J Med. 2016 Nov 10;375(19):1856-1867; Seiwert et al. Lancet Oncol. 2016 Jul;17(7):956-965; Cohen et al. Lancet. 2019 Jan 12;393(10167):156-167;

# INFLECTION POINT TORAGEN SEEK TO RAISE \$10 MILLION IN SERIES A ROUND - 2-3 YEAR RUNWAY



# **DEVELOPMENT TEAM**





Andrew Sharabi, MDPhD Founder and CEO Specializes in treating Head & Neck Cancer



Anita Busquets, CFO Experienced startup executive 7<sup>th</sup> company



Rick Lumpkin, PhD Director of R & D Over 30 yrs of early-stage biotech experience



James Kanter, PhD Chemistry Manufacturing expert



John Reiner, PhD Chemist Enantiomer/SAR Lead



Elizabeth Vadas, PhD Formulation Expert Lead Developer at Merck



Roger Dilts, PhD Development Expert in assays development to choose development candidates

# **ADVISORS**





Jeff Hartlin Outside Counsel

Ezra Cohen, MD **Clinical Advisor** 

Dennis Carson, MD Scientific Advisor

John Major Board Member

Daniel Solorio Regulatory Ops Michael Swit Regulatory Counsel



Faye Hunter Licensing

# IN SUMMARY



Clinical Stage Ready Company Novel IP and Research Pipeline Technology designed to enhance PD-1 inhibitor drugs Seeking Orphan Drug Designation in US

Significant Market ~ \$2 billion

# **THANK YOU!**



#### FOR MORE INFORMATION PLEASE VISIT

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