SGX942 Reduces the Duration of Severe Oral Mucositis in Head and Neck Cancer

Oreola Donini*, PhD, Chief Scientific Officer, Soligenix, Inc.

Richard Straube*, MSc, MD, Chief Medical Officer, Soligenix Inc.

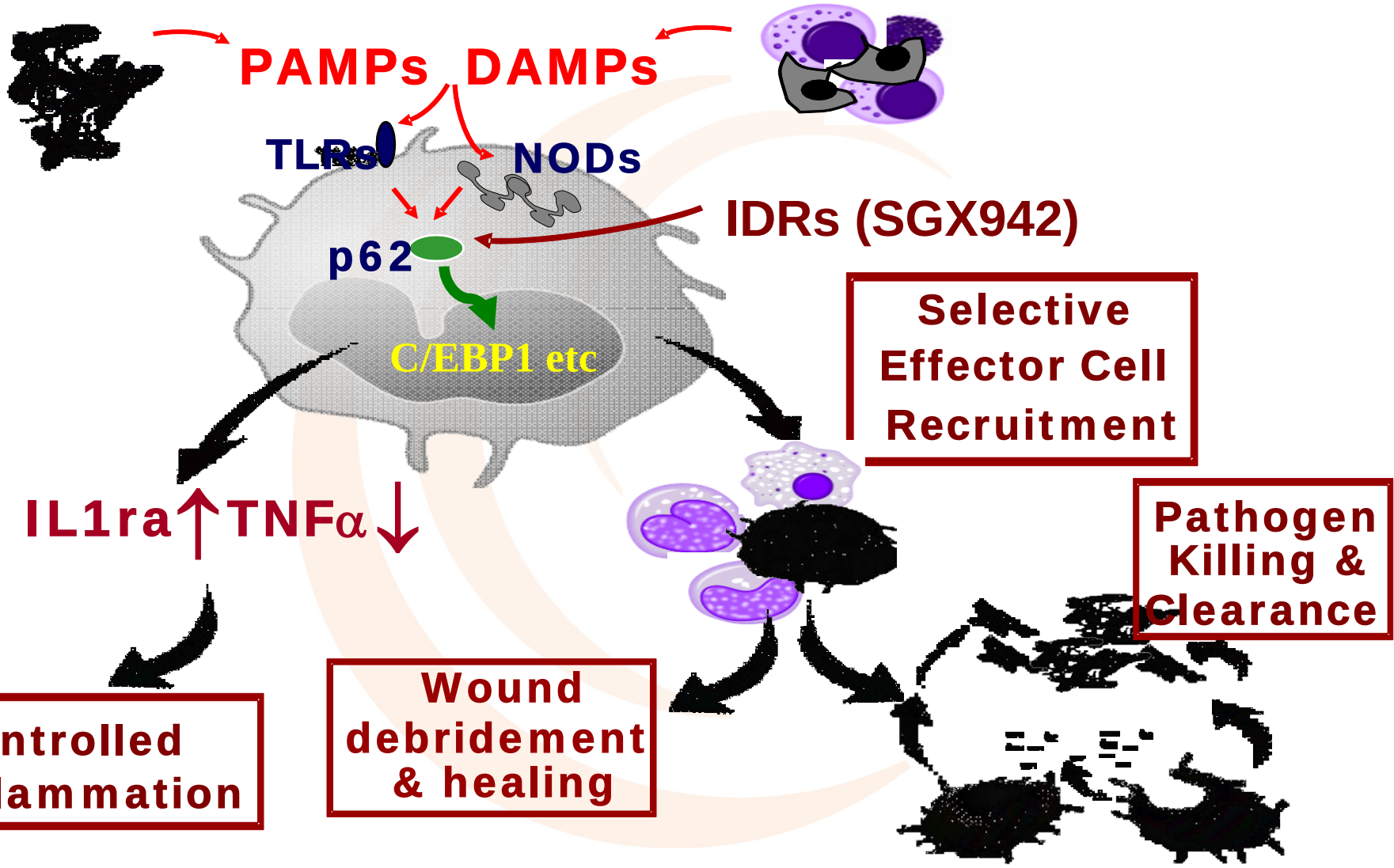
Multinational Association for Supportive Care in Cancer Conference, 2016

June 25, 2016

**Conflict of Interest Statement: OD and RS receive compensation from Soligenix, Inc., and hold equity in Soligenix, Inc; OD is a co-inventor of SGX942.*

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
Soligenix, Inc.			x	OD	OD/RS		OD/RS	

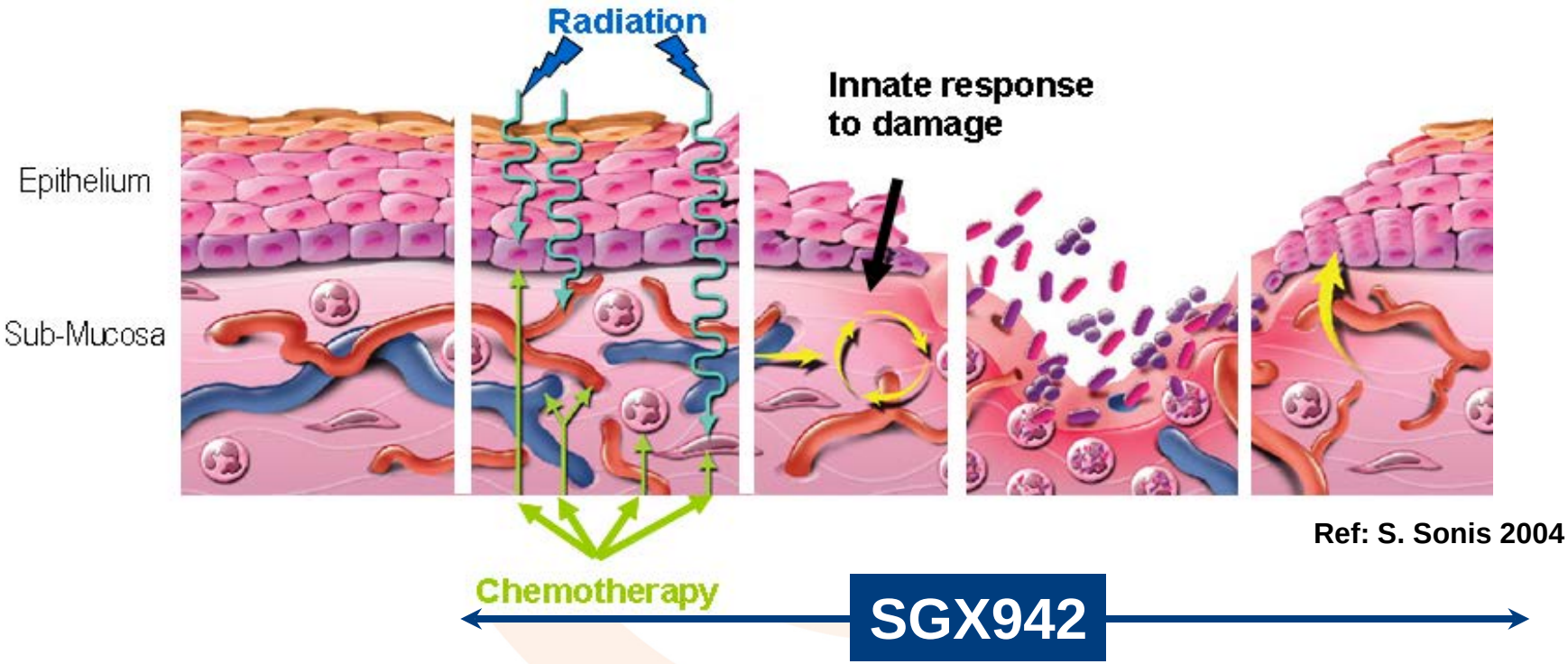
SGX942: An Innate Defense Regulator



Yu et al. JBC 2009; 284(52): 36007-11.

Pathobiology of Mucositis

- Innate Defense Regulator: impacts all stages of mucositis initiation and progression

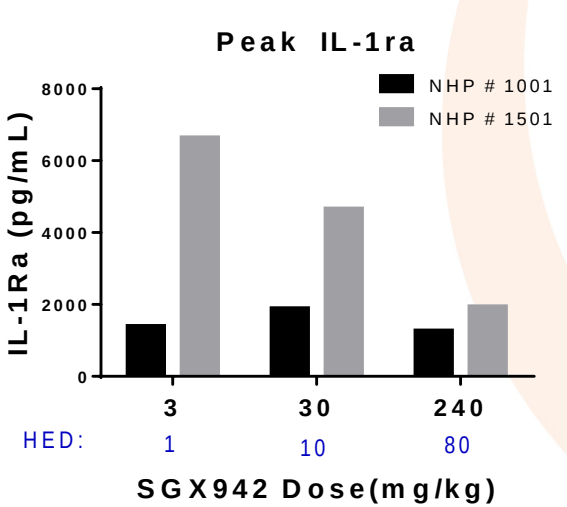


Ref: S. Sonis 2004

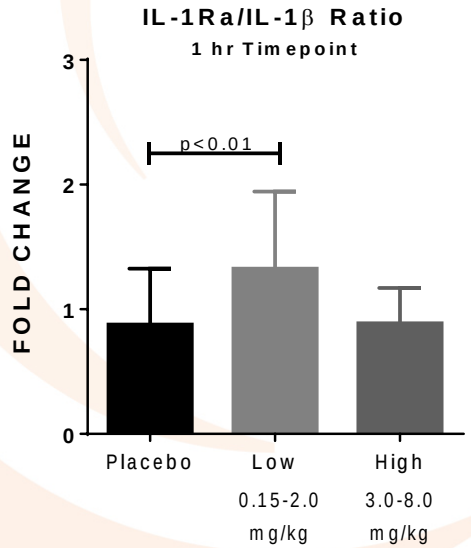
- Active in nonclinical models of chemotherapy and radiation induced mucositis

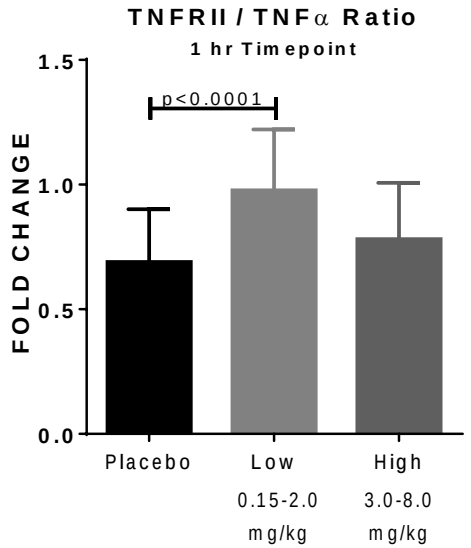
Dose Selection

- Activity in oral mucositis (OM) in preclinical models at human equivalent dose of 1-2 mg/kg
  - Higher dose levels could not be assessed in rodents
- Anti-inflammatory markers indicated 1-2 mg/kg as the most effective dose in nonclinical and phase 1 studies



PRIMATES





PHASE 1

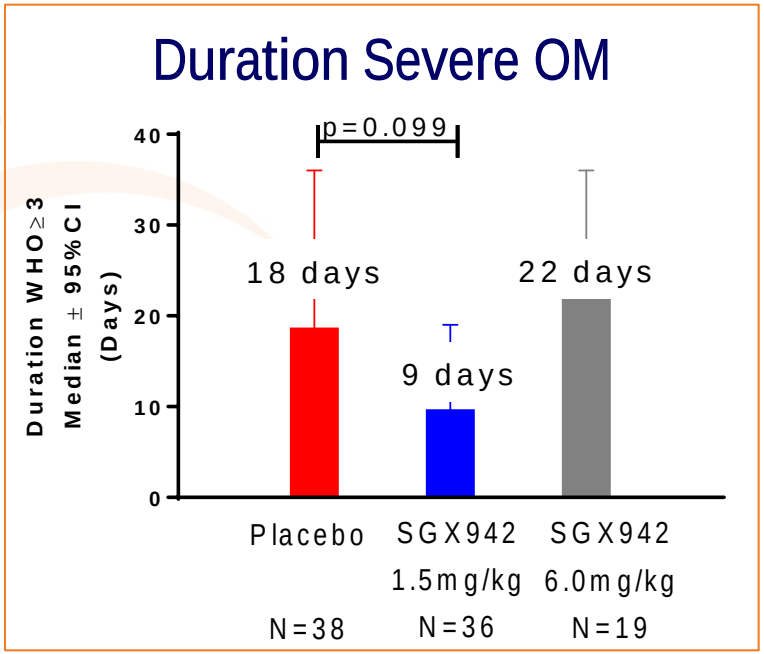
North et al. J Biotech 2016; 226:24-34

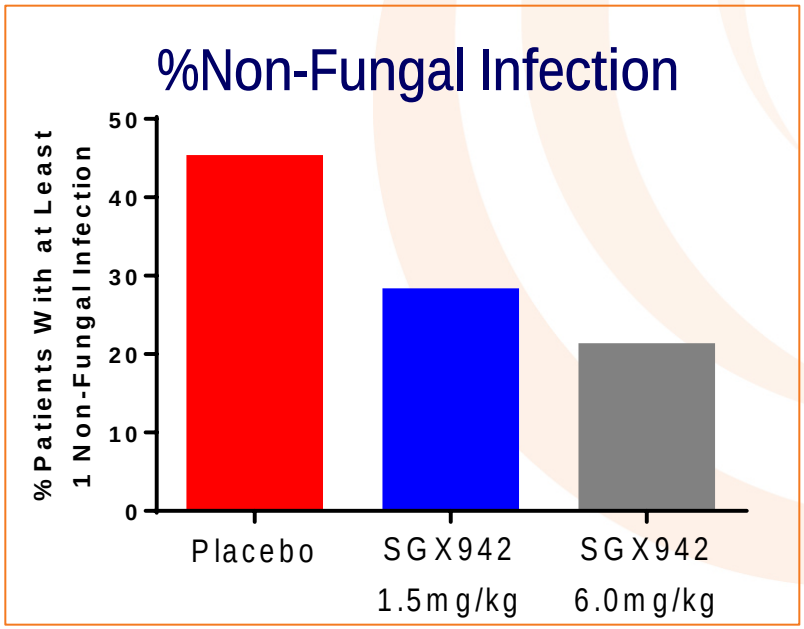
Phase 2 Study Design

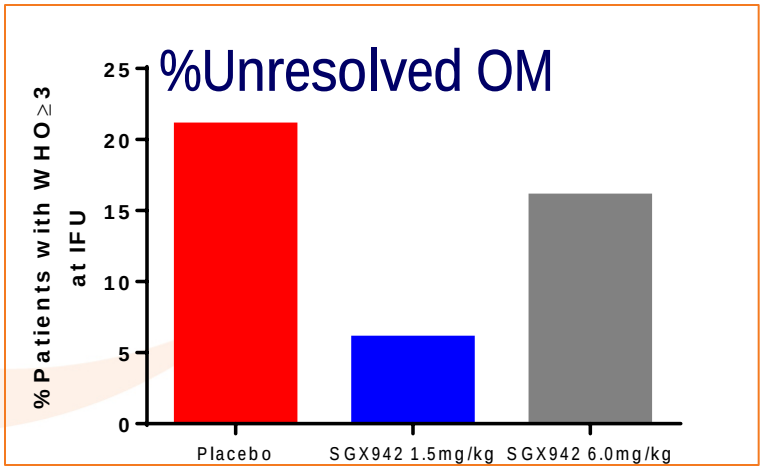
- Enrolled 111 head and neck cancer (HNC) patients planned to receive at least 55 Gy radiation and either weekly (30-40 mg/m^2) or every 3rd week (80-100 mg/m^2) cisplatin
  - 96 patients received at least 55 Gy irradiation and constituted the primary mITT analysis population
- Dose escalating: Placebo, 1.5, 3.0 or 6.0 mg/kg administered twice weekly
  - 3.0 mg/kg included as a “safety step” only; not used for efficacy analysis
- Key efficacy endpoints: incidence and/or duration of severe OM
- Key safety endpoints: AEs, SAEs, lab results

Clinically Meaningful Results

- 50% decrease in duration of severe (WHO≥3) OM
- Reduced infection rates
- Does not protect tumor ("complete resolution" favored SGX942 1.5 mg/kg group)

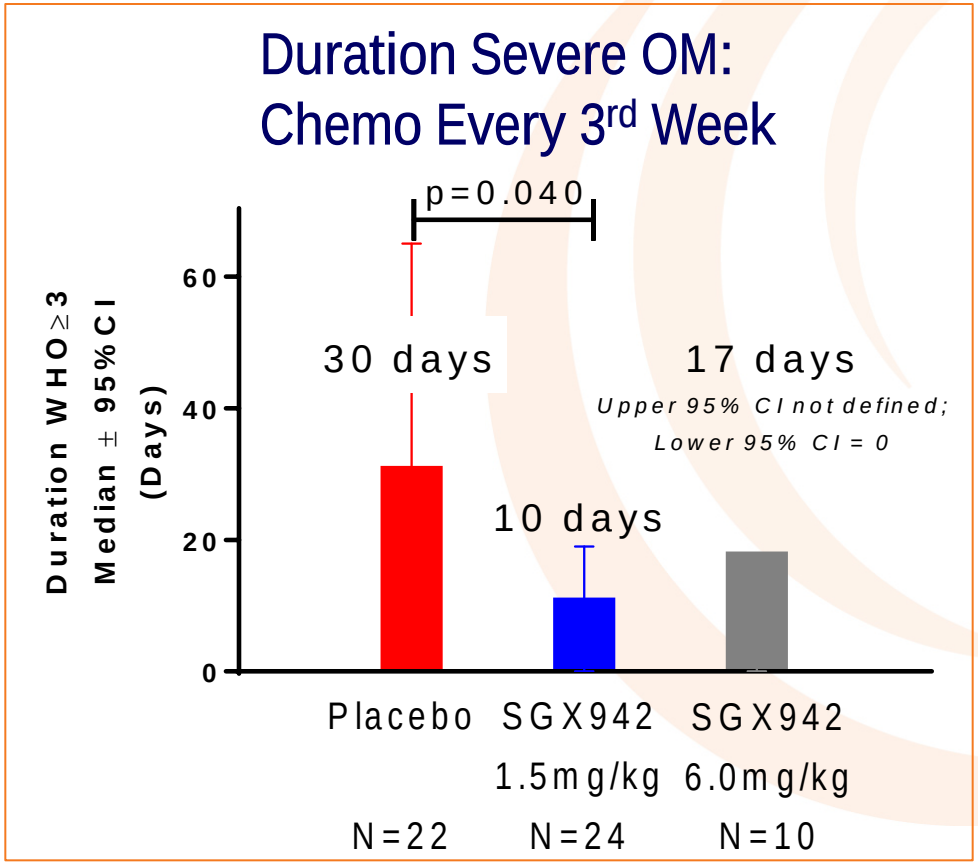


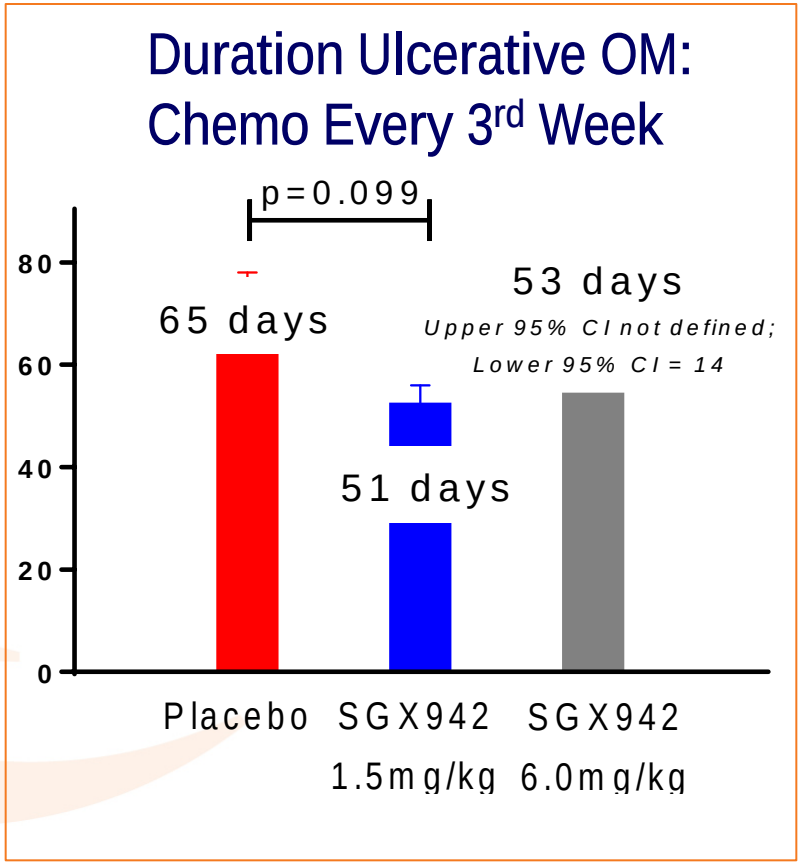




More Disease = Bigger Effect Size

- Subjects with higher incidence of OM experienced more benefit from SGX942
  - Reduced duration of ulcerative (WHO≥2) OM also observed





Effective Dose = 1.5 mg/kg

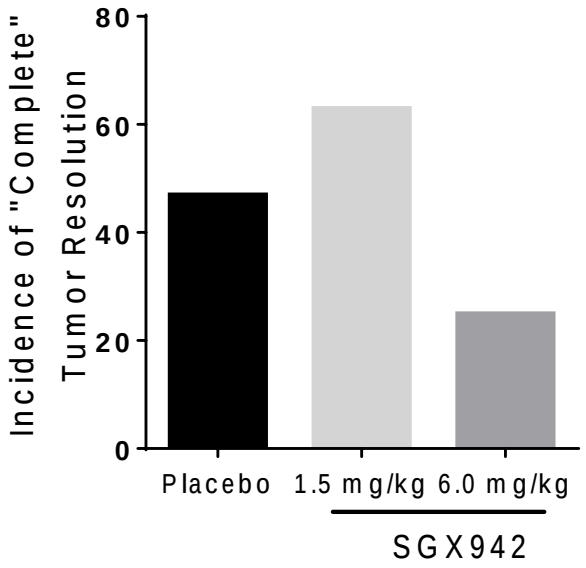
Endpoint	1.5 mg/kg	6.0 mg/kg
mITT: Duration of SOM	✓✓	–
mITT: AUC of SOM	✓	–
mITT: Incidence	✓	–
mITT: Residual SOM @ 1 m	✓✓	✓
q3wk: Duration of SOM	✓✓✓	✓
q3wk: AUC of SOM	✓✓	✓
q3wk: Incidence of SOM	✓	✓
mITT: Nonfungal infections	✓	✓
mITT: Complete tumor response	✓	–

– = no better than placebo ✓ = + trend ✓✓ = p<0.10 ✓✓✓ = p<0.05

Safety

- SGX942 was well-tolerated in HNC patients undergoing chemoradiation therapy
  - No differences in the nature or severity of AEs and SAEs between treatment groups
  - No significant shifts in laboratory values
  - No impact on tumor resolution
- Consistent with 84-subject Phase 1 study in healthy volunteers

%"Complete" Tumor Resolution at 1 month post EOT



Conclusions

- A non-linear dose response curve was observed, consistent with Phase 1 clinical and nonclinical studies
  - SGX942 (1.5 mg/kg) decreased SOM 50% and 67% in patients at highest risk for SOM
  - SGX942 (6.0 mg/kg) was less effective treating OM
- Achieved all study objectives:
  - ✓Showed safety in a sick patient population
  - ✓Identified most appropriate clinical endpoint
  - ✓Confirmed effective dose of SGX942
  - ✓Determined clinical effect size of SGX942
  - ✓Characterized patient population
  - ✓Determined that nonclinical biology translates to human setting
    - Decreased duration OM
    - Decreased incidence infection
    - No detrimental impact on tumor control
- Results support further clinical study of SGX942 in OM in HNC

Acknowledgments

National Institute of Dental and Craniofacial Research

- Phase 1 SBIR grant

Medical Advisory Board:

- Dr. Steve Sonis, Dr. Dorothy Keefe, Dr. Mark Schubert

Clinical Sites:

- University of Kentucky (Dr. M. Kudrimoti)
- Gibbs Cancer Center, Spartanburg Regional Hospital (Dr. A. Curtis)
- Veteran's Affairs Long Beach Hospital (Dr. S. Azawi)
- University of Michigan Health System (Dr. F. Worden)
- Willis-Knighton Cancer Center (Dr. S. Katz)
- Washington University (Dr. D. Adkins)
- Wake Forest Health Sciences Medical Center (Dr. M. Bonomi) ***and***
- IDR-OM-01 Study Group