

# Regional Clinical Trials

Michael B. Williams, MD, MS  
Urologic Oncology  
Associate Professor  
Department of Urology  
Eastern Virginia Medical School  
Norfolk

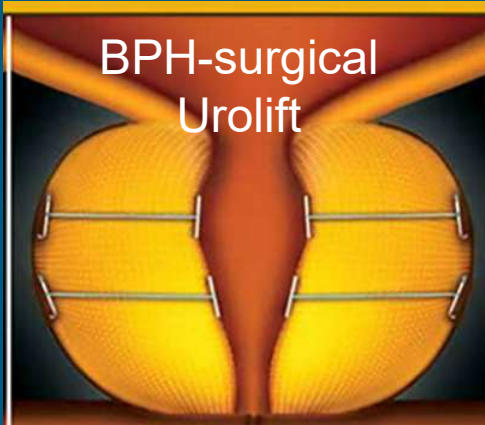
# Disclosures

- PI/SI for several trials in Prostate & Bladder cancer
  - Myovant
  - PASS
  - Bayer
  - Veru
  - Merck
  - Janssen
  - Arquor

# History of Clinical Trials in Our Practice

- Multiple national and international trials have been conducted over the years
  - BPH
  - Urethral Stricture
  - Stones
  - ED
  - Peyronie's Disease
  - Malignancy

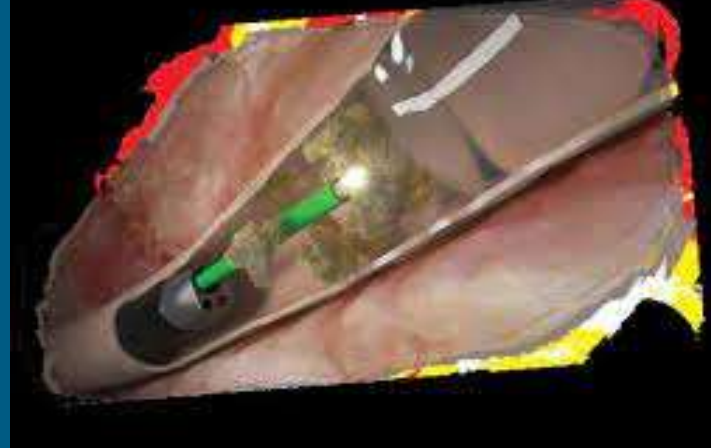
# FDA approved Devices or Products



**Dutasteride**

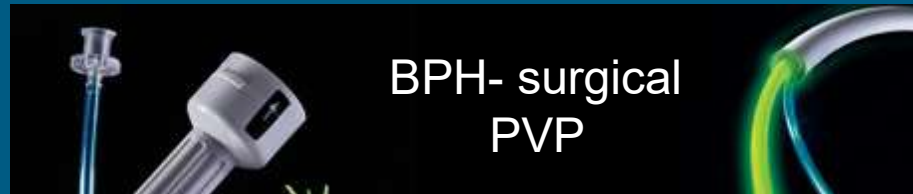
BPH-medication

Backstop stone antimigration



collagenase clostridium histolyticum

Only FDA approved for  
Peyronie's Disease



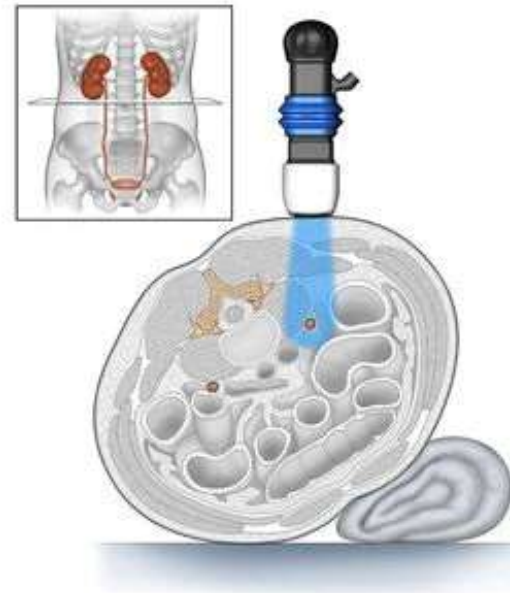
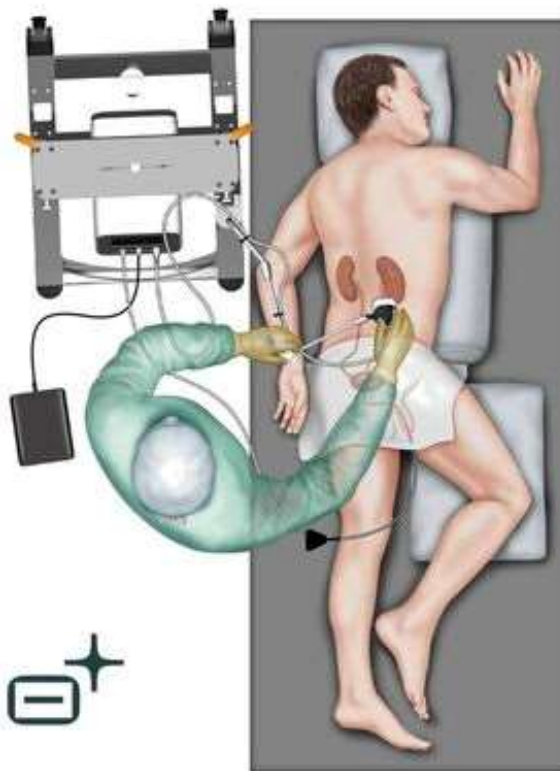
BPH- surgical  
PVP

# Trials Currently Active

- Stone disease
  
- Prostate Cancer
  - Active Surveillance
  - CSPC – M1
  - CRPC – M0/1
  
- Bladder Cancer
  - NMIBC

# In-office Shock wave lithotripsy

World's First Office Based Kidney Stone Treatment



# Prostate Cancer

- Multiple trials across several areas
  - 8 currently active trials
- Active Surveillance
- Imaging
- Treatment

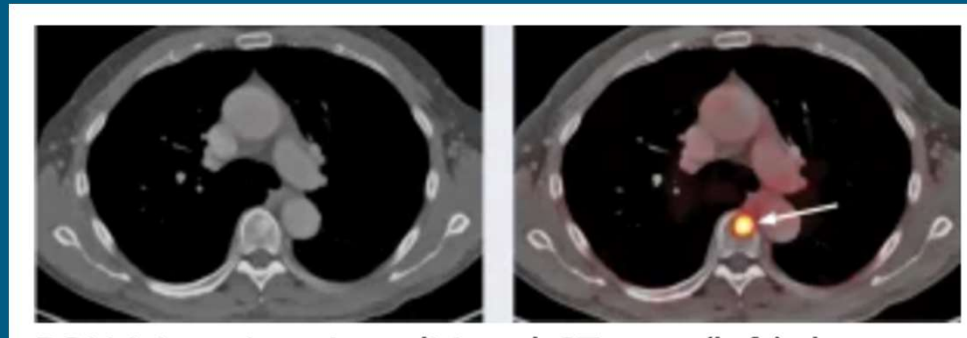
# Active Surveillance

- PASS – Biomarker study
- OncoCell MDx– SAFELY
  - immunogenic assay
  - 10 yr life expectancy
  - Goal: improve detection of poor risk individuals
- MDxHealth– GPS
  - Genomic Prostate Score
  - Already on market; real world registry study



# Imaging

- Pylarify– Lantheus
  - Piflufolostat F18
  - PSMA PET CT
  - More accurate assessment for M1 prostate cancer
  - Registry trial to better understand utilization in real world



# Treatment

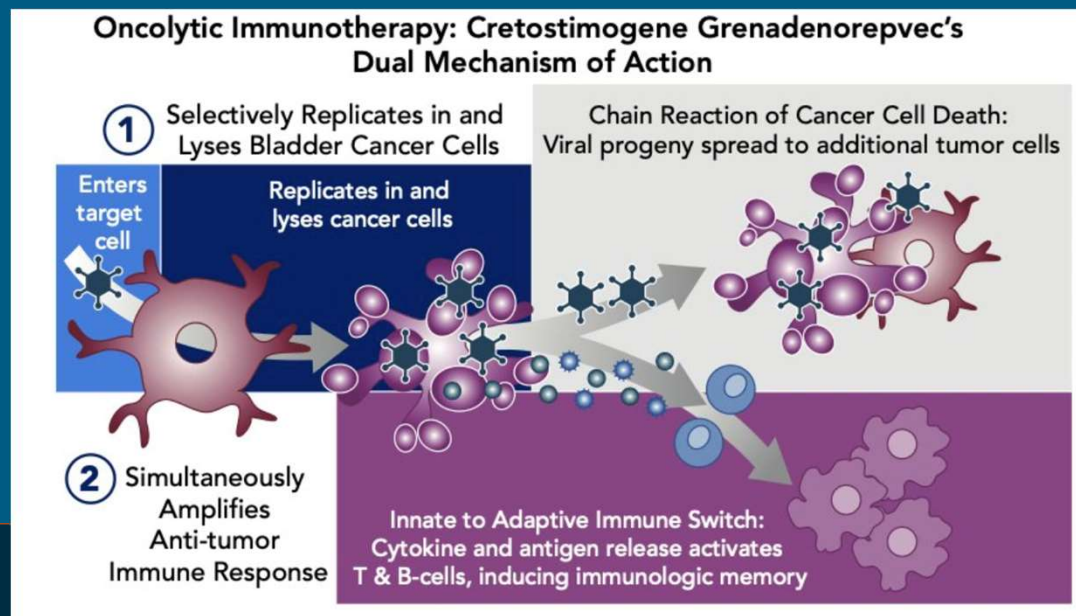
- DebioPharm
  - 3 month LHRH antagonist
    - The only injectable is currently 1 month
- Francis Medical– VAPOR2
  - Low volume targetable GG1–2
  - Utilizing water vapor to destroy lesion
- Dendreon
  - M1 CRPC
  - SOC =Sipuleucel T
    - Adding a booster at 6 months

# Bladder Cancer

- Currently 5 active trials
- NMIBC
  - Intermediate risk
  - High risk
  - BCG refractory

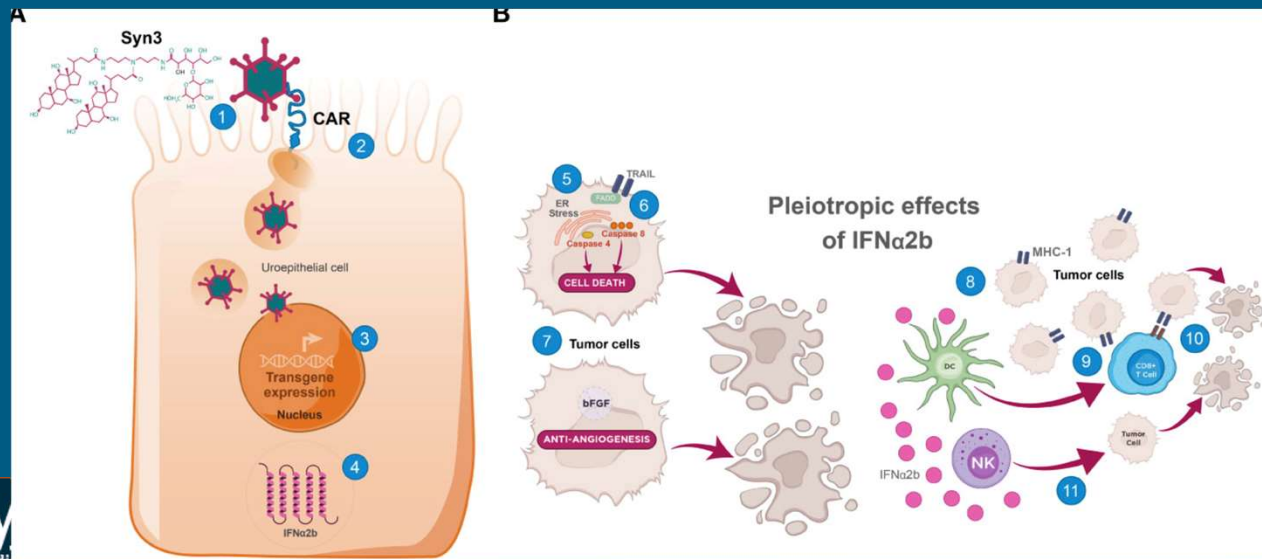
# NMIBC Intermediate Risk

- CG Oncology– PIVOT 006
  - Cretostimogene grenadenorepvec
  - Binds to Coxsackie and adenovirus receptors in tumor cells
  - Expresses GM CSF
  - Fast track designation from FDA



# NMIBC Intermediate Risk

- Ferring – ABLE 32
  - Nadoferogene firadenovec
  - Adenoviral vector that infects and replicates within urothelial cells and cancer cells
  - Produces IFNa2b

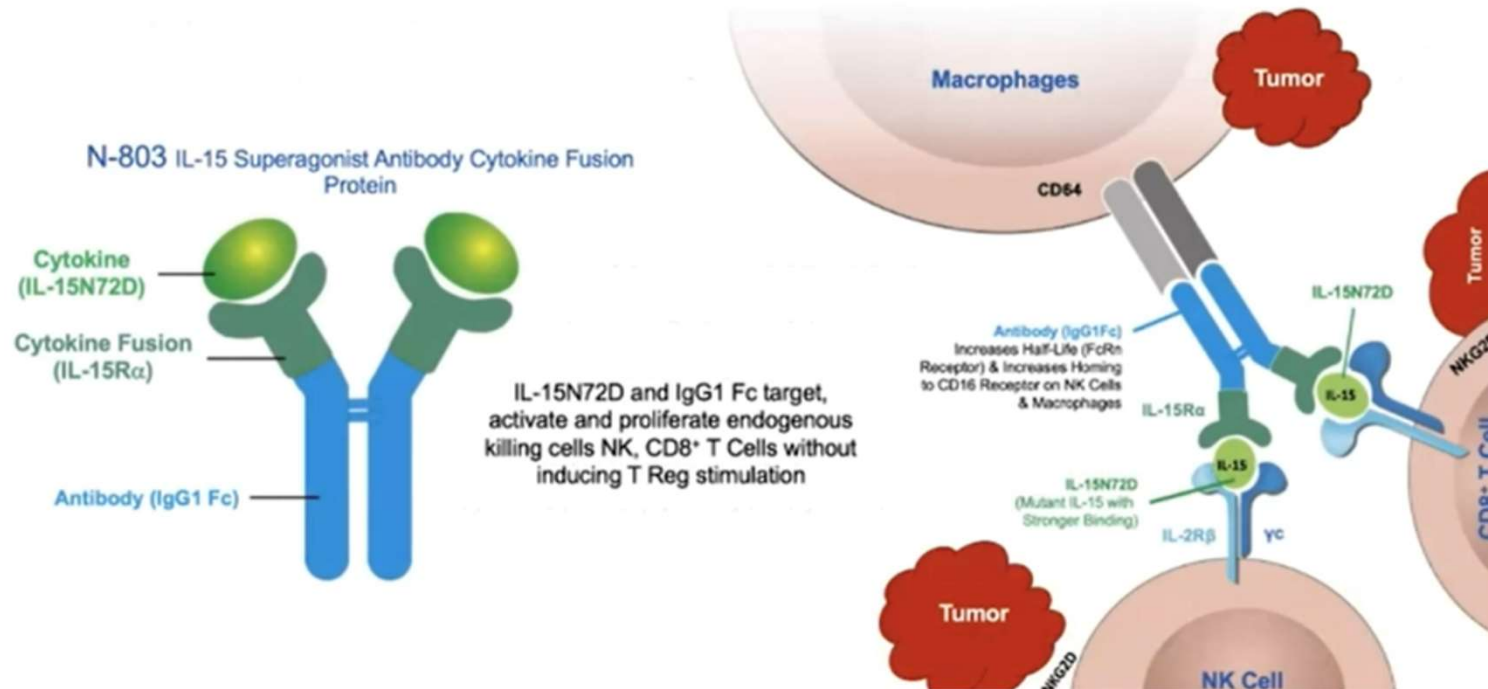


# NMIBC High risk

- CG Oncology CORE 008
  - Cretostimogene grenadenorepvec
- Immunity Bio – Quilt 2.005
  - N803 + BCG
  - Nogapendakin alfa inbakicept– PLMN

# Super IL15 agonist

## N-803 Mechanism of Action



# BCG refractory

- Ferring ABLE-41
  - Registry trial for nadoferogene firadenovec
- CG Oncology CORE 008
  - Cretostimogene grenadenorepvec



# Summary

- Multiple trials currently on going within our region for GU maladies
- Due to the recent advances in bladder cancer management, more to come in this aspect in the future.

*Teaching. Discovering. Caring*

# Thanks!