The Organ Sparing Cancer Therapy

Delivering better outcomes to more patients

December 2019

Steba biotech Innovation

Disclaimer

This document contains "forward-looking" statements – statements that are not historical facts and that involve risks, uncertainties, and assumptions, including statements related to Steba Biotech's overall strategy; plans to obtain reimbursement and launch TOOKAD® in several European countries and the US; future regulatory interactions with the FDA; plans to develop TOOKAD® in new indications. These forward-looking statements are based upon current expectations of Steba biotech's management. Forward-looking statements involve risks and uncertainties. Steba biotech's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include without limitation, the risk that unfavorable economic conditions may adversely affect TOOKAD®'s commercial potential; the risk that the FDA may not grant marketing approval for TOOKAD® based on data of the PCM301 study; the risk that clinical studies for TOOKAD® in new indications may not lead to regulatory approval. If any of these risks or uncertainties materialize, or if any of our underlying assumptions prove to be incorrect, our results may differ materially from those expressed or implied by such forward-looking statements . You are advised that any forward-looking statements you see in this document speak only as of the date of this document. We assume no obligation and do not intend to publicly update or revise these forward-looking statements for any reason.

An oncology revolution at the verge of a major value inflection

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Highly Validated

Lead indication approved in EU, IS, Mexico. NDA for accelerated approval accepted by FDA

Broad Potential

~$18B market potential as single agent and as immuno-oncology combination

Set-up for Growth

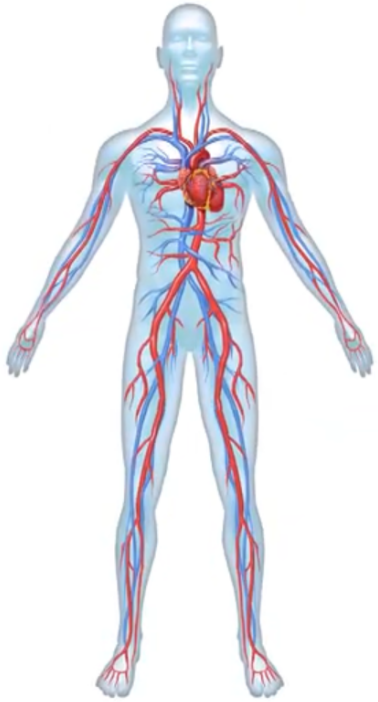
Full WW rights/ value retained; >$40mn non-dilutive funding; Backed by leading Centers

Imminent Inflection

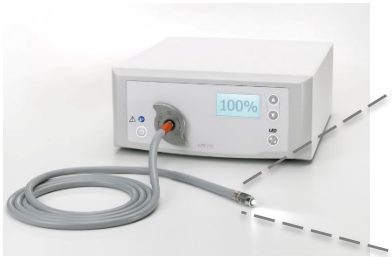
US launch of lead indication and multiple pipeline readouts anticipated for 1H 2020

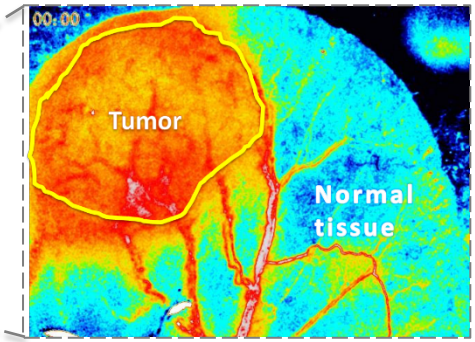
TOOKAD®: Selective and EMA-Approved Mode of Action

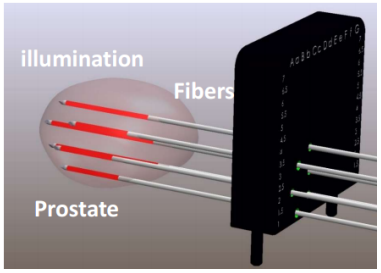
Injection of TOOKAD® → **Illumination of Tumor** → **Selective Tumor Destruction**



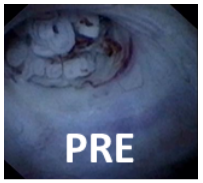
- Drug is inert without light
- Restricted to vasculature
- $T_{1/2}$ of ~1 hour

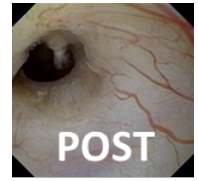






- Endoscope (GI/URO)
- Minimally invasive insertion of fibers for other indications



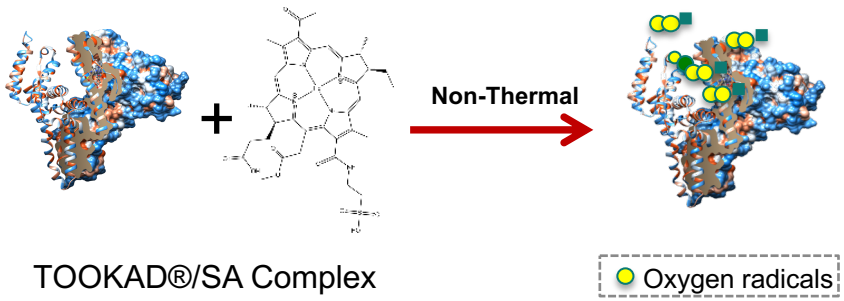


- Non-thermal, vascular occlusion leads to self-propagating necrosis* from vessels
- Only at site of illumination
- Selective to tumour tissue due to tumor microenvironment

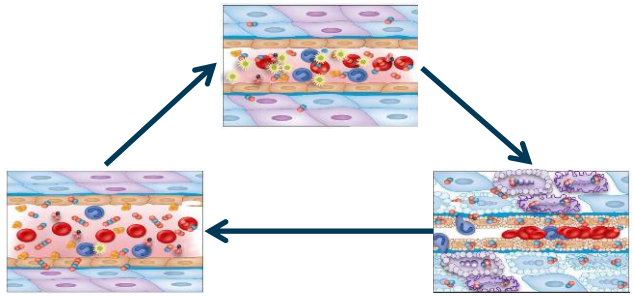
*Immunogenic cell death with increased immune system priming versus typical apoptosis
GI = Gastrointestinal / URO = Urology

Differentiated, Non-Thermal Mode Of Action

Step 1 | Image guided illumination of circulating TOOKAD®/SA generates oxygen radicals

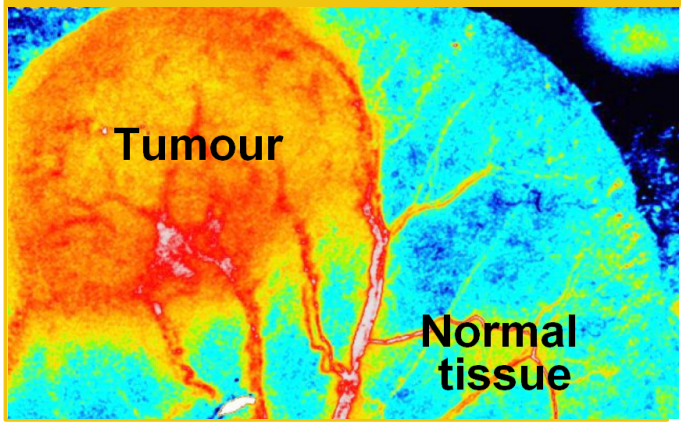


Step 3 | Self-propagating coagulative necrosis starting from vessels results in complete tumour ablation

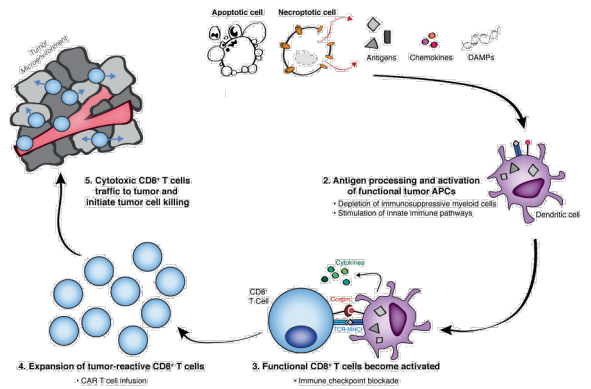


1 2 3 4

Step 2 | The oxygen radicals generated initiate rapid vascular occlusion of the tumour



Step 4 | Cell necrosis in TOOKAD® VTP triggers local inflammation and anti-tumour immunity



Sources: 1) Madar-Balakirski, N. *et al. PLoS One* (2010) 2) Taneja, S. S. *Physiol. Beha. J Urol.vior* (2016) 3) Kimm, S. Y. *et al. Radiology* (2016). 4) Neuschmelting, V. et al. Theranostics (2018). 5) Ashur et al, *J. Phys. Chem A* 2009; Oles et al (2018)

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Beginning Surely
TOOKAD® for Localized Prostate Cancer

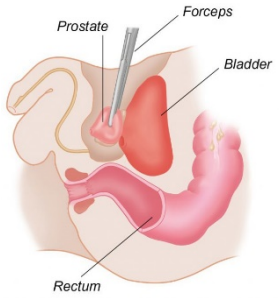
1

Filling a Major Unmet Need in Localized-Prostate Cancer

~1.1MM/Year Newly Diagnosed Localized Prostate Cancer Patients WW[1]

21%[2] | **25%[2]** | **23%[2]** | 17%[2] | 14%[2]

Very Low | **Low** | **Favorable Intermediate Risk** | **Unfavourable Intermediate Risk** | **High**



Active Surveillance (AS)
- High patient anxiety and chance of progression to metastatic stage ✗

TOOKAD®
- Minimally invasive tumour eradication with only transient toxicities ✓

Radical Prostatectomy (RP)
- High rates of erectile dysfunction and urinary incontinence ✗

1) GlobalData; localized prostate cancer accounts for 90-95% of all new prostate cancer cases 2) Percentages based on proprietary US market research including 100 high prescribing urologists 3) TOOKAD has been approved by the EMA for the treatment of low risk localized prostate cancer and is currently under FDA review for low and favorable intermediate risk localized prostate cancer

Highly Credentialed Profile with Game Changing Efficacy

Highly Credentialed Profile to Support Launch

2-years results[1]

THE LANCET Oncology

4-years results[2,3]

of THE JOURNAL UROLOGY®

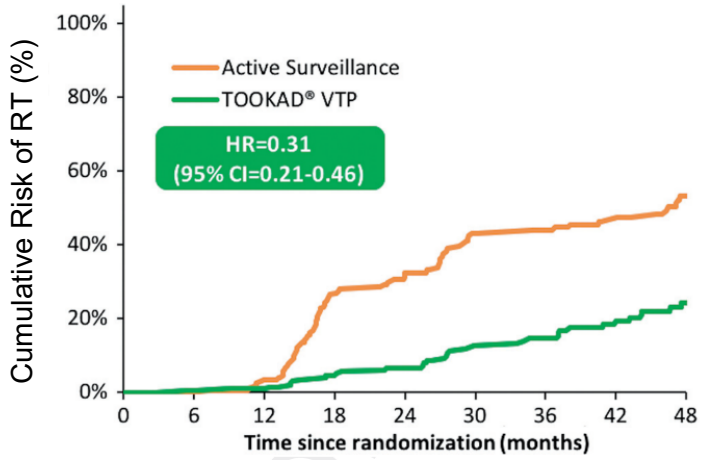
5-years results

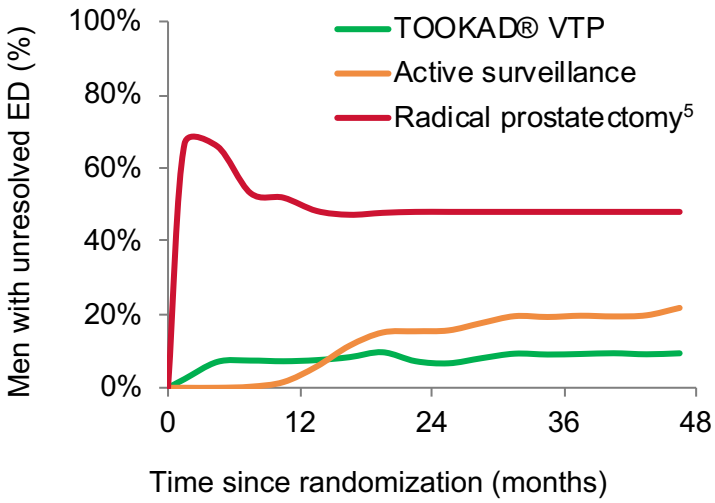
Under publication

TOOKAD® 4 Years Clinical Results vs Active Surveillance[2,3]

Lower Overall Progression Rates	HR 0.35 (95%CI = 0.25-0.48)[2]
Lower Conversion to Radical Therapy	~50% avoided at 4 years vs. AS[2]
Less Erectile Dysfunction	37% reduction over 4 years vs. AS[3]
Less Urinary Incontinence	64% reduction over 4 years vs. AS[3]
No Loss of Options	Salvage therapy still possible[4]

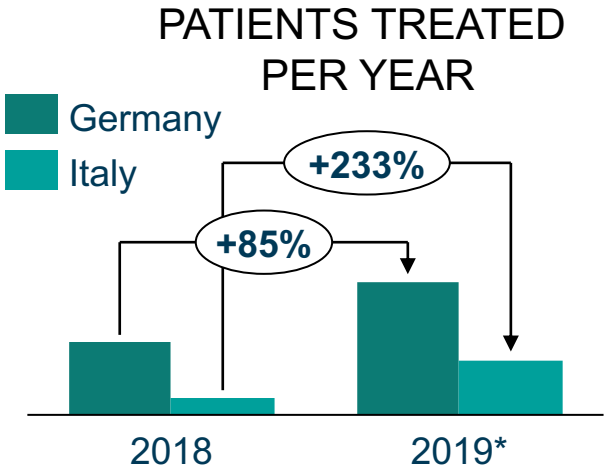
Long-Term Clinical Benefit (4 Years Follow-Up)[2,3]





Sources: 1) Azzouzi, A. R. *et al. Lancet Oncol.* (2017) 2) Gill, I. S. *et al. J. Urol.* (2018) 3) EMA European Public Assessment Report for TOOKAD (padeliporfin) – Sept 2017 4) Pierrard, V *et al. J. Urol.* (2018) 5) Donovan, J. L. *et al. NEJM* (2016)
ED = Erectile Dysfunction, UI = Urinary Incontinence

EU Launch is Ready for Scale-Up



*"**Finally, there is an approved therapy that I can offer my patients instead of just actively monitoring**. Most of my patients prefer a therapy with less side effects to Active Surveillance."*

*"My patients are extremely satisfied and tell me of a very good quality of life after therapy. They say **life goes on as if there hadn't been cancer**"*

*~50% of procedures for of procedures until 2019 are scheduled but still need to be conducted

Prominent Supporters Around the Globe

Inderbir Singh Gill, USC

Peter T. Scardino, MSKCC

Freddie Hamdy, Oxford

Jonathan A. Coleman, MSKCC

David Paul Kelsen, MSKCC

Francesco Montorsi, UniSR

Hans Gerdes, MSKCC

Manfred Wirth, TU Dresden

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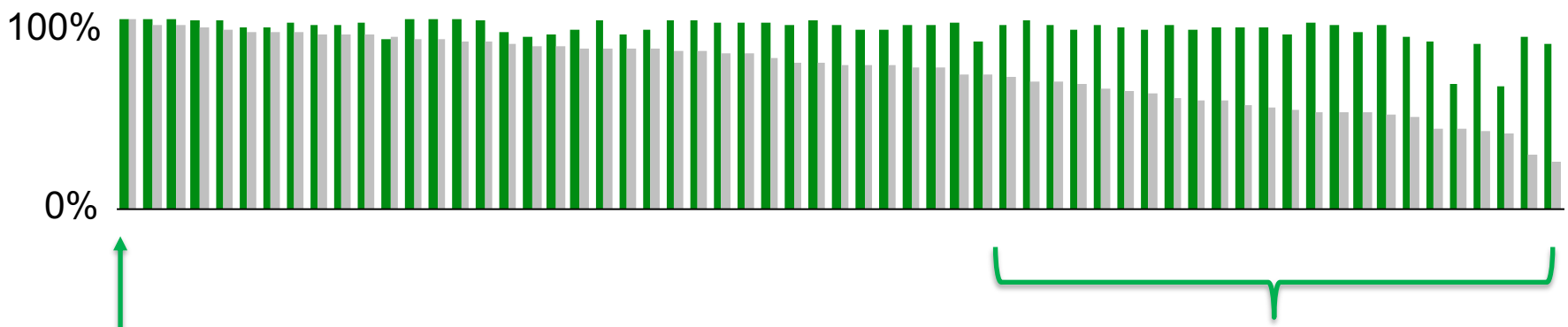
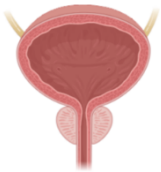
Growing **Boldly**
Revolutionizing Localized Cancer Care

2

Potential for Survival Impact to Guide Bold Development

5y-OS for different localized tumors depending on surgery[1]





Localized Prostate Cancer EMA approved under FDA review. Proofs eradication of tumour at favorable safety

GI and Uro indication with high unmet for surgery ineligible patients
-> *Big impact, fast development*

FDA Accelerated Approval

"instead of having to wait to learn if a drug actually extends survival for cancer patients, the FDA may approve a drug based on evidence that the drug shrinks tumors, because tumor shrinkage is considered reasonably likely to predict a real clinical benefit"

Sources: 1) SEER Stats (Surveillance, Epidemiology and End Results Program) analysis based on 3 million tumor records between 2000 – 2016

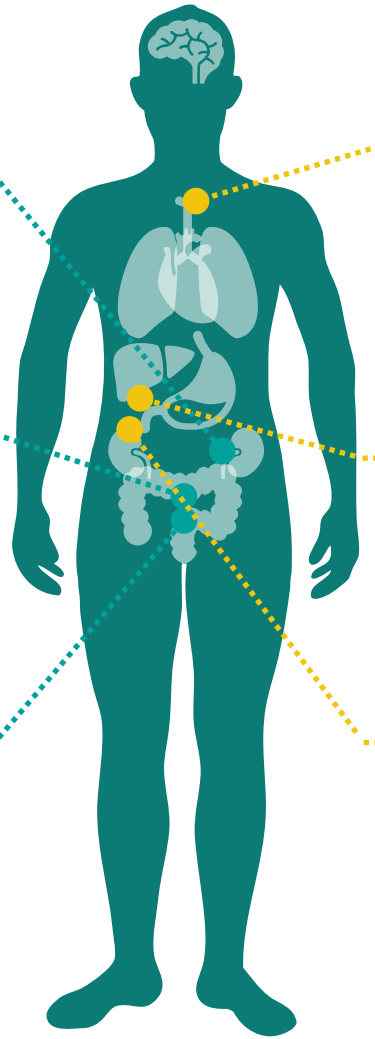
Fast Execution supported by Franchise Model

Uro-Oncology Franchise

Urinary Tract
- UTUC endoscope Tx r/r or ineligible for surgery (I)

Bladder Cancer
- high-risk NMIBC r/r to BCG (PC)

Prostate Cancer
- LR L-PCa (M)
- FIR L-PCa (Reg)
- UIR L-PCa (III)
- Salvage post-RT L-PCa (III)
- HR L- PCa (PhI combo ready)



GI-oncology Franchise

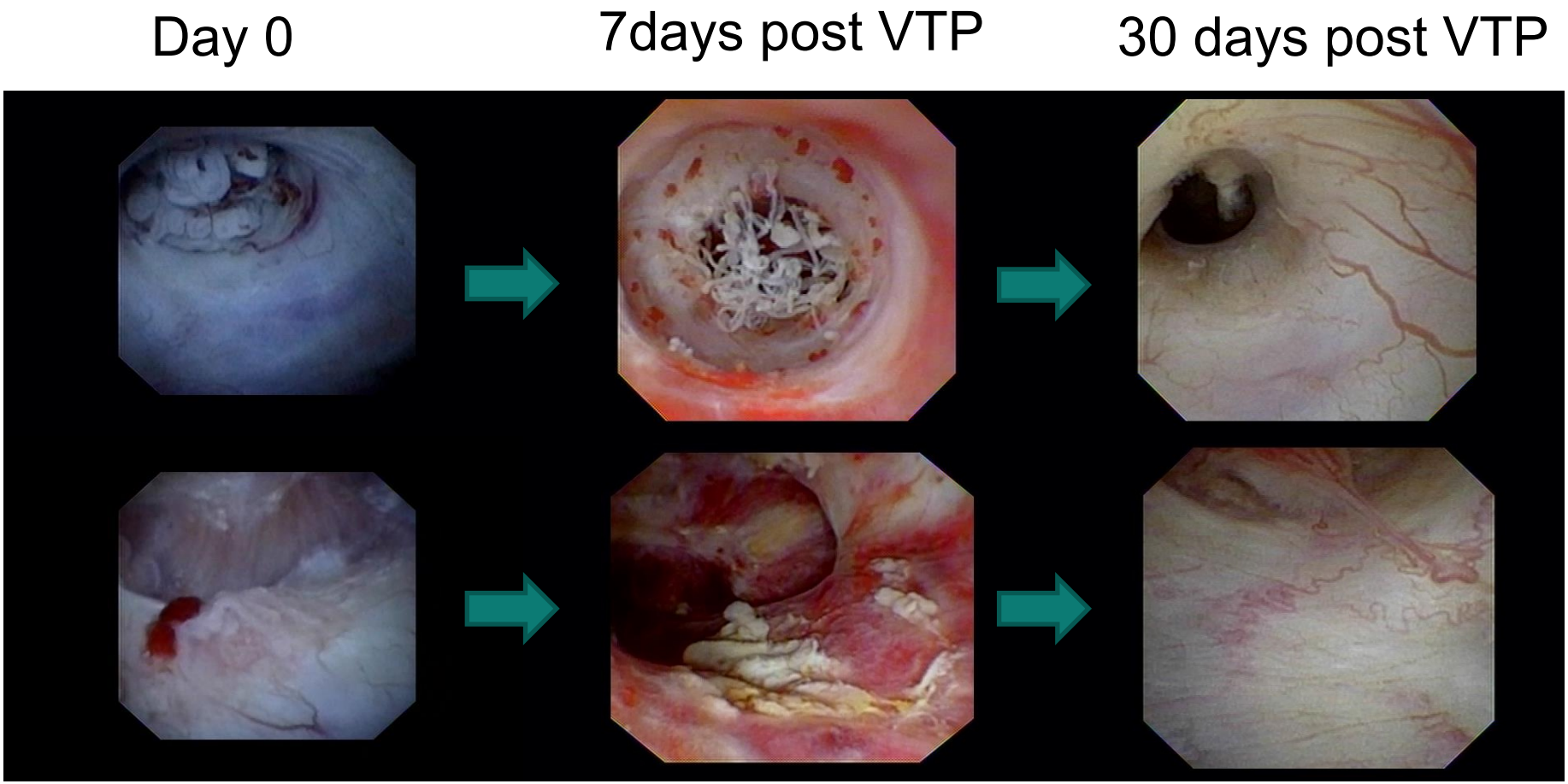
Esophageal Cancer
- Palliation [w/ dysphagia] (I)
- Treatment Stage III ineligible for surgery RT (I)

Cholangiocarcinoma
- Inoperable Stage I-III (II)

Pancreatic Cancer
- Inoperable Stage I-III PanC (PC)

L-Pca = Localized Prostate Cancer, UIR = unfavorable intermediate risk, FIR = favorable intermediate risk
PC = Preclinical, RT = Radiotherapy

First and Exceptional PoC in Upper Urinary Tract Cancer



High rate of durable responses in the first nine treated patients[1]

1) NCT03617003 , *data on file*

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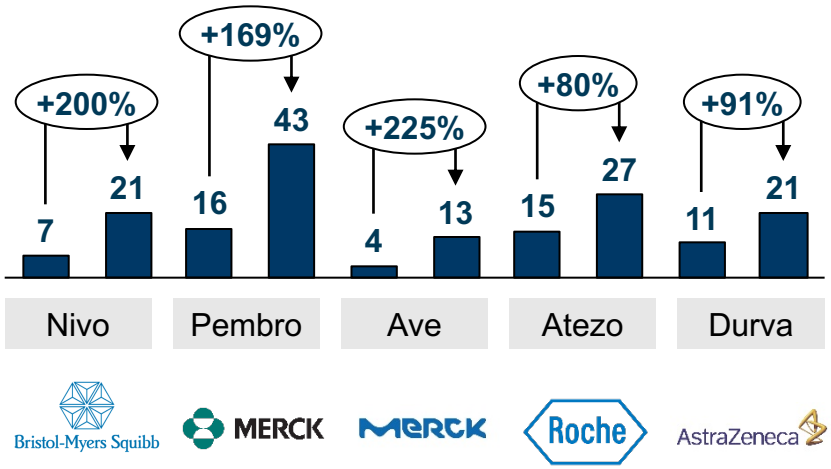
Expanding Widely
A novel Foundation for Immuno-Oncology

3

Replacing Chemo as IO-Partner in Metastatic Settings

CTx Combo trial 2017 – 2018[1]



But

- Efficacy often limited by the tolerability of the combination
- Chemotherapy results in systemic immune suppression which could potentially have negative effects the efficacy of IO agents

	Chemo-Therapy	TOOKAD®
Cell death	Apoptopic	Necrotic
Antigen release	↑/↑↑	↑↑↑
Neoantigen priming	↑/↑↑	↑↑↑
Systemic Tox	↑↑↑	*None*
Systemic Immune-suppression	↑↑↑	*None*

Potentially safer and more potent than chemotherapy

Sources: 1) Analysis based on CT.gov

Extensive Preclinical Program Supports Rationale

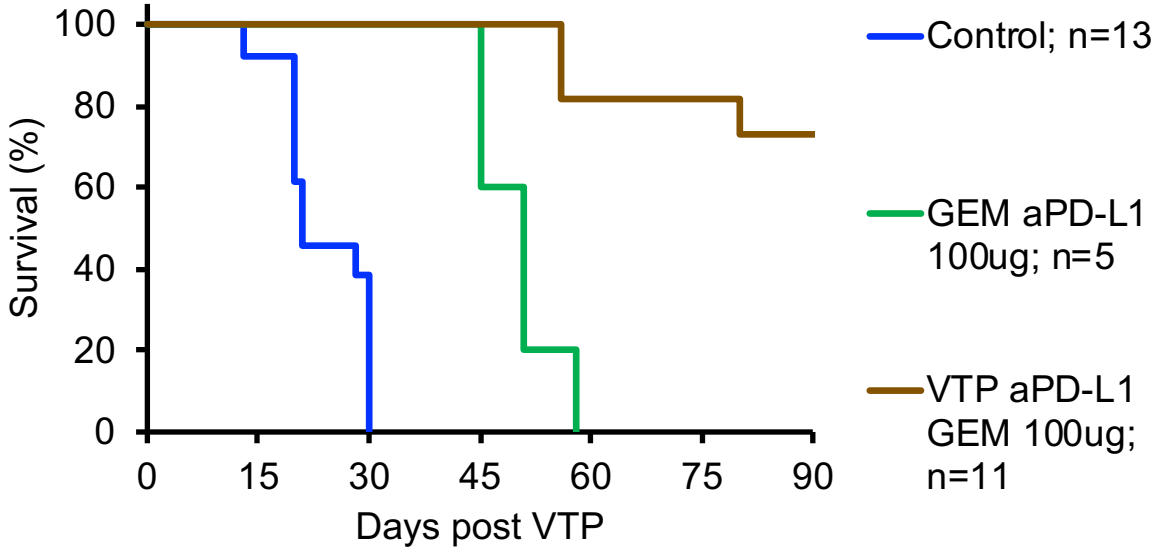
מכון ויצמן למדע
WEIZMANN INSTITUTE OF SCIENCE

1884
Memorial Sloan Kettering Cancer Center™

CSH
Cold Spring Harbor Laboratory

Synergistic effects of TOOKAD + PD-L1 inhibitor in orthotopic TNBC model

More and deeper responses



Extensive Preclinical Immuno-Oncology Program[1-10]

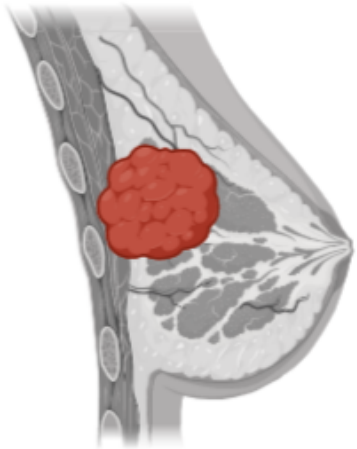
- Pronounced pro-inflammatory modulation of the tumour microenvironment
- Upregulation of checkpoints on tumour cells and immune cells
- Synergistic combination effects with checkpoint inhibitors in multiple preclinical orthotopic tumour models

Sources: 1) Lebdai S. et al, *Potentiating vascular-targeted Photodynamic therapy through CSF-1R modulation of myeloid cells in a preclinical model of prostate cancer*, 2019, Oncoimmunology, In the press 2) R. Coradi et al, *Effectiveness of the combination of vascular targeted photodynamic therapy and anti-cytotoxic T-lymphocyte-associated antigen 4 in a preclinical mouse model of urothelial carcinoma*, 2019, Int. J. Urol, 26, 414-422 3) Kim, K. et al, *Androgen deprivation therapy potentiates the eficacy of vascular targeted photodynamic therapy of prostate cancer xenografts*, Clin Cancer Res. 2018, 24, 2408-2416 4) O'Shaughnessy, M.J. et al, *Systemic antitumor immunity by PD-1/PD-L1 inhibition is potentiated by vascular-targeted photodynamic therapy of primary tumors*. Clin. Can. Res., 2018, 24(3), 522-529 5) Kim, K., et al., *Bombesin Antagonist Based Radiotherapy of Prostate Cancer Combined with WST-11 Vascular Targeted Photodynamic Therapy* (2017) Clin. Can. Res, 23, 3343-3351 6) Agemy, L., et al, *Enhancing antitumor immunity by photodynamic therapy with gemcitabine in metastatic 4T1 breast tumor*. Ann. of Oncol., 27 Suppl 9, Abst 401P 7) Murray, K.S., et al, *Treatment effects of WST11 vascular targeted photodynamic therapy for urothelial cell carcinoma in swine*. J. Urol., 2016. 196(1): p. 236-243. 8) Uzana R. et al, *Palliative treatment of obstructive esophageal cancer by vascular targeted photodynamic therapy (VTP): Preclinical study in orthotopic rat model*., J. Clin. Oncol. 2016, 34, Suppl S, Abst 59 9) Preise, D., Scherz, A. and Salomon, Y., *Antitumor immunity promoted by vascular occluding therapy: Lessons from vascular-targeted photodynamic therapy (VTP)*. Photochem. & Photobiol. Sci., 2011. 10(5): p. 681-688. 10) Preise, D. et al, *Systemic antitumor protection by vascular-targeted photodynamic therapy involves cellular and humoral immunity. Cancer Immunology Immunotherapy*, 2009. 58(1): p. 71-84.

TNBC PD-[L]1 Combo Trial Ready to Start Mid-2020

Memorial Sloan Kettering Cancer Center

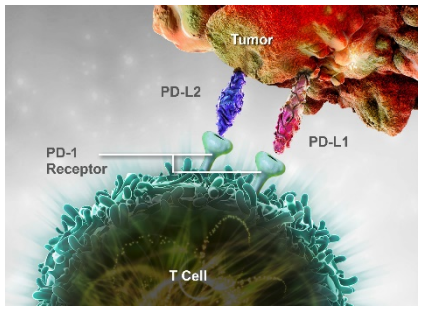
A Pilot Study to Assess the Feasibility and Safety of TOOKAD in Combination with a PD-[L]1 Inhibitor and Single-dose Cyclophosphamide[1] in HER2 negative[2] and (plus trastuzumab) in HER2 positive Metastatic Breast Cancer



HER2+ (n=10)

HER2- (n=10)

- If ≥16/20 pts complete the study -> **Feasible**
- If ≥7/10 pts/arm no gr3/4 tox -> **Safe**
- Secondary endpoints: ORR/ irIRR/ PFS; detailed immune profiling -> **Effective**

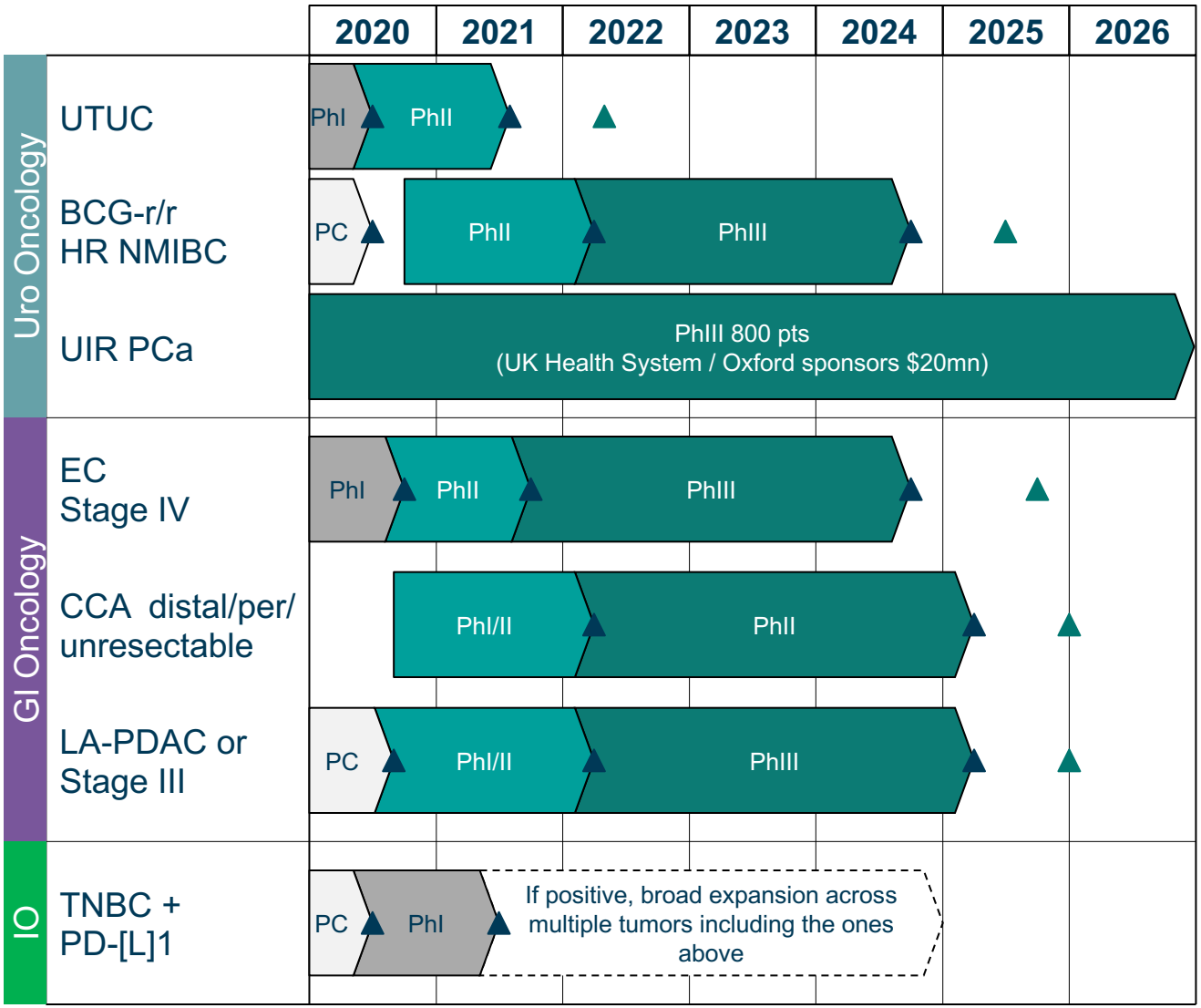


Co-Principal

- Jonathan Coleman, MD
- Amy Deipolyi, MD/PhD

1) Metronomic dose with the aim to break down the tumour stroma but not for anti-tumour efficacy
2) Includes TNBC patients

Multiple Near-Term Catalysts Support Continuous Growth



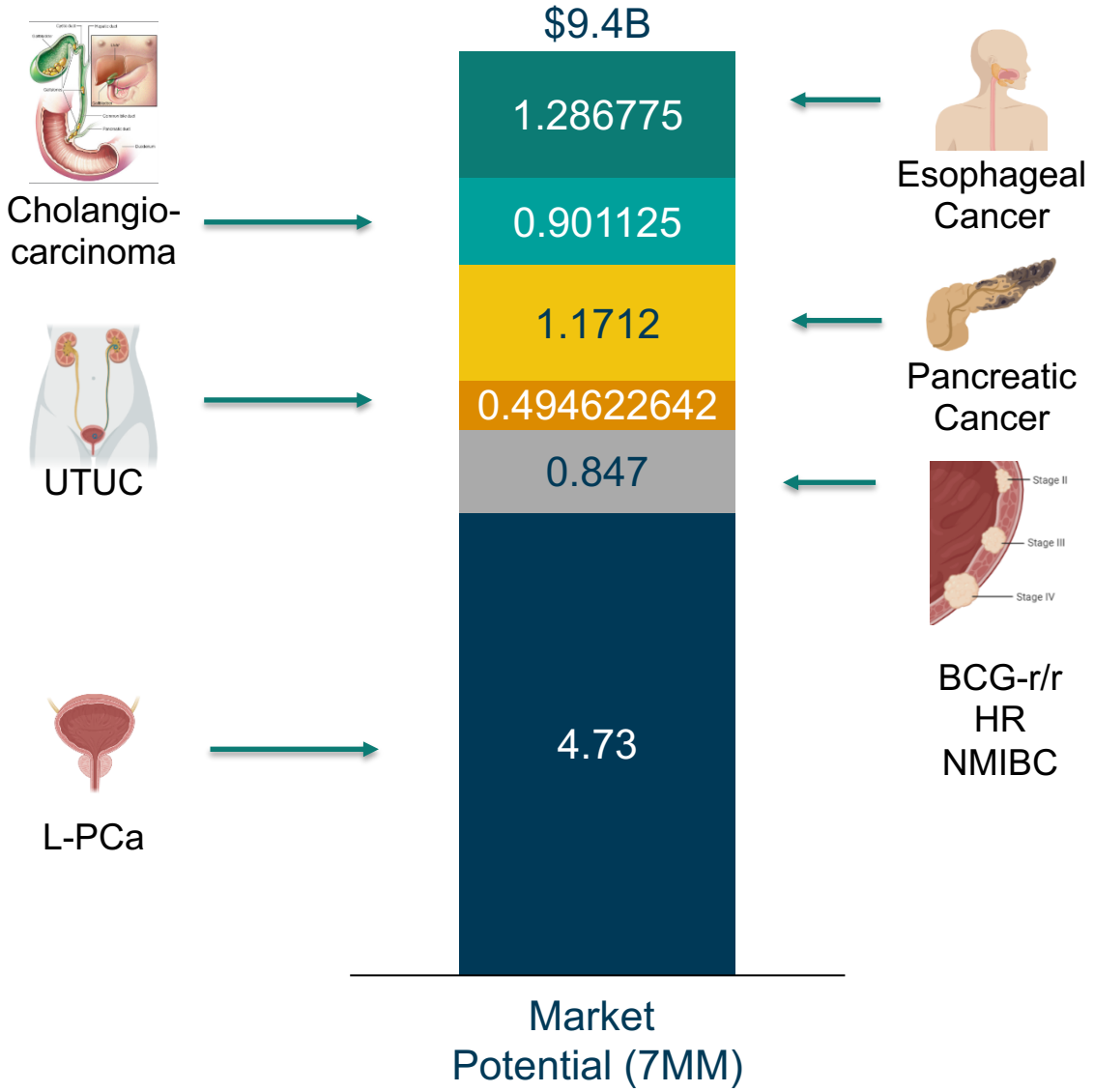
Milestones 1H 2020

- Additional PhI Data
  - UTUC
  - Esophageal C.
- Preclinical Data
  - NMIBC
  - PDAC
- Initiation of TNBC Pilot trial in combo with PD-[L]1

▲ Data readouts
▲ Reg Approval based on PhIII

Preclinical (PC) | PhI | PhII | PhIII

Market Potential of >$9B in Localized Disease (7MM)



Market potentials were calculated based on the 7MM newly diagnosed patients with localized, non-metastatic disease (GlobalData), which are not eligible for surgery (SEER Stats database). Assumed prices range between $22k and $57k per patient depending on the potential clinical benefit TOOKAD could bring in the respective indications (5yOS with surgery vs without surgery; value-based pricing)

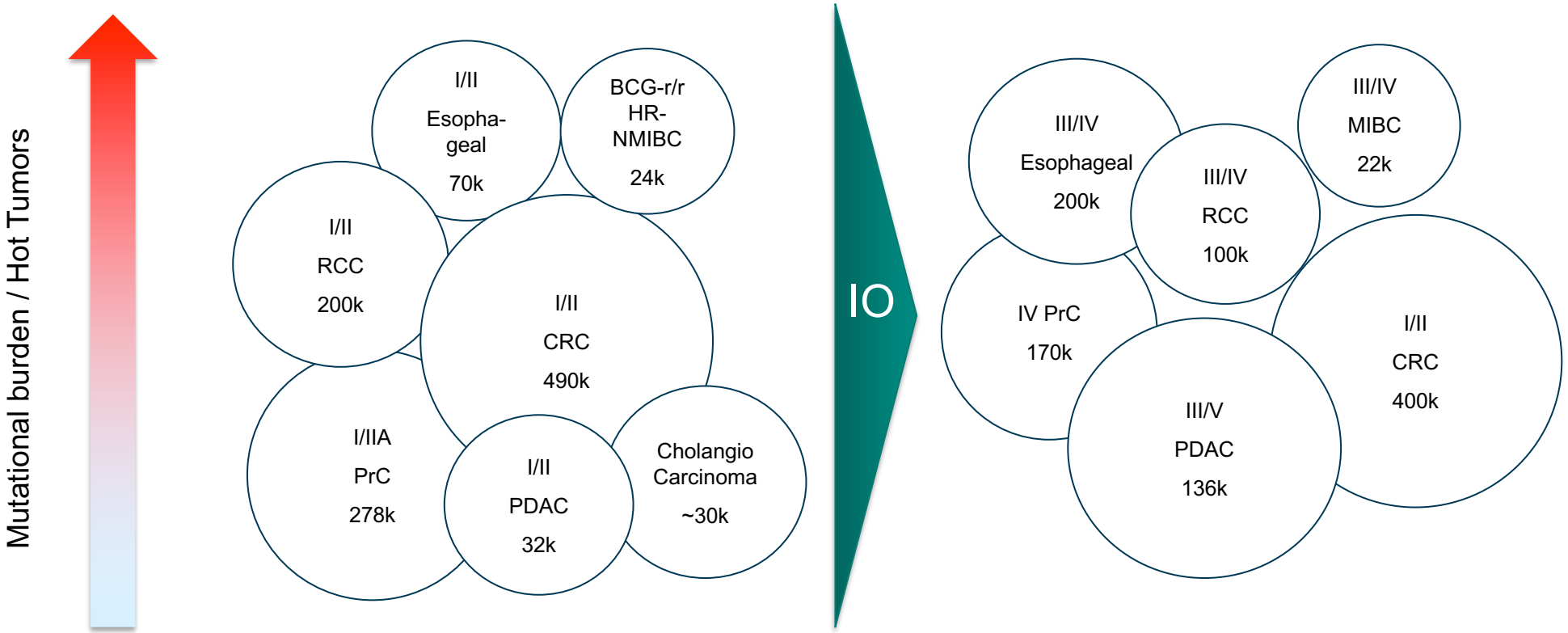
Market Potential Reaches ~$18B including IO

Grow (~1.1 million pts/y; 7MM)

Single-agent in localized settings

Expand (~1.0 million pts/y; 7MM)

IO combo in metastatic setting



7MM annual incidence 2024; Source: GlobalData

Backed by a Broad Network of High-Profile Institutions

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WEIZMANN INSTITUTE OF SCIENCE

Memorial Sloan Kettering Cancer Center

USC University of Southern California

UNIVERSITY OF OXFORD

CSH
Cold Spring Harbor Laboratory

JOHNS HOPKINS
SCHOOL of MEDICINE

FOX CHASE CANCER CENTER
TEMPLE HEALTH

VANDERBILT UNIVERSITY