

Økonomisk Ugebrev

21st of April 2021

Henrik Winther, SVP BD



Unmet needs in Metastatic Breast Cancer

From a treatment perspective:

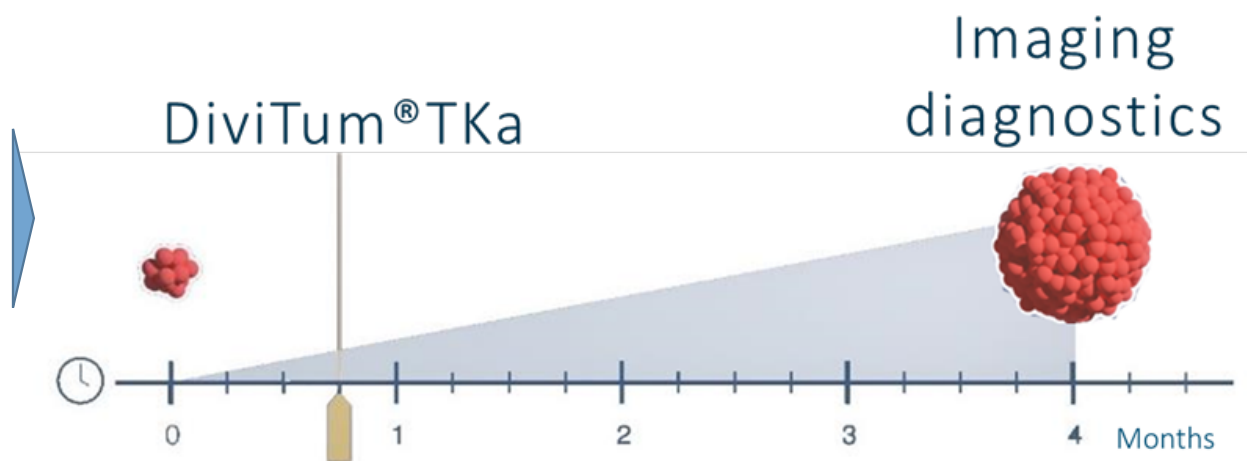
- Efficient tool to allow for faster and better treatment (Tx)
– incl. tool to ID Tx-resistance as early as possible
- Tool to allow for confidence in choosing the right treatment / avoiding futile therapy

From a monitoring perspective:

- Avoidance of invasive and radiation-based tests
- Reduction in number and costs of diagnostic tests



DiviTum[®]TKa provides easy, early and safe response to whether or not the patient's cancer treatment is effective








DiviTum[®]TKa measures cell proliferation rate in a blood sample for faster evaluation of cancer treatment effects

References: See <http://biovica.com/technology/publications/>

Very strong clinical results and data for DiviTum®TKa peer-reviewed & published in clinical oncology journals

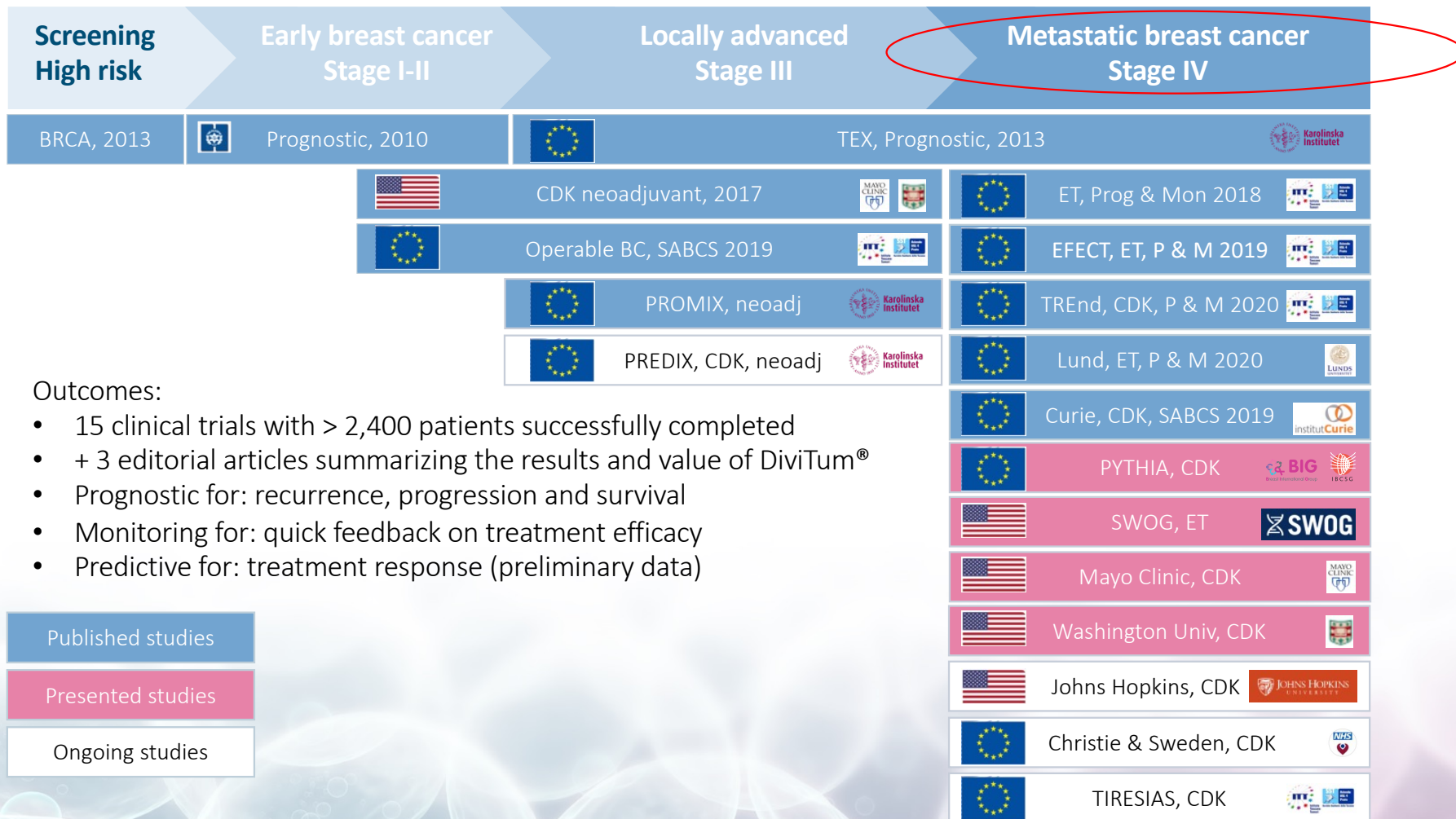
- 24 published and peer-reviewed articles with DiviTum®TKa
- Summary of results from articles:
 - Prognostic: risk for cancer recurrence, progression & survival
 - Monitoring: quick feedback on treatment efficacy

Cancer area	Patients	No of Studies
 Breast Cancer	1,293	13
 Gastrointestinal	713	4
 Lung Cancer	281	2
 Blood Cancer	440	4
 Other	368	1
	3,095	24



Summary of clinical results available at biovica.com.

DiviTum®TKa – Extensive breast cancer study program



Outcomes:

- 15 clinical trials with > 2,400 patients successfully completed
- + 3 editorial articles summarizing the results and value of DiviTum®
- Prognostic for: recurrence, progression and survival
- Monitoring for: quick feedback on treatment efficacy
- Predictive for: treatment response (preliminary data)

Published studies

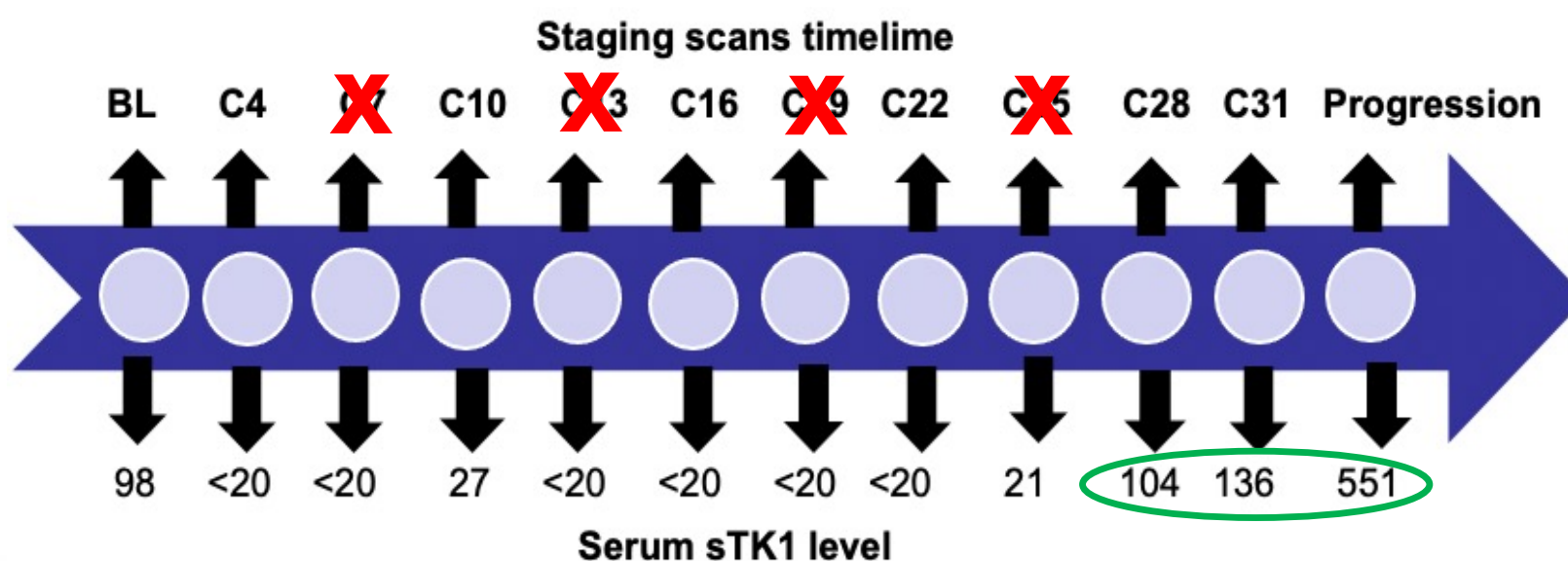
Presented studies

Ongoing studies

SABCS 2020 DiviTum®TKa studies, conclusions, and the fit to clinical needs & clinical utility

STUDY / COLLABORATOR	CONCLUSION	TKa CLINICAL UTILITY
S0226 / SWOG	<ul style="list-style-type: none"> TKa PROGNOSTIC for PFS/OS in mBC TKa PREDICTIVE for treatment (Tx) in mBC TKa strong MONITOR of mBC during Tx 	<ul style="list-style-type: none"> Strong liquid* biomarker to monitor mBC during endocrine Tx Treatment prediction <p>* Avoid invasive- & radiation-based tests</p>
PALBO-DOSING /WASH.U.	<ul style="list-style-type: none"> TKa strong MONITOR of CDK 4/6 Tx in mBC TKa detects cancer progression 3 mths earlier than imaging during CDK 4/6 Tx in mBC 	<ul style="list-style-type: none"> Confidence in right Tx Reduction in diagnostic (imaging) testing
PYTHIA / BIG & IBCSG (Prospective)	<ul style="list-style-type: none"> TKa is an early and strong PREDICTOR of CDK 4/6 Tx 	<ul style="list-style-type: none"> Avoidance of CDK 4/6 futile therapy Faster and better Tx

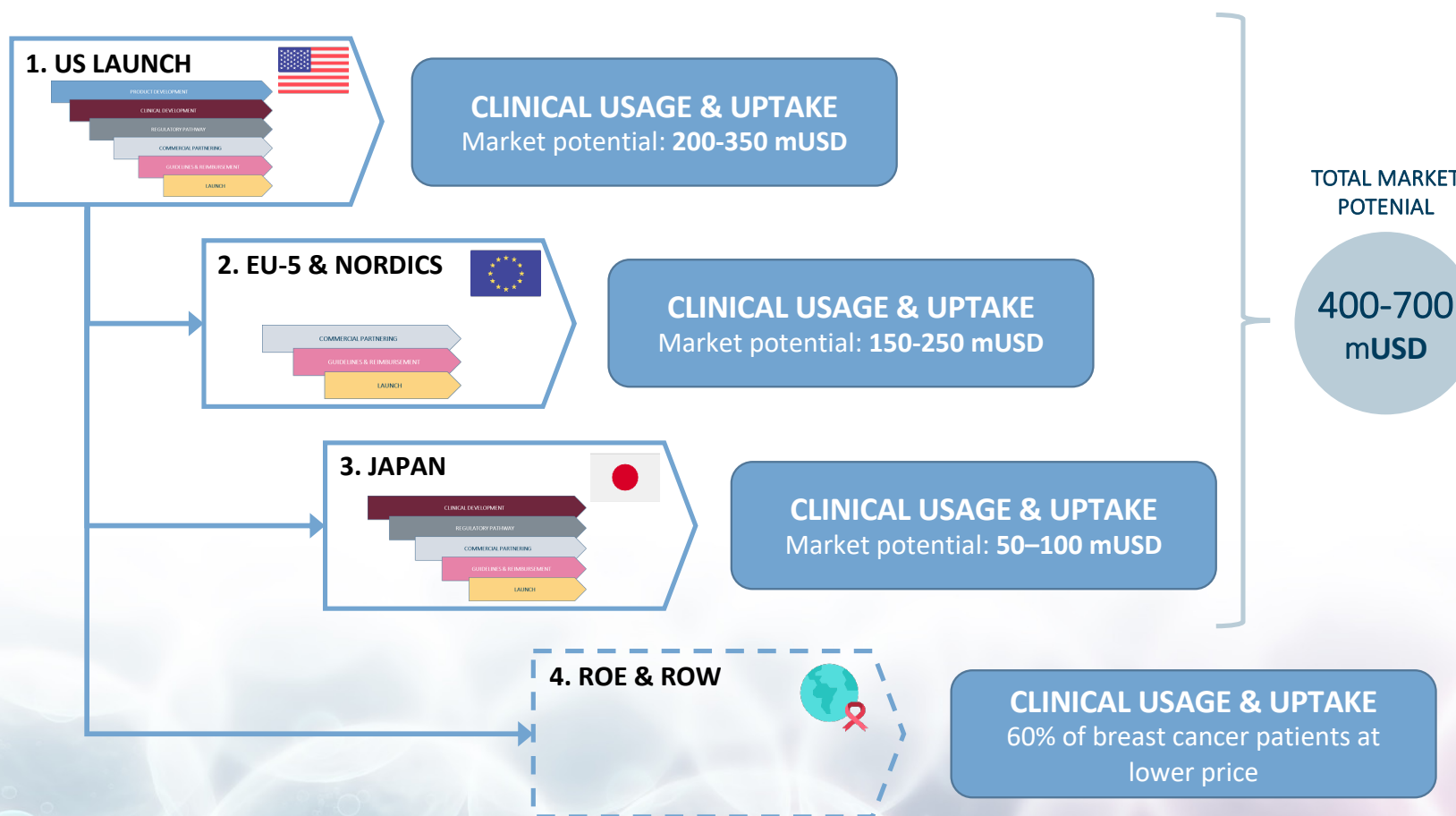
Results and consequences of the Wash. U. study - imaging scan reduction and replacement with DiviTum®TKa



From: Wash U poster, SABCS 2020

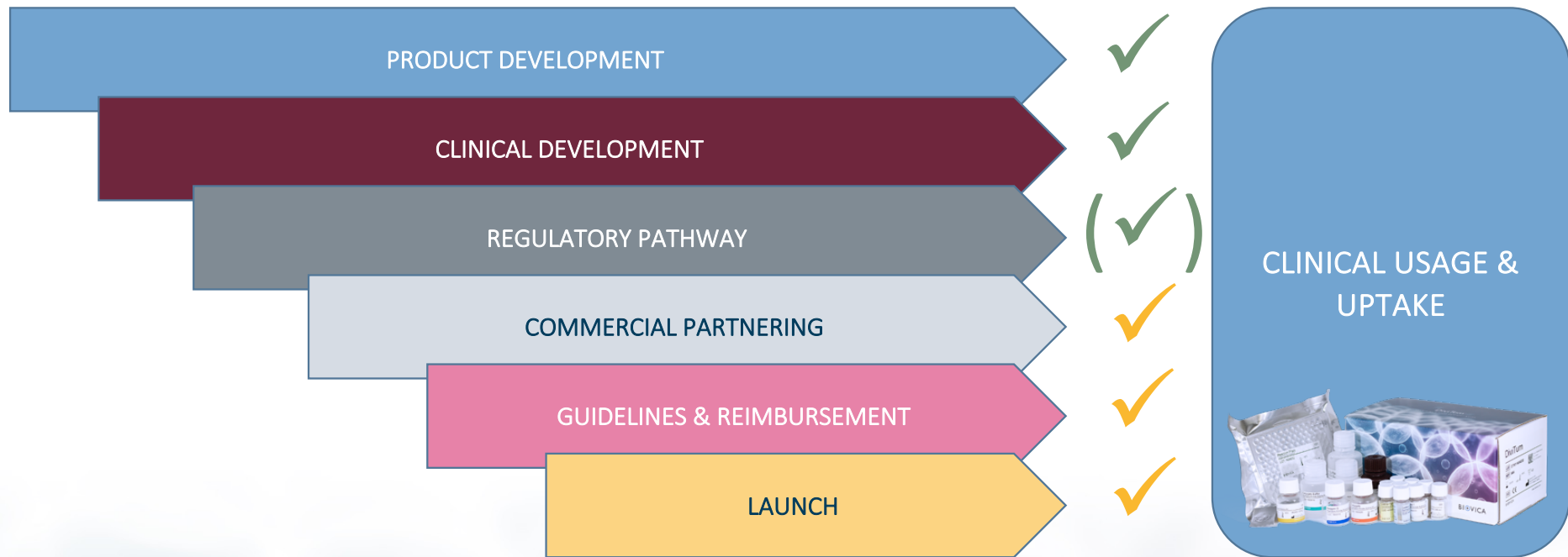
In patients with persistently low TKa values, DiviTum®TKa may offer the opportunity to reduce imaging scan frequency

Market potential & geographical roll-out plan for DiviTum®TKa in metastatic breast cancer



Source: (1) Globocan 2018 and Biovica Market Research

DiviTum[®]TKa – US commercialization activities & status



- ✓ Completed
- ✓ Running full speed
- ✓ To be initiated

FDA resumed its review of the 510(k) application

Day 1: FDA receives 510(k) submission.

By Day 7

FDA sends **Acknowledgement Letter**.
OR
FDA sends **Hold Letter** if unresolved issues with User Fee and/or eCopy.

By Day 15

FDA conducts **Acceptance Review**.
FDA informs submitter if 510(k) is accepted for **Substantive Review** or placed on **RTA Hold**.

By Day 60

FDA conducts **Substantive Review**.
FDA communicates via a **Substantive Interaction** to inform the submitter that the FDA will either proceed with **Interactive Review** or that the 510(k) will be placed on hold and **Additional Information** is required.

By Day 90

FDA sends final **MDUFA Decision** on 510(k).

By Day 100

If MDUFA Decision is not reached by Day 100, FDA provides **Missed MDUFA Decision Communication** that identifies outstanding review issues.

25th Sep: 510(k) application submitted to the FDA
Lead reviewer assigned

30th Oct: FDA announces 90 day-pause due to resource allocation
Lead reviewer reallocated to review of Covid-related EUA

13th Nov: Substantive Review status received from the FDA

29th Jan: FDA resumes review of DiviTum®Tka 510(k)-application
Lead reviewer re-assigned

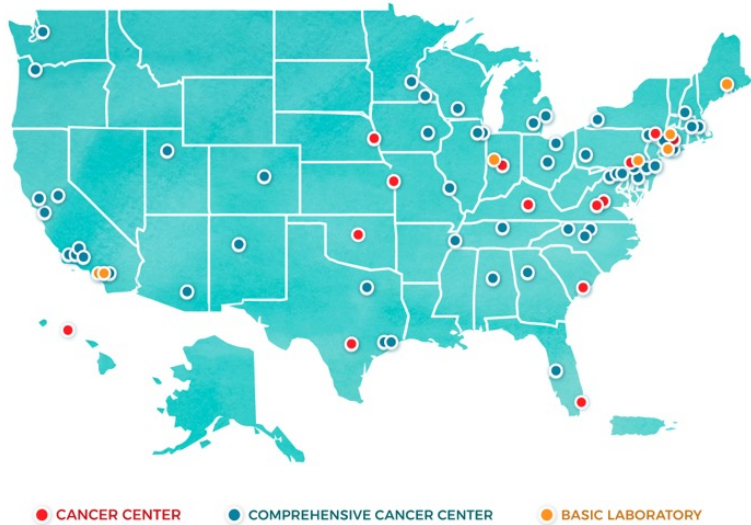
Note: FDA doesn't commit their standard 510(k)-timeline

Status: FDA review is ongoing – Biovica expects decision before end of Q3

Source: <https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process#timeline>

Focus on key cancer centers, reference labs, IDNs & payers

71 NCI-designated cancer centers



Major reference laboratories

Company	# of labs	Oncology labs
LabCorp	31	2
Quest Diagnostics	32	5
SONIC HEALTHCARE USA	11	2
BioReference LABORATORIES <small>an OPKO Health Company</small>	16	1
MAYO CLINIC LABORATORIES	2	2
ARUP LABORATORIES	1	1
NEO GENOMICS	8	8
Cleveland Clinic Laboratories	1	1

IDNs/Payers



These will be customers and at the same time, partners

Key Opinion Leader Collaborators

– key success factor for clinical acceptance/guidelines/reimbursement



Matthew P. Goetz
M.D.
Mayo Clinic



Daniel F. Hayes
M.D, Professor
University of Michigan
Ex. ASCO President
SWOG Transl. Med.



Vered Stearns
M.D & Professor
Johns Hopkins



Geoffrey Shapiro
M.D, Ph.D
Dana Farber



Matthew J. Ellis
M.D, Professor
Baylor Collage



William Gradishar
M.D, Professor
Northwestern Med.



Richard Finn
M.D, Ass. Professor
UCLA



Cynthia X. Ma
M.D, Professor
Washington University



Angelo Di Leo
M.D, Ph.D
Hospital of Prato
IBCSG Exec. Committee
BIG against BC Exec Board
ESMO Lifetime Achievement



Martine J. Piccart
M.D, Professor
Université Libre de Bruxelles
Founder Big against BC
Ex. ESMO President



Jonas Bergh
M.D, Professor
Karolinska Institutet
ESMO BC Award
Ex Chairman SweBCG
EMA Advisory Group
Member Nobel Assembly



Luca Malorni
M.D, Ass. Professor
Hospital of Prato
Baylor Collage



Thomas Hatschek
M.D, PhD
Karolinska Institutet



Samuel Rotstein
M.D, PhD
Karolinska Sjukhuset

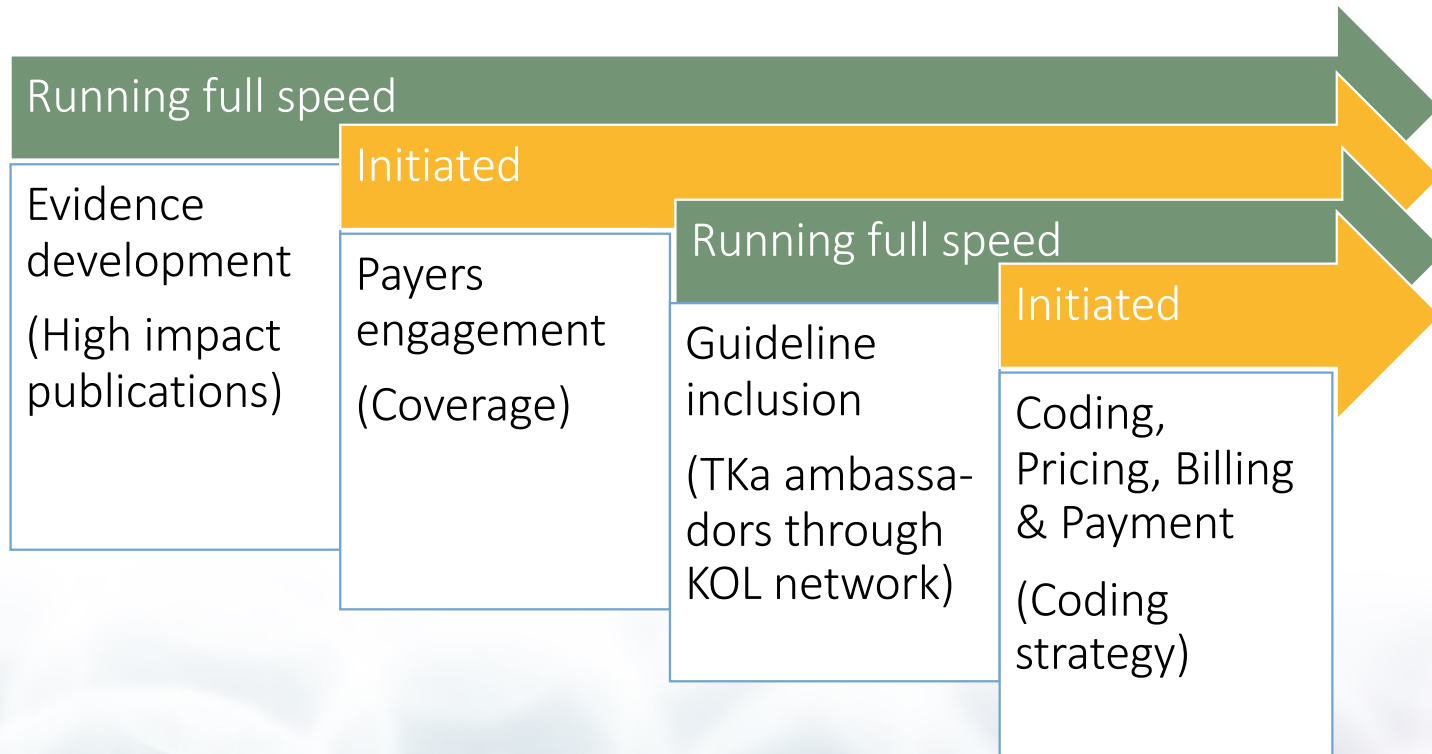


Henrik Lindman
M.D, Ass. Professor
Uppsala Universitet
Vice Chairman SweBCG



Sacha Howell
M.D, PhD
Senior Lecturer and Honorary
Consultant in Medical Oncology
The Christie NHS Foundation Trust

US product reimbursement process in execution

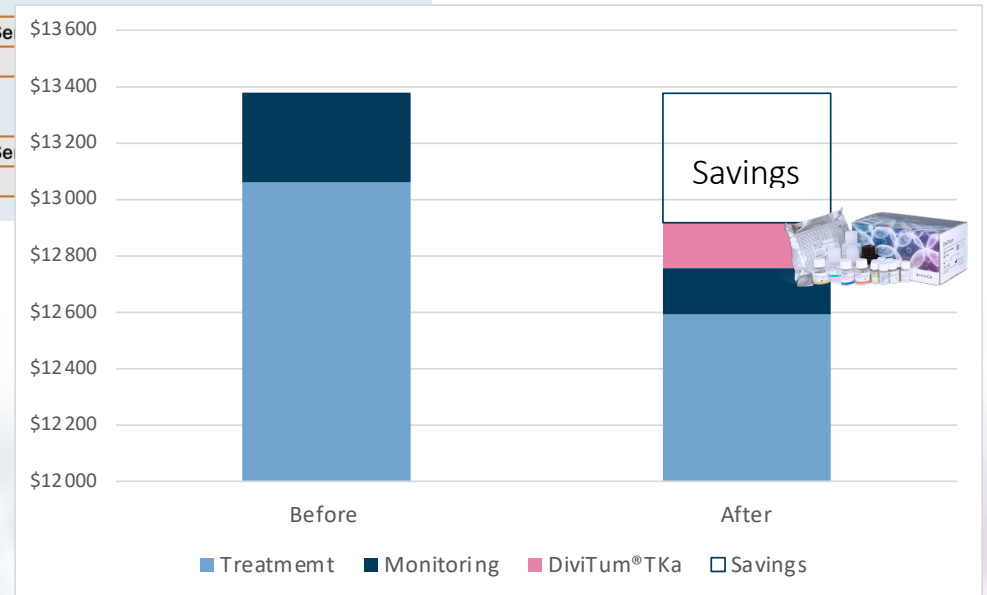


DiviTum®TKa budget impact model

– adding DiviTum®TKa saves up to three times the investment

Parameters of Interest							
Monitoring Frequencies	DiviTum® Testing	< CT Scans >		< Bone Scans >		< Biomarkers >	
		Pre-DiviTum®	Post-DiviTum®	Pre-DiviTum®	Post-DiviTum®	Pre-DiviTum®	Post-DiviTum®
Monitoring Technology On/Off	On	On	On	On	On	On	On
Time Until First Follow-Up	2 weeks	12 weeks	12 weeks	12 weeks	12 weeks	4 weeks	4 weeks
Subsequent Follow-Up Period 1 <i>Interval Unit</i>	Monthly	Quarterly	Semi-Annually	Quarterly	Se		
<i># Follow-Ups for Subs Period 1</i>	6	2	1	2			
Subsequent Follow-Up Period 2 <i>Interval Unit</i>	Quarterly	Quarterly	Semi-Annually	Quarterly	Se		
<i># Follow-Ups for Subs Period 2</i>	6	6	3	6			

- Model designed for a payer managing 1M lives
- User dials in their own test utilization (and test costs)
- DiviTum®TKa modelled at 300-500 \$/test
- Reduction in CT scans and bone scans and futile therapy
- Results: DiviTum®TKa savings, ~3 times the investment



Large potential to expand outside initial markets & applications!

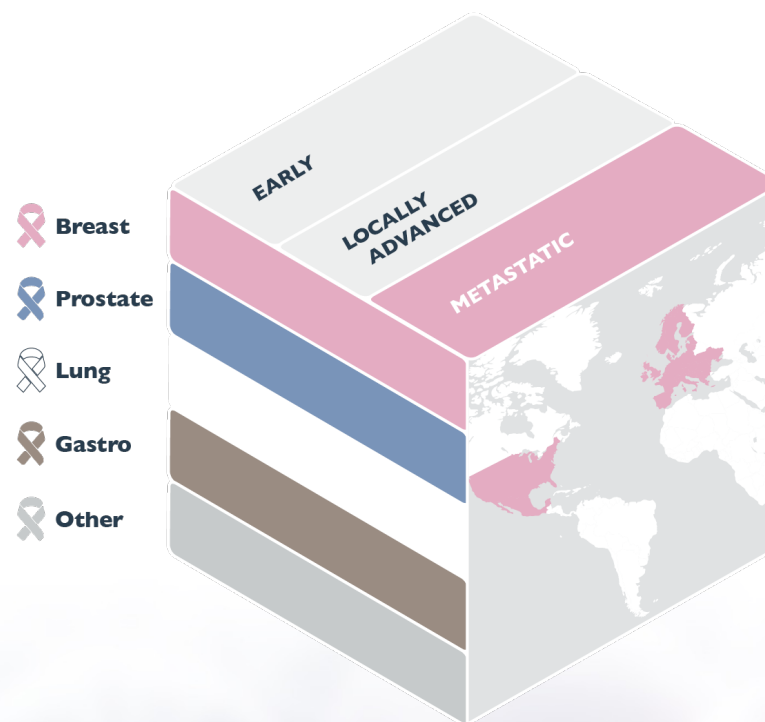
Near term market expansion:

- Geographic expansion MBC Europe and Japan
- Locally advanced breast cancer, which adds an additional 30-40% potential on existing markets

Medium term expansion:

- Lung cancer
- Gastrointestinal cancer
- Prostate cancer

Near term/ongoing: Pharma Collaborations - including early and late (CDx) stage drug development



Initial application addresses 1% of people living with cancer!

*) Based on Globocan 2018-data

Summary

- DiviTum®TKa addresses key unmet needs for personalized treatments within metastatic cancer
- Immediate potential of \$ 400-700 M for initial roll-out (MBC in US, Euro-5, Nordics & Japan)
- Strong scientific collaborations and evidence as strong foundation for commercialization process
- Significant potential beyond initial roll-out (30-40% expansion with locally advanced BC)

Upcoming milestones:

- 510(k) approval & US launch (Q3 2021)
- 1st US product reimbursement (2021)
- 1st Euro-5 & Nordic launch by end of 2021

More info: <http://biovica.com/investor-relations/analytiker/>

