Biovica Capital Market Day

11th of May 2020

14:00-16:00 CET

Capital Market Day 11th of May 2020

1. Where we are and where we are heading – Anders Rylander, CEO
2. An oncologist's perspective – Samuel Rotstein Ph.D., MD, Karolinska Hospital
3. US launch plan – Robert Dann, SVP Marketing, US Business
4. EU launch & CDx opportunity – Henrik Winther, SVP Business Development
5. Q&A session – All

Send your question to ir@biovica.com

Where we are and where we are heading

Anders Rylander, CEO

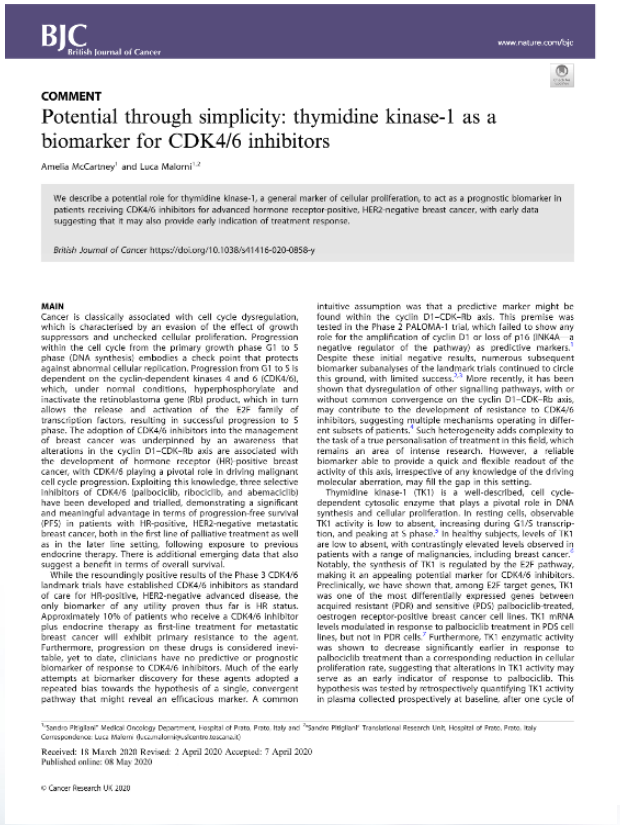
Unmet needs in Metastatic Breast Cancer

- Many treatment options
- Efficacy evaluation
- Treatment resistance
- Time consuming diagnostics

Editorial articles last week confirms unmeet need and DiviTum® potential value

”The broad applicability of TK1 as a marker of prognosis and early resistance to a uniform regimen may represent an appealing clinical and research tool that can be generalized to a large population of patients.” - Amelia McCartney

”DiviTum is the pioneering technology to document TK1a as a breast cancer biomarker to estimate prognosis and early recognition of treatment resistance that can be clinically very useful.” - Luca Malorni



BJC
British Journal of Cancer
www.nature.com/bjc

COMMENT

Potential through simplicity: thymidine kinase-1 as a biomarker for CDK4/6 inhibitors

Amelia McCartney[1] and Luca Malorni[1,2]

We describe a potential role for thymidine kinase-1, a general marker of cellular proliferation, to act as a prognostic biomarker in patients receiving CDK4/6 inhibitors for advanced hormone receptor positive, HER2-negative breast cancer, with early data suggesting that it may also provide early indication of treatment response.

British Journal of Cancer https://doi.org/10.1038/s41416-020-0858-y

MAIN

Cancer is classically associated with cell cycle dysregulation, which is characterised by an evasion of the effect of growth suppressors and unchecked cellular proliferation. Progression within the cell cycle from the primary growth phase G1 to S phase (DNA synthesis) embodies a check point that protects against abnormal cellular replication. Progression from G1 to S is dependent on the cyclin-dependent kinases 4 and 6 (CDK4/6), which, under normal conditions, hyperphosphorylate and inactivate the retinoblastoma gene (Rb) product, which in turn allows the release and activation of the E2F family of transcription factors, resulting in successful progression to S phase. The adoption of CDK4/6 inhibitors into the management of breast cancer was underpinned by an awareness that alterations in the cyclin D1–CDK–Rb axis are associated with the development of hormone receptor (HR)-positive breast cancer, with CDK4/6 playing a pivotal role in driving malignant cell cycle progression. Exploiting this knowledge, three selective inhibitors of CDK4/6 (palbociclib, ribociclib, and abemaciclib) have been developed and trialled, demonstrating a significant and meaningful advantage in terms of progression-free survival (PFS) in patients with HR-positive, HER2-negative metastatic breast cancer, both in the first line of palliative treatment as well as in the later line setting, following exposure to previous endocrine therapy. There is additional emerging data that also suggest a benefit in terms of overall survival.

While the resoundingly positive results of the Phase 3 CDK4/6 landmark trials have established CDK4/6 inhibitors as standard of care for HR-positive, HER2-negative advanced disease, the only biomarker of any utility proven thus far is HR status. Approximately 10% of patients who receive a CDK4/6 inhibitor plus endocrine therapy as first-line treatment for metastatic breast cancer will exhibit primary resistance to the agent. Furthermore, progression on these drugs is considered inevitable, yet to date, clinicians have no predictive or prognostic biomarker of response to CDK4/6 inhibitors. Much of the early attempts at biomarker discovery for these agents adopted a repeated bias towards the hypothesis of a single, convergent pathway that might reveal an efficacious marker. A common intuitive assumption was that a predictive marker might be found within the cyclin D1–CDK–Rb axis. This premise was tested in the Phase 2 PALOMA-1 trial, which failed to show any role for the amplification of cyclin D1 or loss of p16 [INK4A - a negative regulator of the pathway) as predictive markers.[1] Despite these initial negative results, numerous subsequent biomarker subanalyses of the landmark trials continued to circle this ground, with limited success.[2,3] More recently, it has been shown that dysregulation of other signalling pathways, with or without common convergence on the cyclin D1–CDK–Rb axis, may contribute to the development of resistance to CDK4/6 inhibitors, suggesting multiple mechanisms operating in different subsets of patients.[4] Such heterogeneity adds complexity to the task of a true personalisation of treatment in this field, which remains an area of intense research. However, a reliable biomarker able to provide a quick and flexible readout of the activity of this axis, irrespective of any knowledge of the driving molecular aberration, may fill the gap in this setting.

Thymidine kinase-1 (TK1) is a well-described, cell cycle-dependent cytosolic enzyme that plays a pivotal role in DNA synthesis and cellular proliferation. In resting cells, observable TK1 activity is low to absent, increasing during G1/S transcription, and peaking at S phase.[5] In healthy subjects, levels of TK1 are low to absent, with contrastingly elevated levels observed in patients with a range of malignancies, including breast cancer.[6] Notably, the synthesis of TK1 is regulated by the E2F pathway, making it an appealing potential marker for CDK4/6 inhibitors. Preclinically, we have shown that, among E2F target genes, TK1 was one of the most differentially expressed genes between acquired resistant (PDR) and sensitive (PDS) palbociclib-treated, oestrogen receptor-positive breast cancer cell lines. TK1 mRNA levels modulated in response to palbociclib treatment in PDS cell lines, but not in PDR cells.[7] Furthermore, TK1 enzymatic activity was shown to decrease significantly earlier in response to palbociclib treatment than a corresponding reduction in cellular proliferation rate, suggesting that alterations in TK1 activity may serve as an early indicator of response to palbociclib. This hypothesis was tested by retrospectively quantifying TK1 activity in plasma collected prospectively at baseline, after one cycle of

[1]Sandro Pfiglian®. Medical Oncology Department, Hospital of Prato, Prato, Italy and [2]Sandro Pfiglian®. Translational Research Unit, Hospital of Prato, Prato, Italy
Correspondence: Luca Malorni (lucamalorni@usl.toscana.it)

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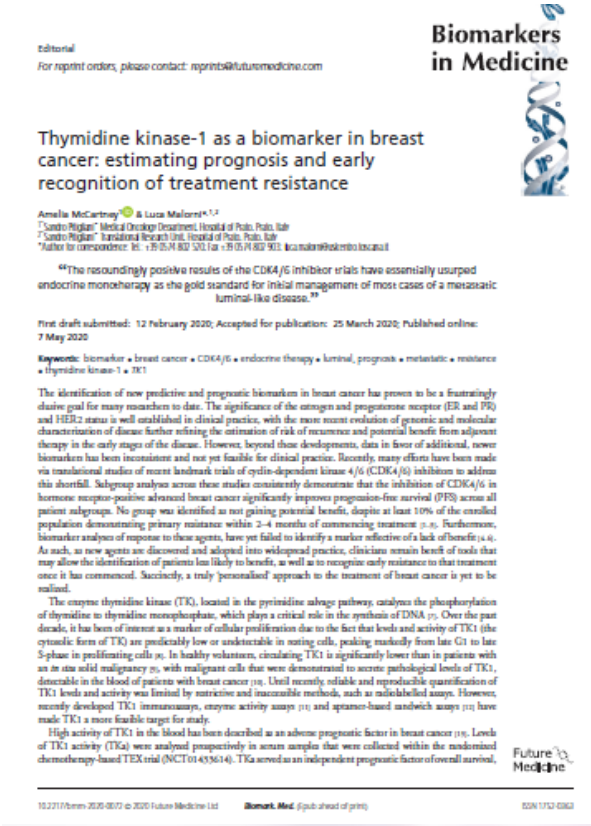

Editorial

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Biomarkers in Medicine

Thymidine kinase-1 as a biomarker in breast cancer: estimating prognosis and early recognition of treatment resistance

Amelia McCartney & Luca Malorni

“The resoundingly positive results of the CDK4/6 inhibitor trials have essentially usurped endocrine monotherapy as the gold standard for initial management of most cases of a metastatic luminal-like disease.”

First draft submitted: 12 February 2020; Accepted for publication: 25 March 2020; Published online: 7 May 2020

Keywords: biomarker • breast cancer • CDK4/6 • endocrine therapy • luminal, prognosis • metastatic • resistance • thymidine kinase-1 • TK1

The identification of new predictive and prognostic biomarkers in breast cancer has proven to be a frustratingly elusive goal for many researchers to date. The significance of the estrogen and progesterone receptor (ER and PR) and HER2 status is well established in clinical practice, with the more recent evolution of genomic and molecular characterization of disease further refining the estimation of risk of recurrence and potential benefit from adjuvant therapy in the early stages of the disease. However, beyond these developments, data in favor of additional, newer biomarkers has been inconsistent and not yet feasible for clinical practice. Recently, many efforts have been made via translational studies of recent landmark trials of cyclin-dependent kinase 4/6 (CDK4/6) inhibitors to address this shortfall. Subgroup analyses across these studies consistently demonstrate that the inhibition of CDK4/6 in hormone receptor-positive advanced breast cancer significantly improves progression-free survival (PFS) across all patient subgroups. No group was identified as not gaining potential benefit, despite at least 10% of the enrolled population demonstrating primary resistance within 2–4 months of commencing treatment [1–3]. Furthermore, biomarker analyses of response to these agents, have yet failed to identify a marker reflective of a lack of benefit [4–6]. As such, as new agents are discovered and adopted into widespread practice, clinicians remain bereft of tools that may allow the identification of patients less likely to benefit, as well as to recognize early resistance to that treatment once it has commenced. Succinctly, a truly ‘personalized’ approach to the treatment of breast cancer is yet to be realized.

The enzyme thymidine kinase (TK), located in the pyrimidine salvage pathway, catalyzes the phosphorylation of thymidine to thymidine monophosphate, which plays a critical role in the synthesis of DNA [7]. Over the past decade, it has been of interest as a marker of cellular proliferation due to the fact that levels and activity of TK1 (the cytosolic form of TK) are predictably low or undetectable in resting cells, peaking markedly from late G1 to late S-phase in proliferating cells [8]. In healthy volunteers, circulating TK1 is significantly lower than in patients with an in situ solid malignancy [9], with malignant cells that were demonstrated to secrete pathological levels of TK1, detectable in the blood of patients with breast cancer [10]. Until recently, reliable and reproducible quantification of TK1 levels and activity was limited by nutritive and inaccessible methods, such as radiolabelled assays. However, recently developed TK1 immunoassays, enzyme activity assays [11] and sptamer-based sandwich assays [12] have made TK1 a more feasible target for study.

High activity of TK1 in the blood has been described as an adverse prognostic factor in breast cancer [13]. Levels of TK1 activity (TKa) were analysed prospectively in serum samples that were collected within the randomized chemotherapy-based TEX trial (NCT01455636). TKa served as an independent prognostic factor of overall survival,

Future Medicine

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Treatment decisions with greater confidence!

Biovica develops and commercializes blood-based biomarker assays to improve monitoring of modern cancer therapies.

The DiviTum® assay, a test for accurately measuring cell proliferation, has successfully demonstrated its capabilities to early evaluate therapy effectiveness in several clinical trials.

Patients and payers will benefit from more personalized treatments.

Key Opinion Leader support - key for clinical acceptance

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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
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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

Strong Clinical Study Results for DiviTum®, peer reviewed and published in oncology journals

- 22 published and peer-reviewed articles with DiviTum®
- Results:
  - Prognostic: risk for cancer, recurrence & progression
  - Monitoring: quick feedback on treatment efficacy

Cancer area	Patients	No of Studies
Breast Cancer	1,065	11
Gastrointestinal	713	4
Lung Cancer	281	2
Blood Cancer	440	4
Other	368	1
	2,867	22

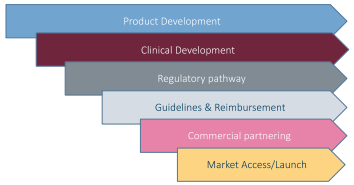
DiviTum® Commercialization process Metastatic Breast Cancer

- Product Development
- Clinical Development
- Regulatory pathway
- Guidelines & Reimbursement
- Commercial partnering
- Market Access/Launch

Clinical Usage & Uptake

Biovica roll-out plan Metastatic Breast Cancer

1. US launch

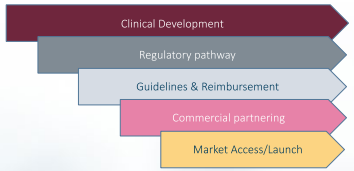


Clinical Usage & Uptake
Market potential $200-350 M

2. EU 5 + Nordics

Clinical Usage & Uptake
Market potential: $150 – 250 M

3. Japan



Clinical Usage & Uptake
Market potential: $50 – 100 M

4. RoE + RoW

Clinical Usage & Uptake
60% of patients with Breast Cancer at lower price

Potential
$400 - 700 M

Large potential to expand outside initial markets & applications!

Near term market expansion:

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

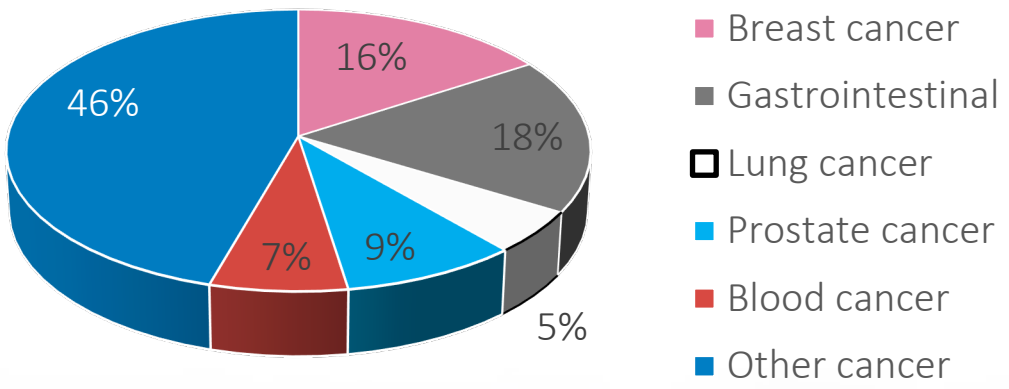
Medium term expansion:

Prevalent population of certain cancers

- Gastrointestinal cancer (7,7 M people)
- Lung cancer (2,2 M people)
- Prostate cancer (3,9 M people)

CAGR: 5% patient growth 2012-2018

43 M people living with cancer



Source: Globocan 2018 5-year prevalence

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An oncologist perspective

Sam Rotstein, MD, PhD,
Associate Professor Oncology, Karolinska Hospital
& Biovica Medical Advisor

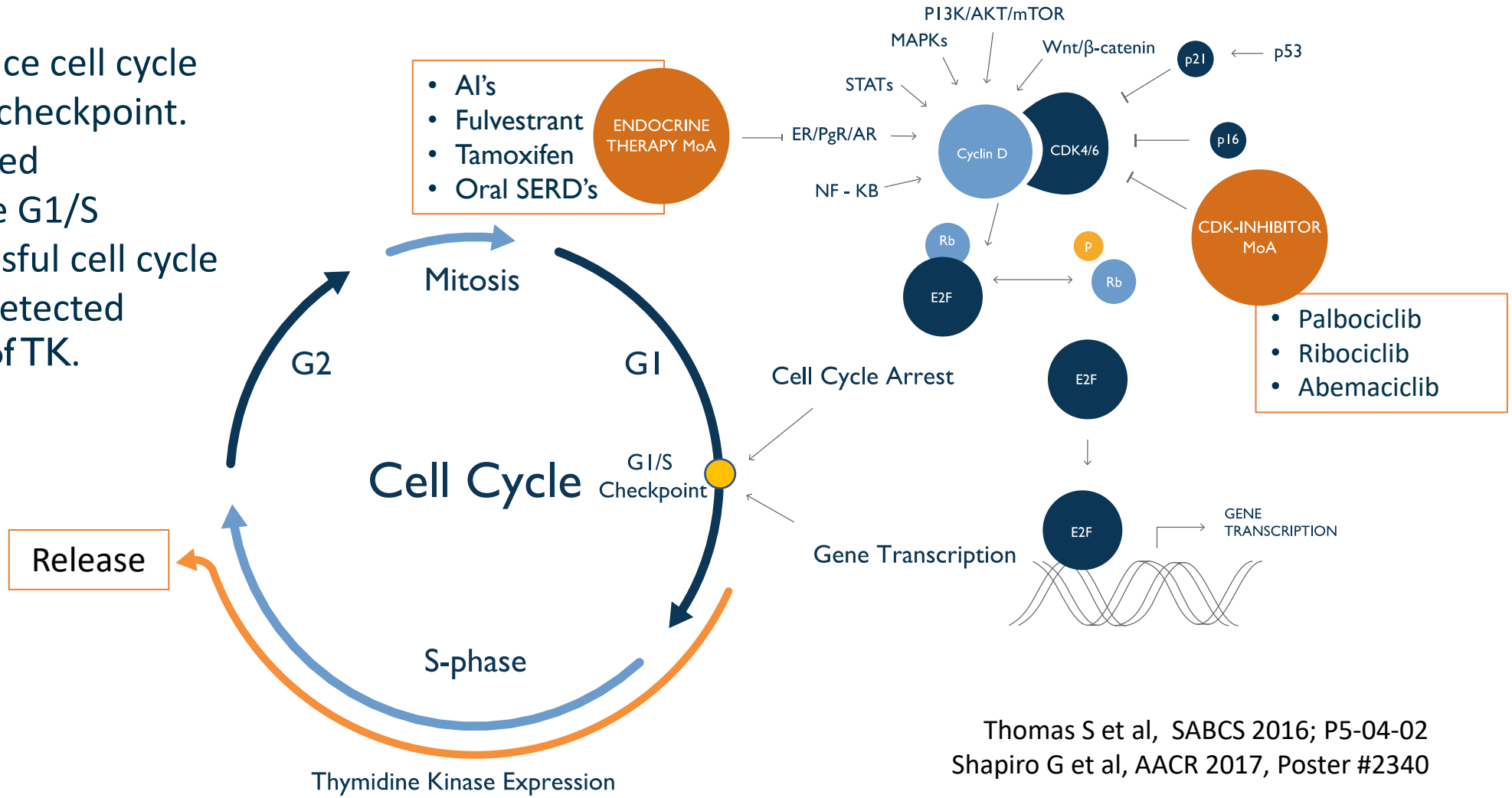
DiviTum® Applications

- Prognostic
  - High proliferation - Highly active tumor - Bad prognosis - High values
  - Slow proliferation– Low tumor activity – Good prognosis - Low values

- Prediction and monitoring
  - Increasing/high values – little or no treatment efficacy
  - Decreasing/unchanged/low values – treatment efficacy

DiviTum® TK - Scientific Rationale for Efficacy Evaluation of Cell Cycle Regulating Drugs

Specific drugs induce cell cycle arrest at the G1/S checkpoint. Since TK is expressed downstream of the G1/S checkpoint, successful cell cycle inhibition can be detected as changed levels of TK.



TK=Thymidine Kinase

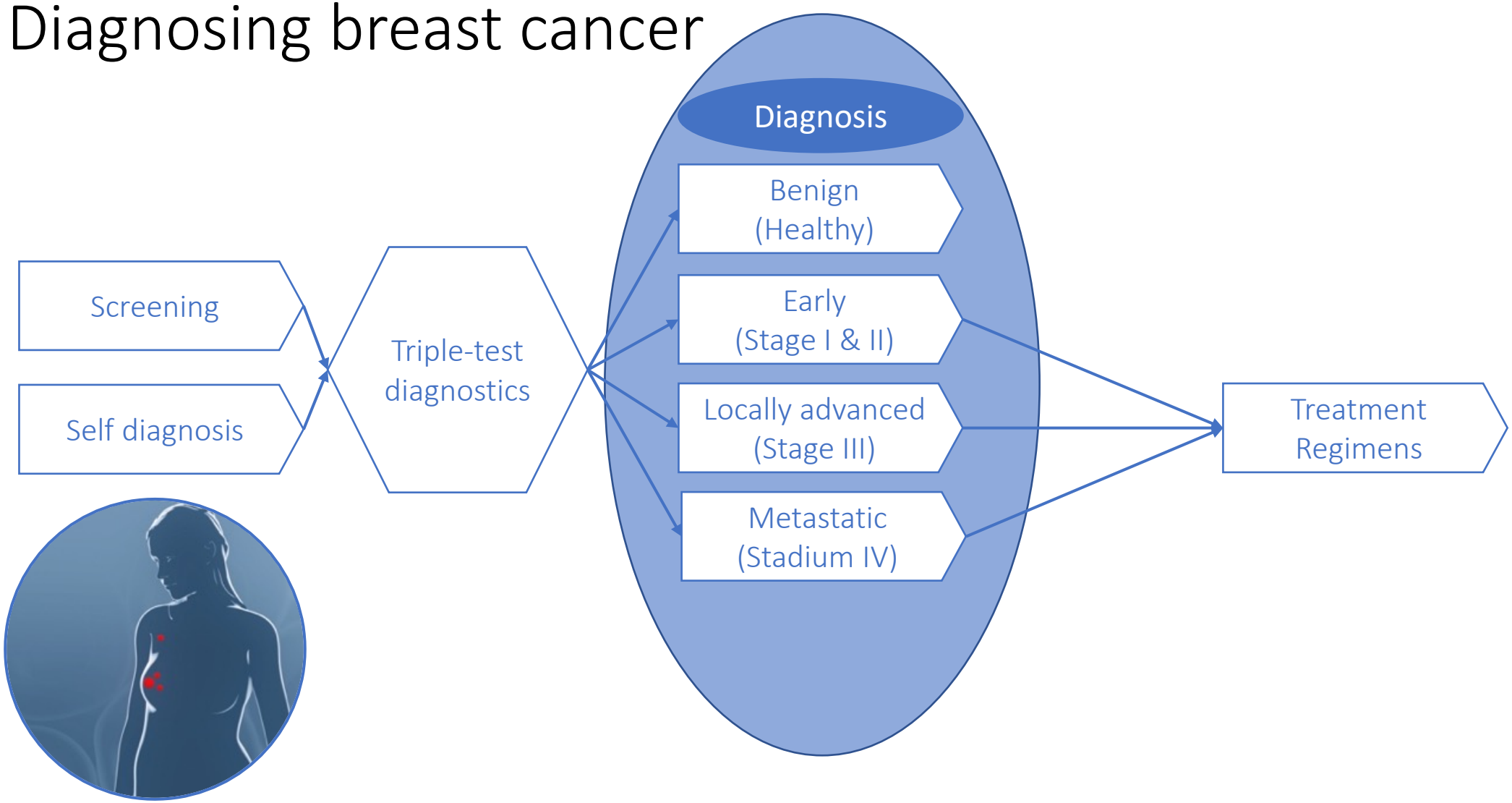
Thomas S et al, SABCS 2016; P5-04-02
Shapiro G et al, AACR 2017, Poster #2340

Todays diagnostics – how does DiviTum® fit?

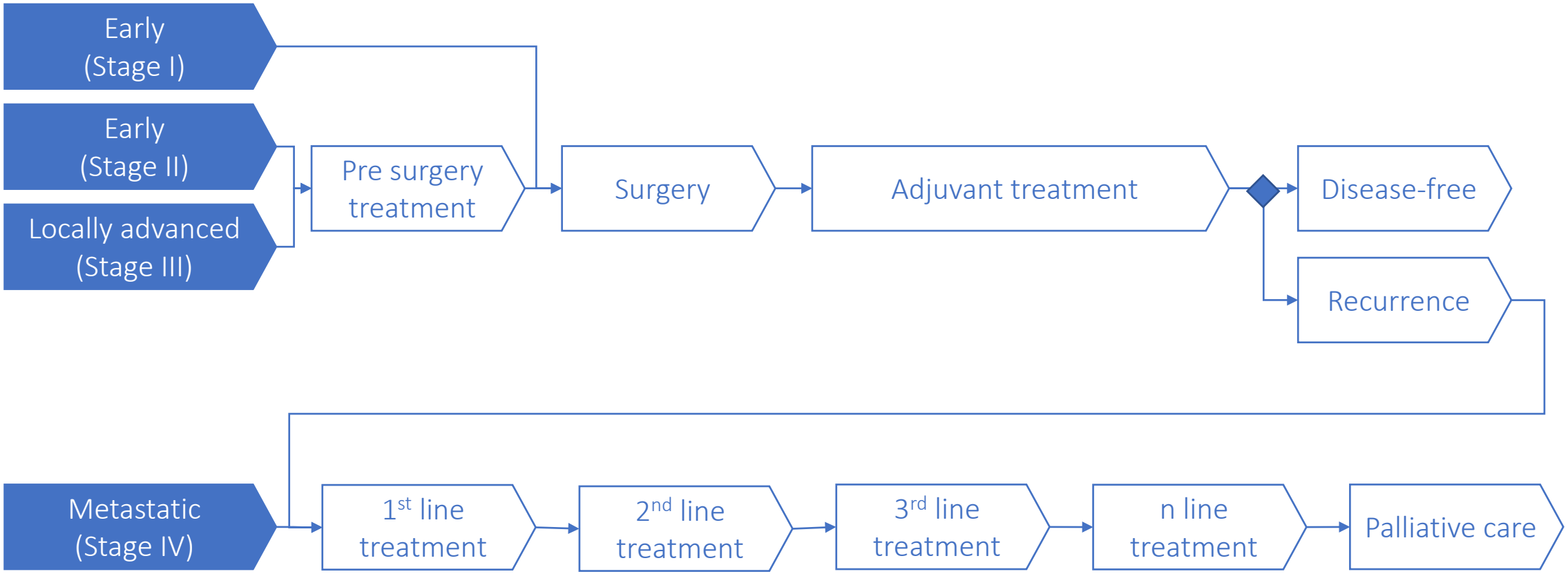
Diagnostics

1. Clinical examination
2. Image and functional investigation
   - CT, MR, PET, Bone scan, Mammography, Ultrasound, Regular X-Ray
3. Biopsy, surgery
   - Hormone receptor determination
   - Proliferation – Ki-67
   - Grade
   - HER-2 status
   - CA 15-3

Diagnosing breast cancer



Breast cancer development

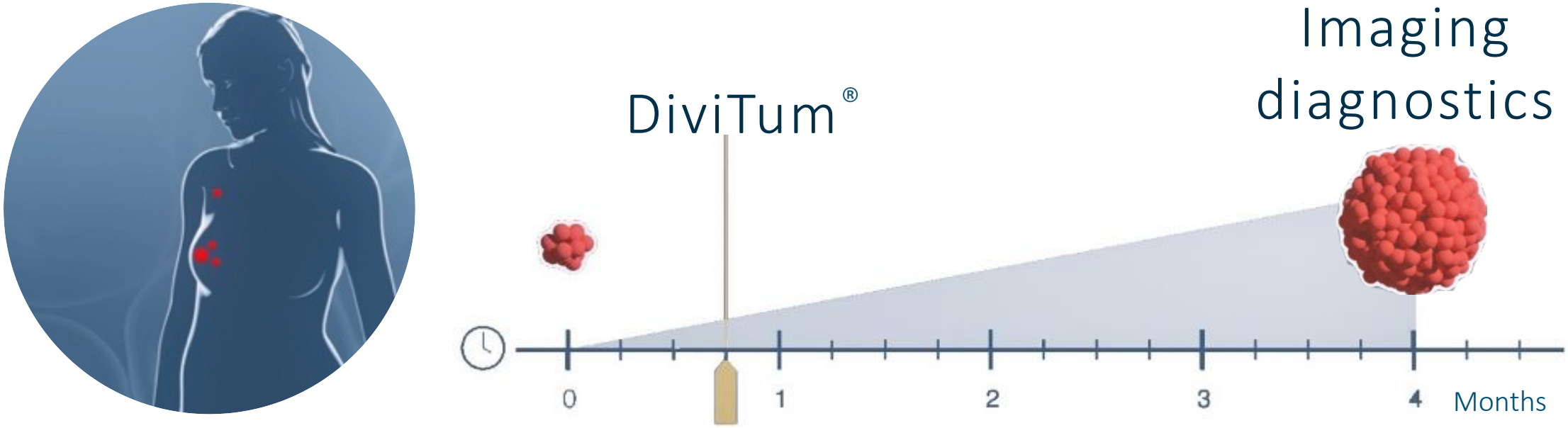


An unmet medical need and highly important to get early feedback on treatment efficacy

- Treatment options
  - Chemotherapy
  - Radiation
  - Endocrine therapies
  - Targeted therapies
  - Immuno-Oncology treatment

All treatments brings side-effects, sometimes severe

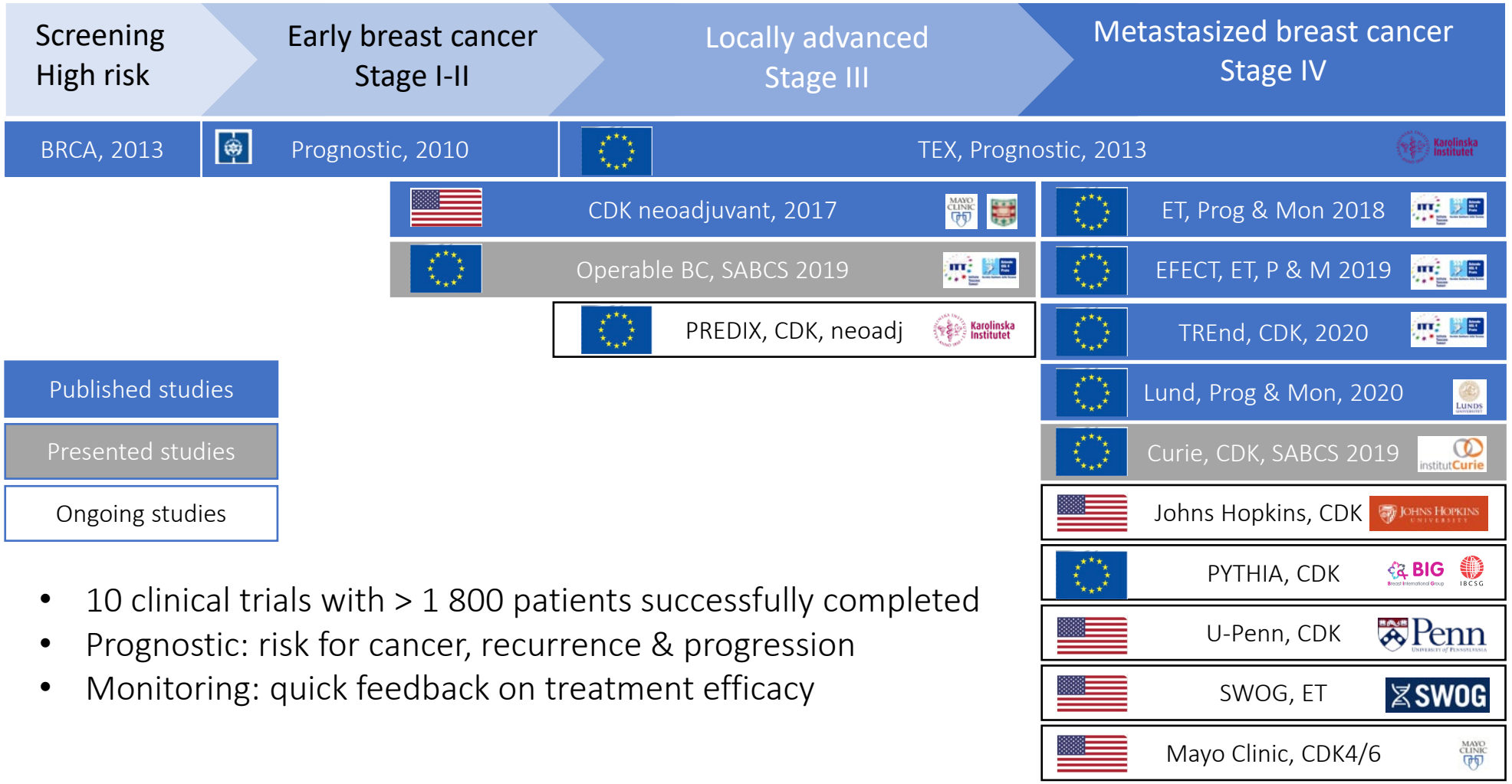
DiviTum® provides early response to whether or not the patient's cancer treatment is effective



DiviTum® measures cell proliferation rate for faster evaluation of cancer treatment effects

References: See http://biovica.com/divitum/publications/

DiviTum® - Breast Cancer Study Program



- 10 clinical trials with > 1 800 patients successfully completed
- Prognostic: risk for cancer, recurrence & progression
- Monitoring: quick feedback on treatment efficacy

What is the value of using DiviTum®?

- What does DiviTum mean for the patient?
- How useful is DiviTum for oncologists?
- Why is DiviTum useful in healthcare?

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US launch plan for DiviTum®

Robert Dann, SVP Marketing, US Business

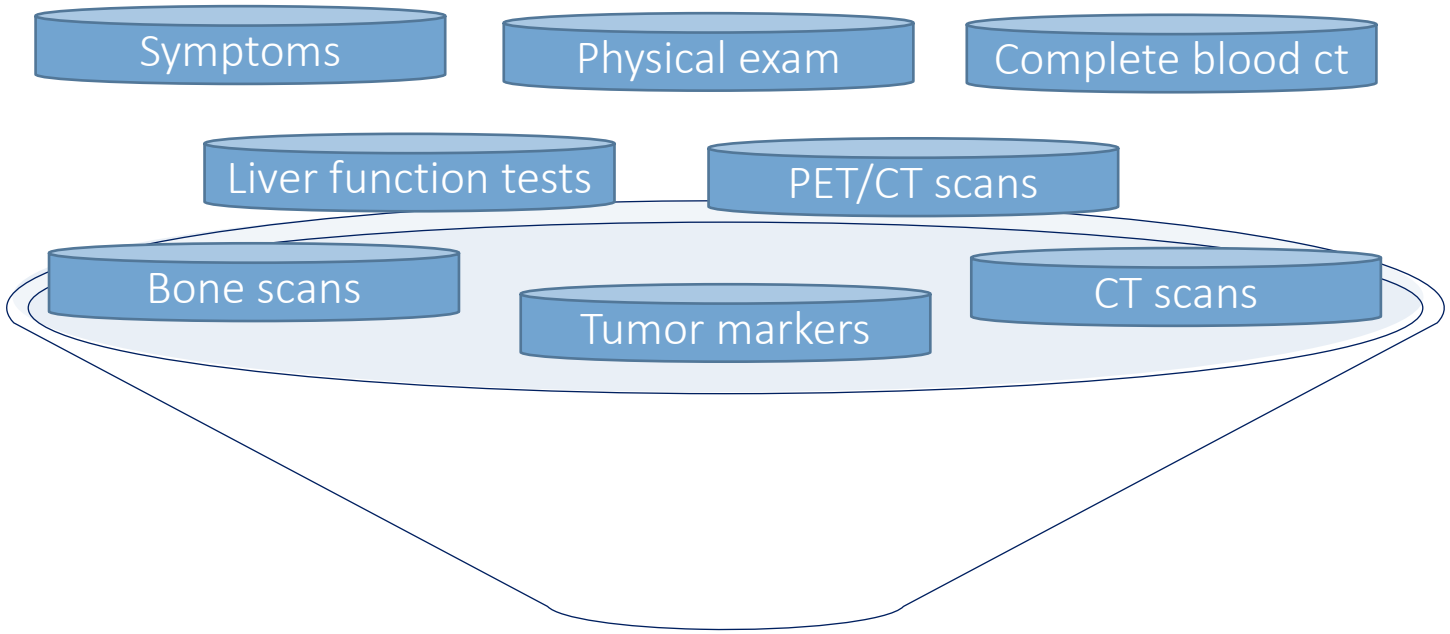
Topics

- The metastatic breast cancer patient population: care path, and needs
- Clinical evidence and clinical utility supporting the launch and beyond
- DiviTum® Go-to-market:
  - Messaging, key audiences, launch timeline, activities, and resources
- Foundations of the DiviTum® forecast

The median patient that we are aiming to help…

- Female, mid 60s
- Metastatic breast cancer
- Recurrent disease from an early stage cancer
- Hormone receptor positive disease
- Health status: generally good
- Time to 1st progression of disease: ~25 months
- Treatments: ~3 endocrine-based therapies (ET), then cytotoxics

And how her treatment is monitored…



- Multiple tests repeated regularly
- Individual tests not always definitive

Monitoring key questions:

- **When to switch** from one ET* to the next
- **When to move** from ET* to cytotoxics or non-ET

Metastatic breast cancer epidemiology/needs

57,000 new arrivals at metastatic breast cancer (16,000 new Dx, 41,000 recurrences)

34,000 with disease suitable for endocrine-based therapies (ET)

31,000 are post-menopausal (within scope of expected label)

1st ET
Median treatment
25 months

→ 2nd ET
Median treatment
10 months

→ 3rd ET
Median treatment
<6 months

→ Cytotoxics

Immediate Needs:

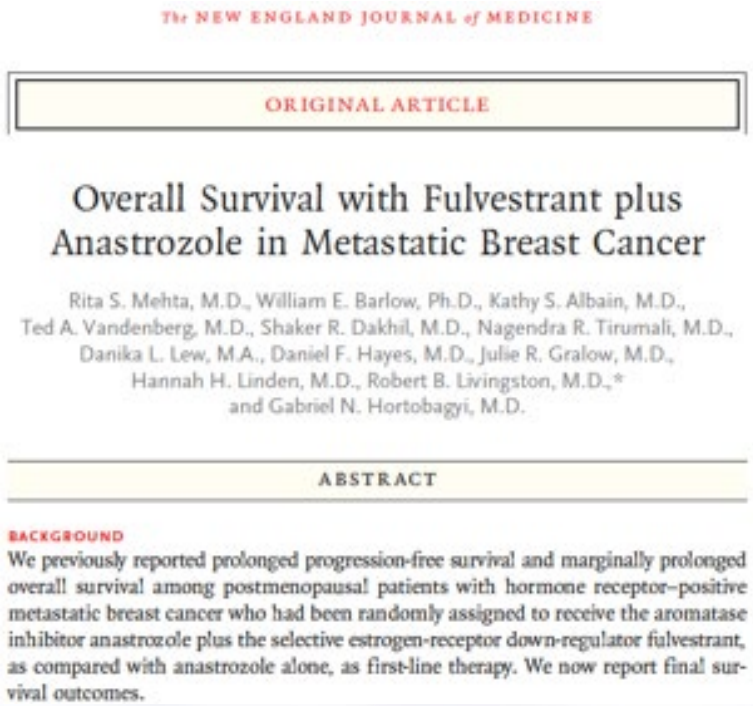
- More confidence that they are choosing the right treatment
- Faster decision making, anything that saves time
- Reduced number of diagnostic tests

- Longer time to cytotoxics (quality of life)
- Reduced out of pocket spend
- Simple, convenient disease monitoring
- Confidence

SWOG's S 0226 trial is the basis for the DiviTum® regulatory clinical validation and for usage

S 0226: Randomized Phase III trial, postmenopausal women with metastatic breast cancer treated with 1st line endocrine therapies

- 707 patients in the US and Canada from 73 sites
- DiviTum study: from ~400 patients with blood samples from 5 time points
- Hypotheses to support regulatory submission
  - Low or declining TKa value is indicative that disease is not progressing soon
  - High or rising TKa value is indicative that disease progression may soon be detectable by conventional measures



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Overall Survival with Fulvestrant plus Anastrozole in Metastatic Breast Cancer

Rita S. Mehta, M.D., William E. Barlow, Ph.D., Kathy S. Albain, M.D., Ted A. Vandenberg, M.D., Shaker R. Dakhil, M.D., Nagendra R. Tirumali, M.D., Danika L. Lew, M.A., Daniel F. Hayes, M.D., Julie R. Gralow, M.D., Hannah H. Linden, M.D., Robert B. Livingston, M.D.,* and Gabriel N. Hortobagyi, M.D.

ABSTRACT

BACKGROUND

We previously reported prolonged progression-free survival and marginally prolonged overall survival among postmenopausal patients with hormone receptor–positive metastatic breast cancer who had been randomly assigned to receive the aromatase inhibitor anastrozole plus the selective estrogen-receptor down-regulator fulvestrant, as compared with anastrozole alone, as first-line therapy. We now report final survival outcomes.

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network

Mehta R et al, NEJM 2019; 380(13):1226-1234

Vision beyond 1st launch: demonstrate clinical utility

Additional studies will provide evidence of:

1. The frequency of other monitoring tests may be reduced when used together with DiviTum.
2. Adding DiviTum to treatment monitoring may enable detection of progressive disease earlier and change in therapy.
3. DiviTum may be more accurate in treatment monitoring than other blood-based tumor markers.
4. Adding DiviTum to treatment monitoring may reduce overall cost of care and improve quality in relation to spend.

DiviTum® Value Proposition

Treatment decisions with greater confidence

- Opportunity to reduce assessments for disease progression
- When it is time to move to the next therapy, make that decision with **more confidence** and **sooner** to when therapy stops working
- **Improve** cost management, workflow, and decision-making
- Time is the patient's most precious commodity. Anything that helps to make the right decisions sooner and with more confidence is a plus.

US Market Commercialization timeline to mid-2021

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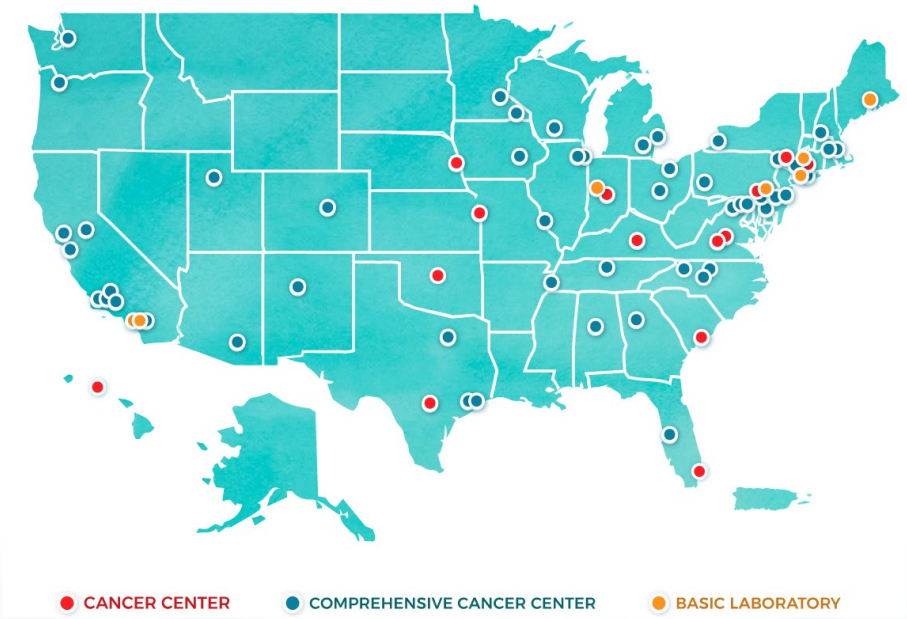
Focus on key cancer centers, reference labs, IDNs & payers

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 an OPKO Health Company	16	1
Mayo Clinic Laboratories	2	2
ARUP Laboratories	1	1
NeoGenomics	8	8
Cleveland Clinic Laboratories	1	1

IDNs/Payers

Kaiser Permanente

Geisinger Health Plan

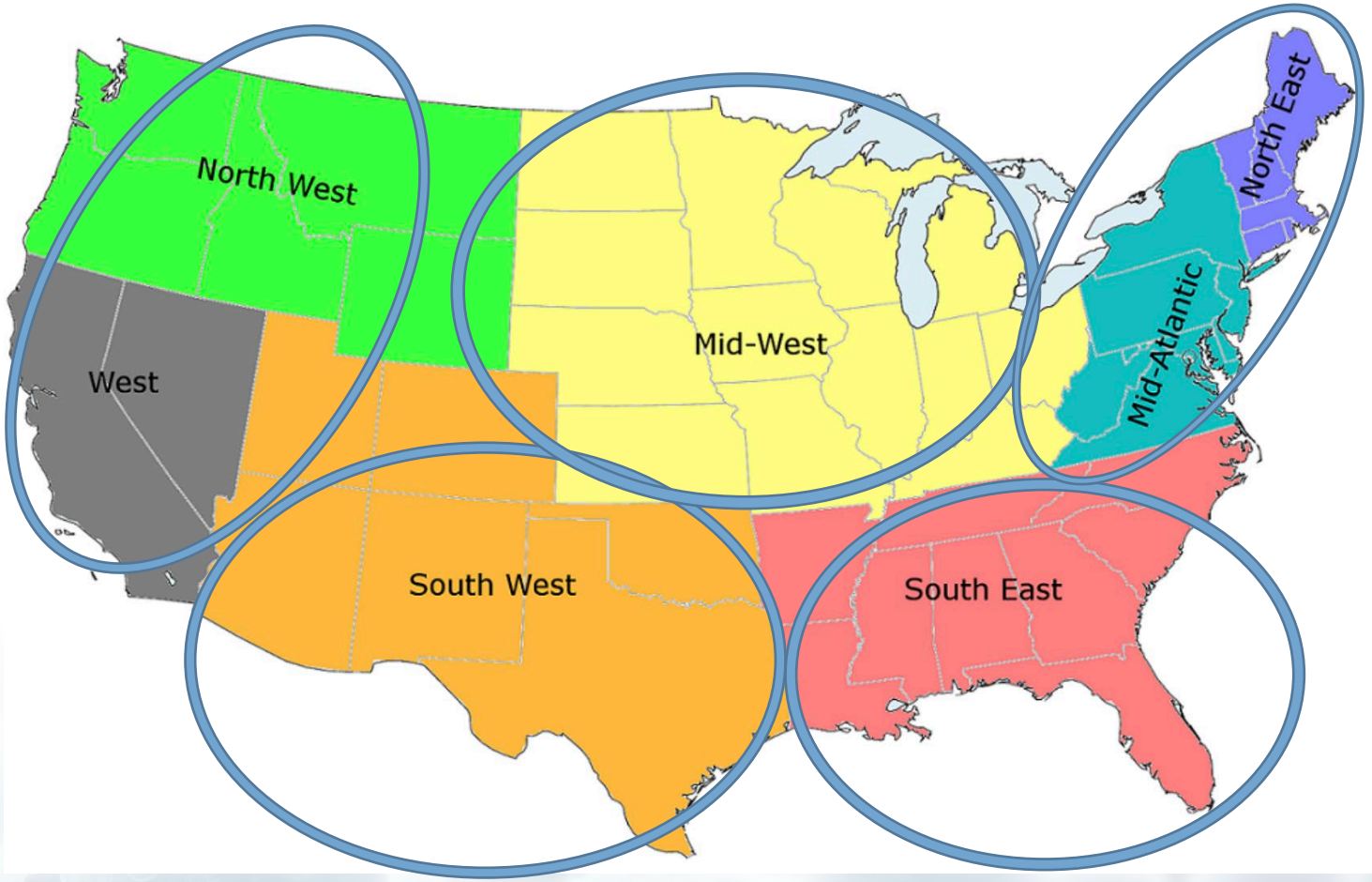
UnitedHealthcare

Anthem

These will be customers and at the same time, partners

Biovica Inc. commercial team development

Hybrid model of shared responsibilities with partners



Biovica central team

- Marketing
- Medical Science
- Market Access

Biovica territory management

- Manage the local ecosystem of stakeholders: key oncologists, labs, payers, patient advocates

Partners (under discussion)

- Provision of lab services
- Central support for pharma collaborations
- Involvement in clinical utility studies
- Further advancing the DiviTum science

US MBC forecast model and assumptions

Defining the market opportunity	Assumption
Target population, new/year	31K new/year: women, postmenopausal, HR+/Her2-
Relevant treatment	3 lines of therapy/patient. DiviTum can start during care
Testing frequency	Baseline, monthly to month 6, X3 monthly thereafter
Test opportunities	~730,000 (initial opportunity, will grow with locally advanced expansion)

Factors defining DiviTum volume uptake	
Lab coverage of the population	Rapid
Reimbursement timing & coverage, risk sharing agreements	Dependent on price, test accuracy, clinical utility, price
Physician uptake	Dependent on accuracy and reimbursement coverage
Competitor share	Launching after DiviTum
Pricing	Preliminary research suggests $3-500/test

Year	Share of test opportunities
3	~15%
10	~50%

Summary: Key success factors for US launch

- Demonstration of clinical and economic utility AND change to current practices.
- Collaboration on pricing and reimbursement with academics, payers and integrated delivery networks.
- A small, skilled Biovica commercial organization supports partners with data, messaging, and evidence of DiviTum's value to US healthcare

Agenda

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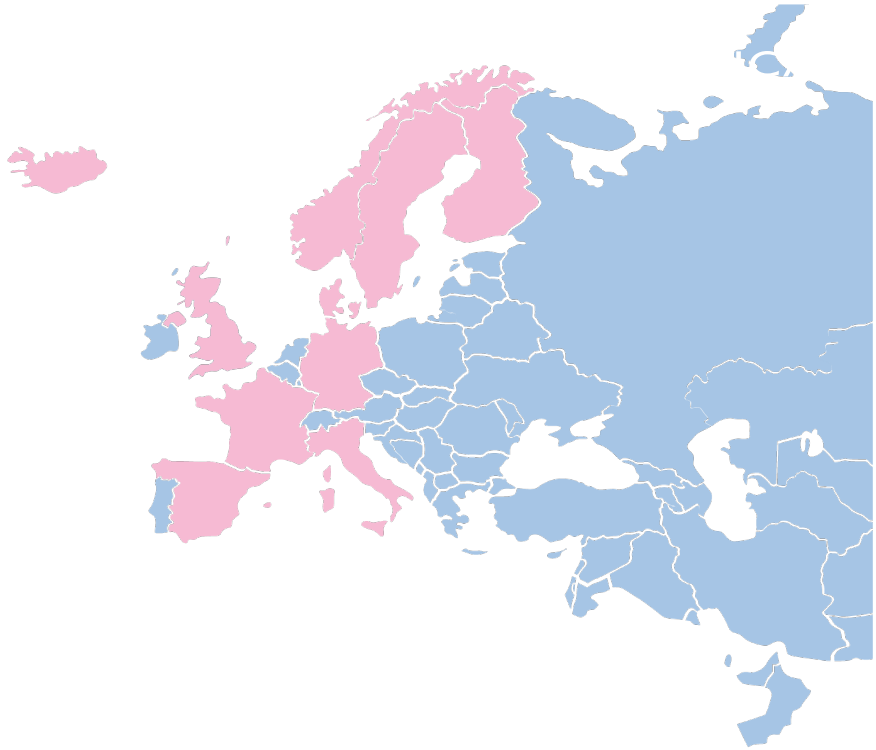
CDx Opportunity

Henrik Winther Ph.D., SVP Business Development

European launches in MBC starting Q3/Q4 2021 - within Big 5 and Nordics

Area	Assumption
Target market	Incidence 40k new/Y: women, postmenopausal, HR+/Her2-; 3 lines of therapy/patient. DiviTum can start during care.
Testing frequency	Baseline, monthly to month 6, X3 monthly thereafter
Test opportunities	945,000 per year (Big 5 & Nordics) (Rest of Europe: 730,000 tests/year)



Launch strategy

- Use learnings from US launch
- Adapt and customize to fit specifics of individual country health systems
- Rely strongly on local partner collaborations for distribution and national marketing

Pricing/test:

- Preliminary research suggested $150-$250/test.
- Test accuracy, results of clinical utility studies and negotiations with payers will determine the final outcome.

Regulatory: DiviTum® assay is already CE labeled

A CDx test assures the safe and effective use of a pharmaceutical drug

CDx test for patient selection:

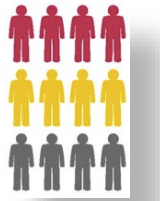
Breast Cancer Patients
(with different biomarker profiles)

Selecting

CDx Test

Looking for patients eligible for drug D treatment

Diagnostic Positive → Treat with drug D



Diagnostic Negative → Do not treat with drug D

CDx test for patient monitoring:

Patients treated with drug D

Monitoring

CDx Test

Measuring if therapy still has effect

Test Positive → Stay on same drug D (continued response to drug D)

Test Negative → Switch to new drug (developed drug resistense to drug D)

Biovica's DiviTum® assay has a broad playing-field - as prognostic, monitoring, and companion diagnostic devices

PATIENT FLOW

Diagnose → Treat → Monitor → Adjusted Treatment

KEY PLAYERS

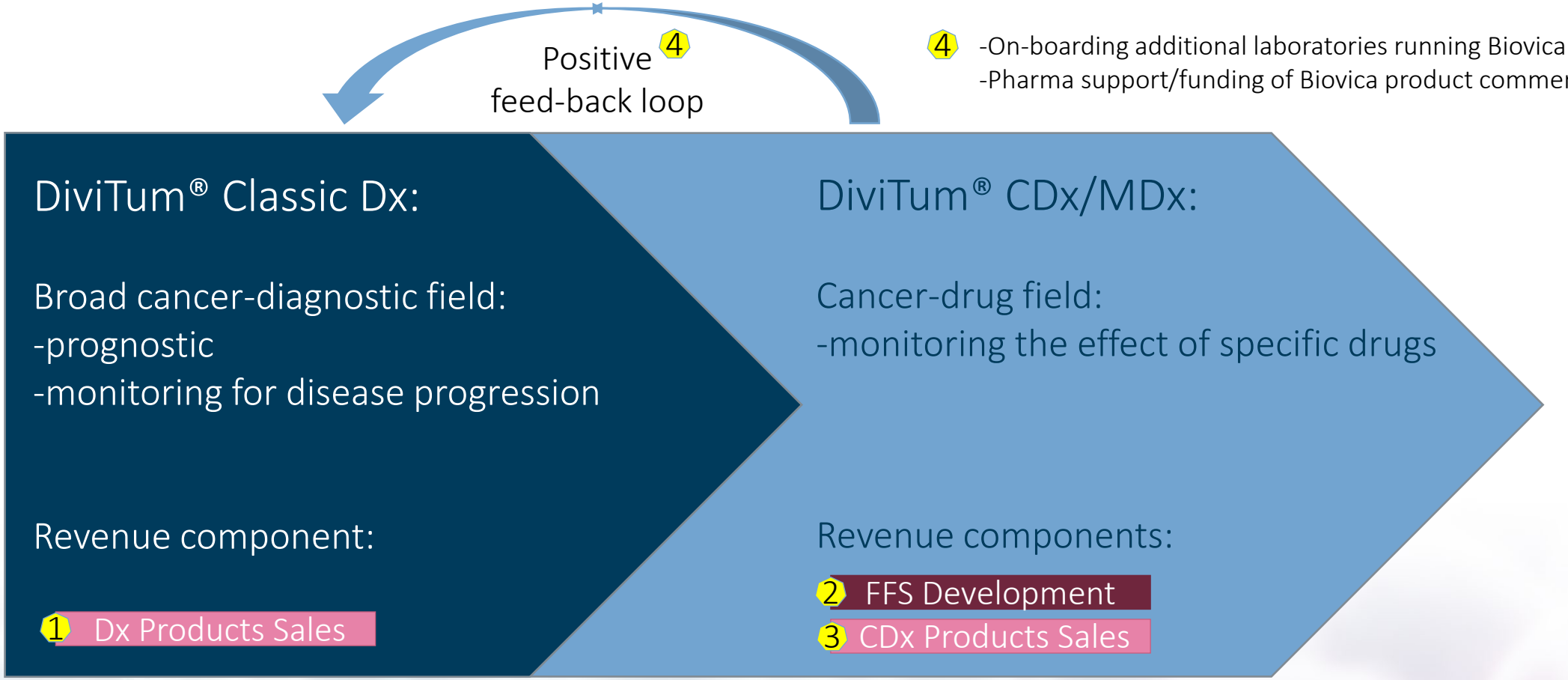
Diagnostic Companies — CDx — Pharma

BIOVICA — CDx — Pharma

Pharma needs monitoring CDx's (MDx's) - as a drug brand differentiator

- The MDx increases the *safety and efficacy* of the Rx and hence differentiates it from any similar drug by:
  - Cut-off tied to one specific drug – i.e. based on clinical samples from patients receiving one specific drug
  - Being recommended by oncologists/KOL's – more patients will be transferred to the safer drug/treatment
  - Oncologist prefer blood-test over imaging (earlier, easier, safer)
  - Reimbursed test - CDx/MDx easier to achieve reimbursement
- MDx testing allows for a *higher price on the Rx*, because the drug will only be used when it is safe and effective to use – avoidance of futile therapy/side-effects

Expanding the DiviTum® market potential - by adding more clinical utility



4 -On-boarding additional laboratories running Biovica test solutions
-Pharma support/funding of Biovica product commercialization

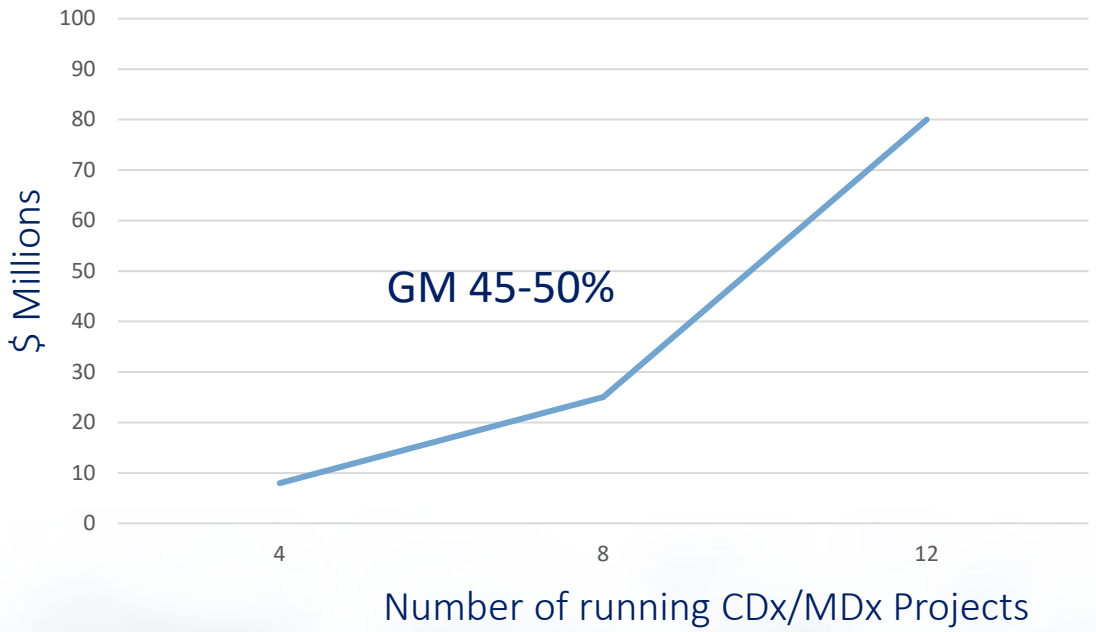
1 Product Sales in chosen markets

2 Fee-for-Services based on time (hourly rate) and materials

3 Product Sales in drug markets

Additional market potential for DiviTum® as a *CDx/MDx-device* - Fee-for-Service Revenue and Product Sales

Fee-for-Service (FFS) Revenue[1]



Product Sales Focus

CDx/MDx products supporting/accompanying[2] therapeutic drugs targeting tumor cell proliferation

DRUG Mode-of-Action	Potential Collaborators
CDK 4/6 inhibitors	Pfizer; Novartis; Eli Lilly
MEK inhibitors	GSK; Roche; Pfizer; AZ
PI3K/TK inhibitors	Novartis; Gilead
SERD's/SERM's	AZ; GNE; Novartis
…	…

[1]During development, registration and commercialization of CDx/MDx Based on inhouse/empirical data (project hrs; hourly rates; materials; services; registration fees)

[2]For the monitoring of response to treatment and early detection of disease progression/switch in therapy

CDx opportunity – Summary:

- Improves patient care by allowing for a more safe and effective use of targeted treatments
- Synergistic with Biovica “core business”
- Self-funded/Pharma sponsored
- High value reimbursed products

Reasons to invest in Biovica

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

Upcoming milestones:

- FDA 510(k) submission (Q3-2020)
- 510(k) approval & US launch (Q1 2021)
- 1st US Reimbursement (2021)
- 1st Euro-5 & Nordic launch by end of 2021

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

Capital Market Day 11th of May 2020

1. Where we are and where we are heading – Anders Rylander, CEO
2. An oncologist's perspective – Samuel Rotstein Ph.D., MD, Karolinska Hospital
3. US launch plan – Robert Dann, SVP Marketing, US Business
4. EU launch & CDx opportunity – Henrik Winther, SVP Business Development
5. Q&A session – All

Send your question to ir@biovica.com

Q&A session