



**BI+VICA®**  
TREATMENT DECISIONS WITH GREATER CONFIDENCE™

A decorative graphic consisting of multiple circles, each containing a plus sign. One circle on the left is highlighted with a blue border and a white plus sign, while the others are grey. These circles are arranged in a grid-like pattern along the top and left edges of the slide.

# Forward Looking-Statements Disclaimer

The Investor Presentation may contain certain statements that are forward-looking. These statements may refer in particular to the Company's business strategies, its expansion and growth of operations, future events, trends or objectives and expectations, which are naturally subject to risks and contingencies. Any such factors, individually or in the aggregate, may cause actual results and developments to differ materially from those expressed or implied by such forward-looking statements.

The Company, its affiliates, directors, advisors, employees and representatives expressly disclaim any liability whatsoever for such forward-looking statements. Further, forward-looking statements speak only as the date of the Investor Presentation.

The Company does not undertake to update or revise the forward-looking statements that may be presented in the Investor Presentation to reflect new information, future events or for any other reason and any opinion expressed in the Investor Presentation is subject to change without notice.

Some of the financial information contained in the Investor Presentation are not directly extracted from the Company's accounting systems or records and/or are not International Financial Reporting Standards (IFRS) accounting measures. Such information has not been independently reviewed or verified by the Company's auditors. In addition, certain financial information is preliminary and has yet not been finalized or subject to review/audit from the Company's auditors. Accordingly, such preliminary financial information may change.

# Executive summary

BI+VICA®



Highly-experienced, US-based specialist sales team, fully owned CLIA-certified lab in San Diego, HQ and research-lab in Uppsala, Sweden



Initial USD 400-700m addressable market in mBC, and an estimated additional USD 1.0 – 1.5bn in follow-on indications



Established commercial agreements in the US, Italy, the Netherlands, and Poland



The first CE-marked, FDA cleared blood test for tumor proliferation, monitoring metastatic breast cancer treatment efficacy.

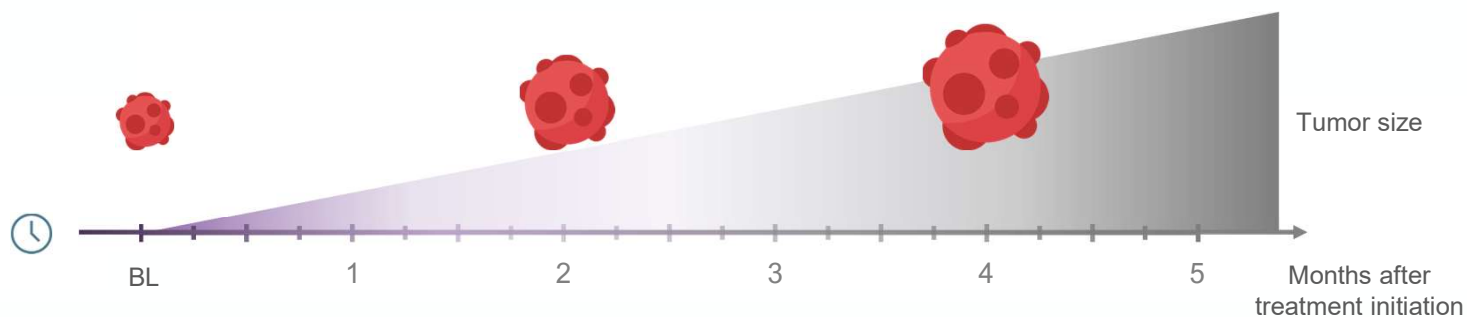


12 weeks earlier detection of progression compared to imaging, with 96.7% and 93.5% predictive accuracy in 30/60-day non-progression for mBC



Clinical evidence generated in other indications, including locally advanced BC, MM, CRPC, and NSCLC

# The cancer treatment monitoring gap



Current treatment monitoring protocols  
**can only detect progressive disease**  
with a >4-month delay

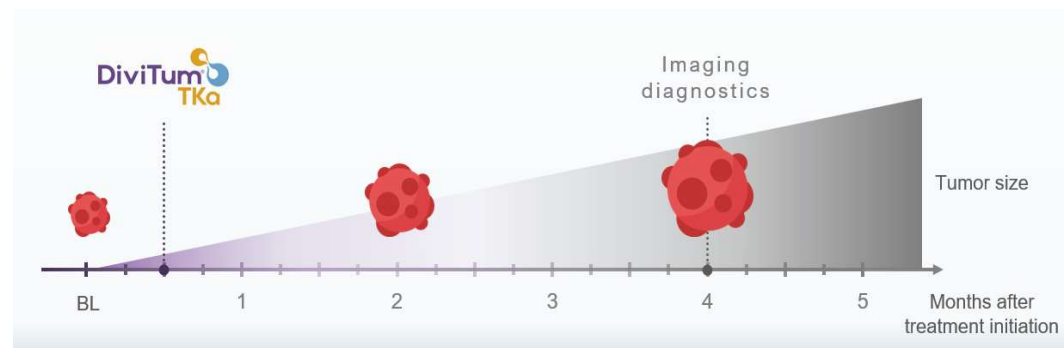
Until progression is detected, patients continue  
treatment with highly toxic therapies, **suffering**  
from **side-effects**, while **missing the chance to**  
**benefit from alternative treatments**

# DiviTum<sup>®</sup> TKa

A paradigm shift in Breast Cancer treatment monitoring

**Predictive & prognostic  
for PFS at baseline and  
during treatment<sup>1,2,3</sup>**

**Detection of tumor  
progression 83 days  
earlier than imaging**



Allows for the monitoring  
of treatment effect in  
mBC patients<sup>4</sup>

**30+** publications covering  
**>12** cancer indications

Complementary to CA15-3  
yet with **stronger  
prognostic potential<sup>2</sup>**

**14 articles** from breast  
cancer trials totaling **>2,000  
patients**

**References:** 1. BioltaLEE study; NCT03439046; ESMO 2021, ASCO 2022. 2. SWOG S0226: Clin Cancer Res (2021) 27 (22): 6115-6123. 3. PYTHIA: Eur J Cancer (2022), volume 164: 39-51 4. PALBO-DOSING: npj Breast Cancer (2022), volume 8, Article number: 3 5

# Biovica's first regulatory cleared product based on the DiviTum<sup>®</sup>TKa test

## Regulatory approvals secured in the EU & the US



**510(k) clearance** granted in July 2022



**Unique product classification code** created by the FDA, enabling clear differentiation to competition enables market access and reimbursement efforts



**CLIA certification** received in February 2023



**CE-marked** according to IVDD in May 2022\*



**PLA code** issued by the AMA in July 2023, enabling identification of DiviTum<sup>®</sup> TKa by payers and providers

\* IVDR only required if significant changes are introduced.

## Broad label across HR+ mBC treatment monitoring

DiviTum<sup>®</sup>TKa is intended to be used as an aid for **monitoring treatment response in HR+ mBC**

Regulatory clearance on the basis of **monthly or bi-monthly testing with DiviTum<sup>®</sup>TKa** in combination with standard imaging protocols for HR+ mBC patients<sup>1,2</sup>

510k clearance allows for **broad application** of DiviTum<sup>®</sup>TKa – applicable in **all standard antiproliferative treatments for HR+ mBC**

References: 1. Krishnamurthy J, et al. npj Breast Cancer 8, 35 (2022). 2. Bergqvist M, et al. Biomarkers, 2023, DOI: 10.1080/1354750X.2023.2168063

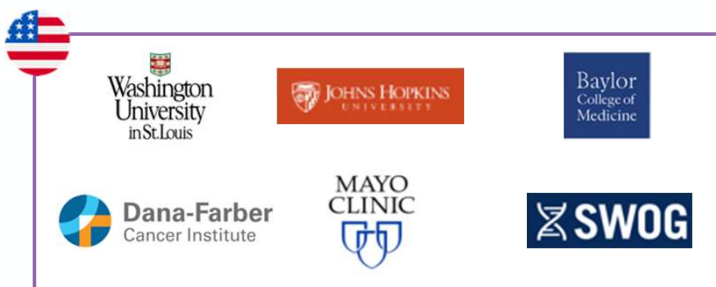


# Validated by a wealth of scientific evidence

## 30+ published and peer-reviewed articles

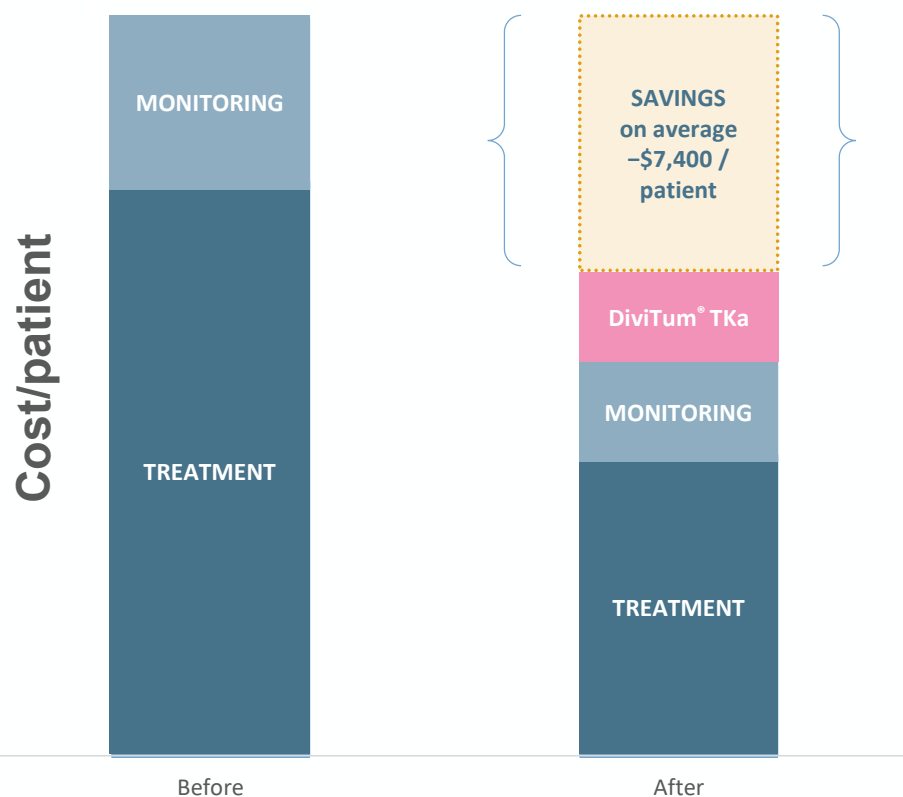
- ⊕ Strong evidence supporting the **use of DiviTum® TKa as a clinical biomarker** of CDK4/6i response
- ⊕ Collaboration with **world-leading academic institutions** and **KOLs**
- ⊕ The DiviTum® TKa test provides feedback on progression up to **83 days earlier than imaging**
- ⊕ **First prospective study published**

Cancer Area	Patients	Nr. of studies
Breast Cancer	3,039	14
Gastrointestinal	713	4
Malignant Melanoma	86	2
Lung Cancer	302	3
Blood Cancer	440	4
Other	457	3
<b>Total</b>	<b>5,037</b>	<b>30</b>



Note: Summary of clinical results available at [biovica.com](http://biovica.com).

# Attractive health economics impact



## DiviTum® TKa health-economic impact

- ↓ Reduction of other monitoring costs by decrease in CT scans, Bone scans etc.
- ↓ Earlier reduction in usage of costly CDK4/6 inhibitor treatment once no longer effective
- ↑ Limited savings by switching to other CDK4/6 inhibitor as 2<sup>nd</sup> and 3<sup>rd</sup> line therapies or when switching from cheaper types of therapy






**DiviTum® TKa can yield cost savings of \$7,400 / patient / year, equal to 3x the cost of the test**

**Net savings of adding a new test is estimated to be 3-times the cost of the new test itself.<sup>1</sup>**

References: 1. Guzauskas G et al, ISPOR 2021 & The study publication is included in the November 2021 issue of the Journal of Medical Economics



# Diagnostic & treatment monitoring landscape

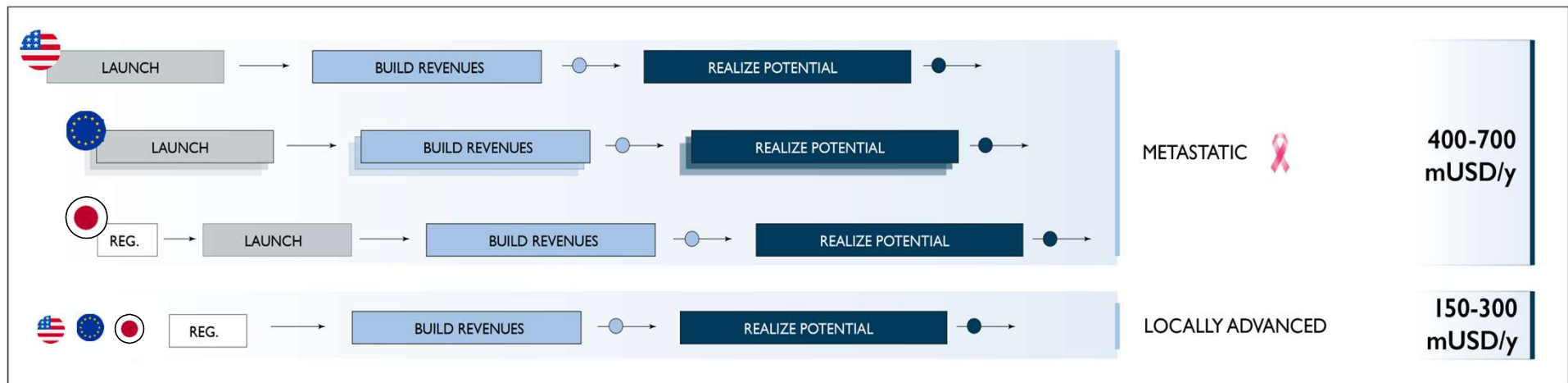
	 <b>Imaging</b> <ul style="list-style-type: none"> <li>Standard method for treatment evaluation</li> <li>Requires 3-4 months follow-up</li> </ul>	 <b>Biopsy</b> <ul style="list-style-type: none"> <li>Used for assessing prognosis</li> <li>Invasive, cannot be used for frequent monitoring</li> </ul>	 <b>Blood-based markers</b> <ul style="list-style-type: none"> <li>Convenient for monitoring</li> <li>No marker established as SoC in mBC</li> </ul>
<b>Source</b>	Tissue, organs, bones etc	Biopsy (tissue)	Blood
<b>Diagnostic Type</b>	Screening / Monitoring	Diagnostic / Prognostic	Monitoring
<b>Examples</b>	PET/CT, MRI	HER2, HR, Ki-67	CA 15-3, CA 27.29      CTC, ctDNA
<b>Regulatory status</b>	FDA, CE	FDA, CE	FDA, CE      LDT, RUO
<b>Guidelines</b>	 Standard of Care	 Standard of Care	At oncologist's discretion      Not included
<b>Cost / Benefit</b>	High cost / high benefit	Low-medium cost / high benefit	Low cost / low benefit      High cost / unproven benefit
<b>Limitations</b>	Radiation exposure & limited access	CT guided biopsy (invasive)	Low sensitivity and specificity      High cost and false negatives



Commercialization –  
capitalizing on a  
scalable launch  
strategy

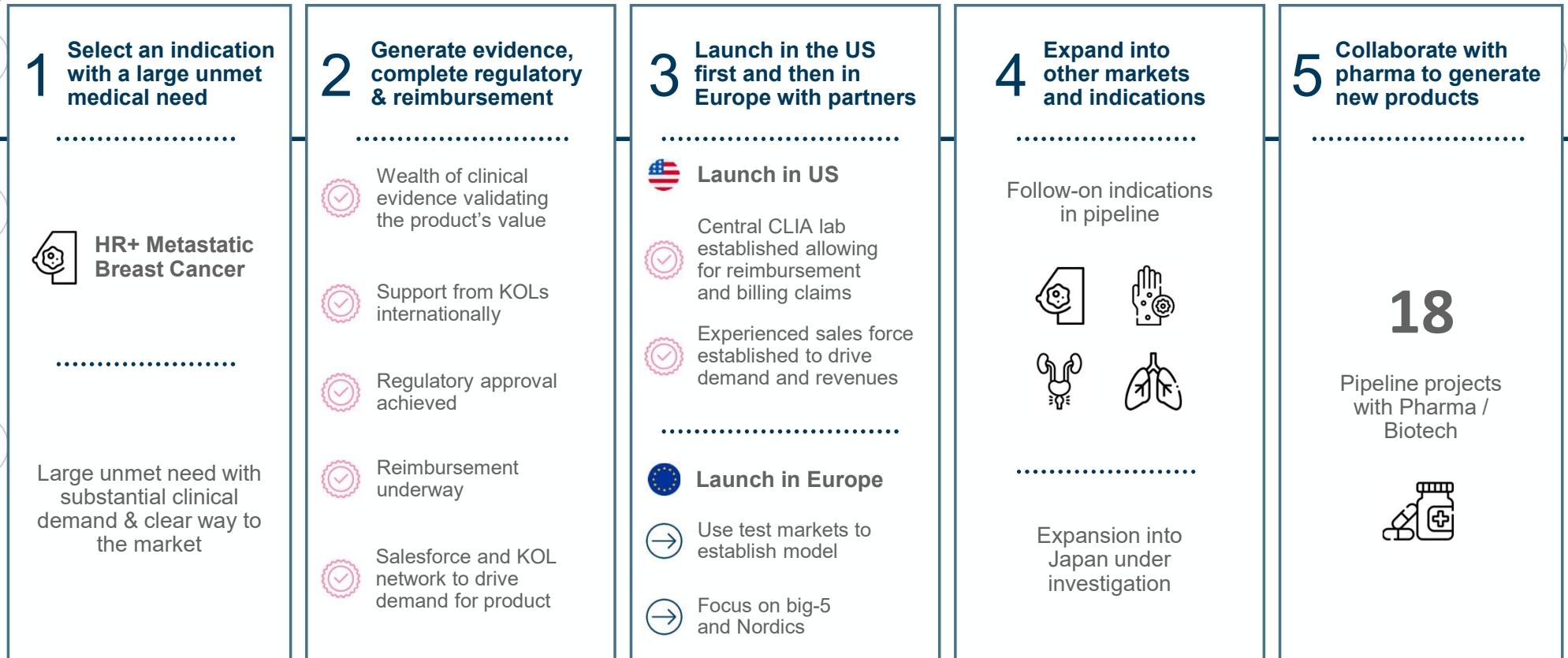


# Strategically designed launch plan ensures growth



Ambition is to realize 15% of market potential within 3 years of market-entry

# Comprehensive go-to-market strategy



# US & EU commercialisation underway

Several key milestones already achieved

## Commercial Milestones in the US & EU



January 2023: **Experienced US Sales Force** hired



March 2023: **Commercial Partnership Agreement** for **Poland, Netherlands**



April 2023: **Commercial Partnership Agreement** for sales force in **Italy**



May – July 2023: **Private Insurance Agreements** with MediNcrease, Contigo Health & Occum Health



September 2023: **Commercial (client bill) agreements with leading healthcare provider in Arizona & largest healthcare provider in Missouri**

\* IVDR only required if significant changes are introduced.

# CLIA Lab

Centralizing process, management & control

**The CLIA lab model enables management of the entire value chain and control over 5 key success factors**

<b>Stakeholder relationships</b>	○ Patient, physician, and payer
<b>Market access</b>	○ Availability to all patients
<b>Reimbursement</b>	○ Insurance coverage, value, utilization
<b>Sample biobank</b>	○ Sample analysis fueling pipeline
<b>Data development &amp; mining</b>	○ Understanding product utilization, utility & correlation

## Biovica field force

Sales Reps, Market Access, Managed Care



**Create awareness / generate demand from physicians**

1

2

## DiviTum order

Educate office on clinical utility, order logistics & financial assistance



**Order commitment – establish ordering channels**

3

4

## Test results

Send results to physicians / institutions



**Results processed – Drive demand, expand reimbursement**

5

6

## Breast oncologists

71 NCI cancer centers with ≈550 oncologists



**Targeted approach – obtain prescriber advocacy**

## Biovica CLIA Lab

Receive samples & run test



**Sample tested – specimen path / logistical hurdles**

## Revenue cycle

Submit insurance claim, bill client / accounts / patients



**Reimbursement**



# CLIA Lab

Building & maintaining stakeholder relationships

## BI+VICA® CLIA Lab

The CLIA lab approach enables direct relationships with all key shareholders, contributing to extensive market insight and building trust

### Understanding patient needs

- ⊕ Who is using DiviTum® TKa
- ⊕ Testing occurrence
- ⊕ Test results - response to therapy
- ⊕ Patient engagement



### Understanding physician needs

- ⊕ How is DiviTum® TKa used
- ⊕ Frequency and nr. of tests / physician
- ⊕ Influence on clinical decisions



### Understanding payer needs

- ⊕ Public insurance (Medicare / Medicaid)
- ⊕ Private insurance (United, Kaiser, Cigna, Anthem, etc.)
- ⊕ Hospitals / Patients








# Targeted initiatives driving access & demand

**Ongoing initiatives targeting the entirety of the value chain aim to create awareness and demand for DiviTum while streamlining the logistical process for all stakeholders**

- ⊕ Strong KOL & regional thought leader relationships
- ⊕ Collaborations with notable cancer institutions including NCI & NCCN designated institutions
- ⊕ Education of community oncologists leveraging existing relationships
- ⊕ Contracts with institutions enabling affiliated oncologists to order DiviTum
- ⊕ Commercial agreements that help in educating self insured employers
- ⊕ Face to face interactions by our field force, driving DiviTum awareness
- ⊕ Engagement at local and national society meetings
- ⊕ Engagement with patient advocacy groups
- ⊕ Biovica Cares financial assistance program
- ⊕ Participation in clinical trials, driving product adoption from institutions and oncologists

# US Reimbursement channel matrix

Reimbursement Channels	Contracted Business (Hospitals)	Public Insurance (Medicare)	Private Insurance
<b>Channel description</b>	Hospitals pay Biovica directly for patient samples tested	Claims are submitted by Biovica and are paid by Medicare	Claims are submitted by Biovica and are paid by private insurance
<b>Expected split (% of total tests)</b>	25%	50%	25%
<b>Requirements for reimbursement &amp; status</b>	<ul style="list-style-type: none"> <li>→ Internal champion (KOLs)</li> <li>→ Clinical utility</li> <li>→ Demand</li> <li>✓ <b>Contracts</b> →</li> </ul>	<ul style="list-style-type: none"> <li>✓ <b>CMS credentialed</b></li> <li>✓ <b>PLA Code</b></li> <li>→ PLA Pricing (Nov-Dec 2023)</li> </ul>	<ul style="list-style-type: none"> <li>→ Demand</li> <li>→ Clinical utility</li> <li>→ Guidelines</li> <li>✓ <b>Contract</b> →</li> </ul>
<b>Reimbursement certainty</b>	Highest degree of reimbursement certainty	High degree of reimbursement certainty	Until guideline inclusion, low / moderate degree of reimbursement certainty
<b>Ongoing reimbursement initiatives</b>	<p>Evidence generation</p> <p><b>Hospital contract</b> with leading healthcare provider in Arizona</p> <p><b>Hospital contract</b> with largest healthcare provider in Missouri</p> <p>✓ Completed → Ongoing</p>	<p>Evidence generation</p>	<p>Evidence generation</p> <p>Commercial agreements</p> <p>    </p>

# Extensive KOL network a significant driver for demand

Focused engagement with targeted medical oncologists, KOLs and cancer centers drives awareness and adoption



**100%**

Engagement with all NCI & NCCN designated cancer centers

**35%**

Conducted clinical presentations with 1500 target Oncologists

Feedback from Medical Oncologists:

*"DiviTum addresses a biomarker white space that is desperately needed to manage MBC patients"*

-NCI/NCCN Center located in the Southwest

*"Identifying non-responding patients enables clinicians to switch therapies when clinically needed"*

-NCI/NCCN Center located in the Northeast

*"Physicians will likely lengthen time between imaging for patients with low TKa values"*

-NCI/NCCN Center located in the Midwest

# Continuous expansion of clinical utility

## Enrolling prospective studies

### TK-IMPACT

#### Observational trial

HR+ mBC

First study in US where DiviTum® TKa is being used by oncologists in "real-time";  
Expected to confirm advantages compared to imaging

CDK4/6i with endocrine therapy

### Drug level study

#### Interventional trial

ER/PR+, HER- mBC

Correlate TKa levels with medication non-compliance, potential drug-drug interaction issues, and effects of medication dose reductions

CDK4/6i with endocrine therapy

## Planned prospective studies

### Early Rx switch

HR+, HER2- mBC

Assess the impact of DiviTum-TKa directed early therapeutic switching and delayed imaging

CDK4/6i with endocrine therapy

### TK-PRECISION

HR+, HER2- mBC

Personalized first-line therapy for patients with HR+, HER2- MBC using a TKa-guided approach.

CDK4/6i with endocrine therapy

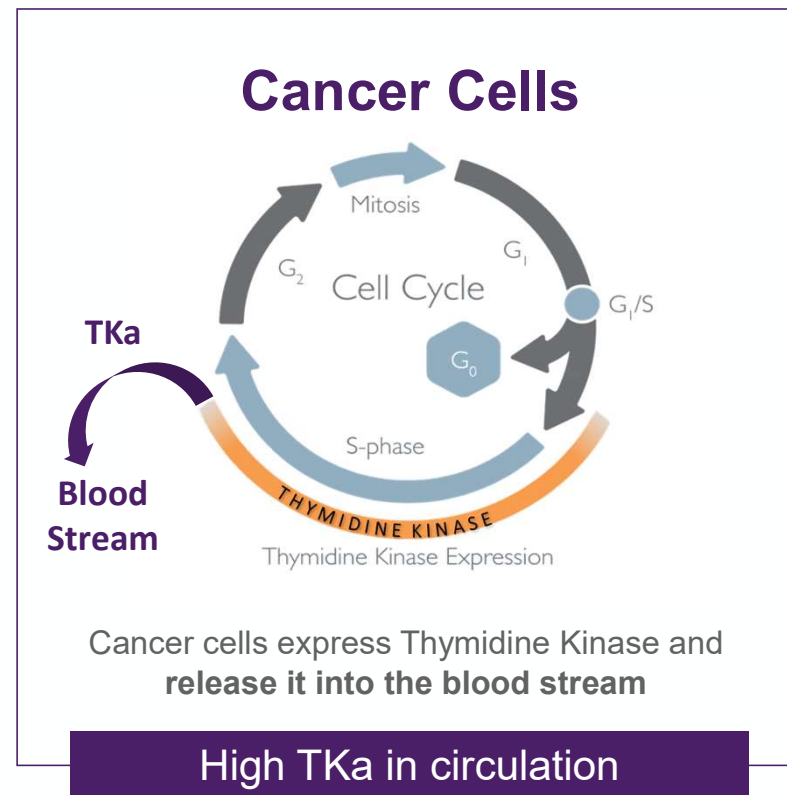
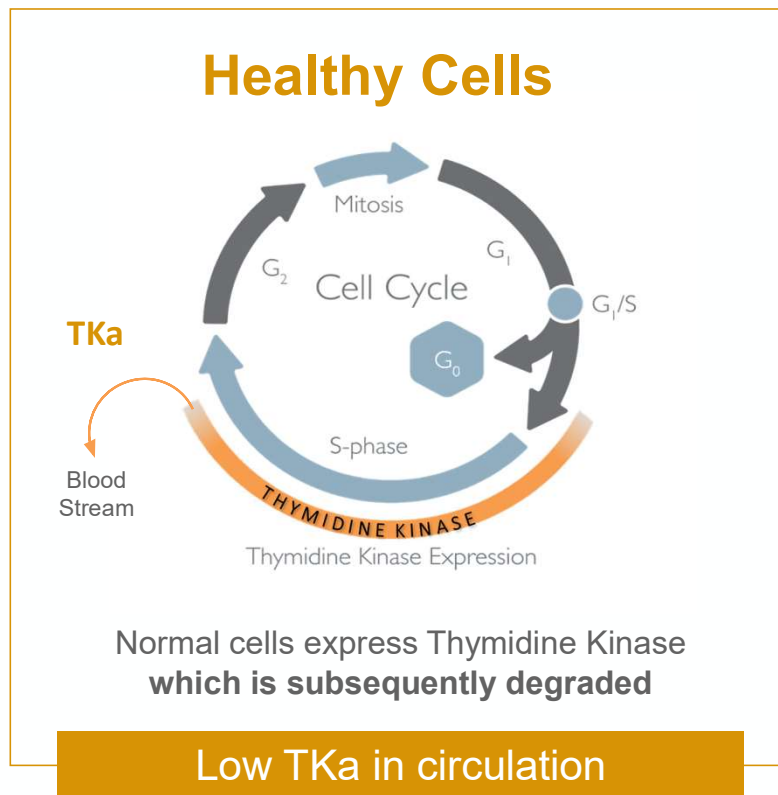


Additional  
opportunities &  
outlook











# Thymidine Kinase (TK) – a cancer-agnostic proliferation biomarker



# Potential of selected indications

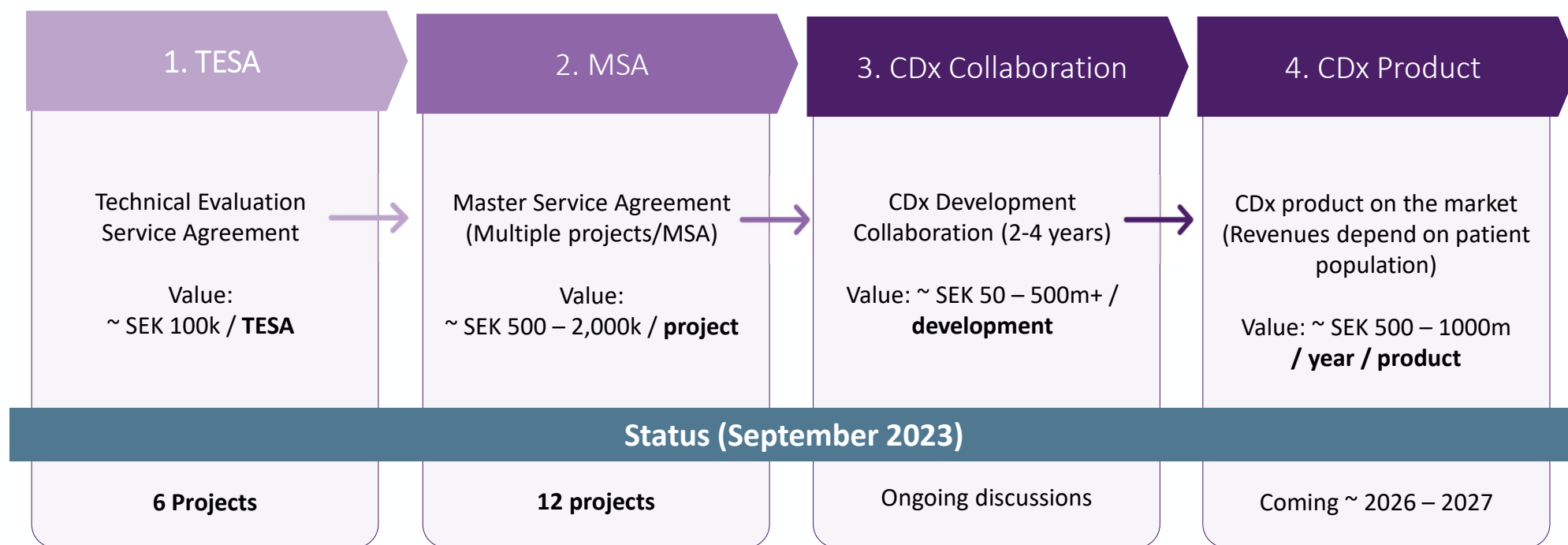
	Breast Cancer		Other Cancer Indications			CDx
	Metastatic	Locally Advanced	Metastatic Malignant Melanoma	Castrate-Resistant Prostate Cancer	Non-Small Cell Lung Cancer	Anti-proliferative drugs
Annual incidence (US, Europe)	 <b>287,850 (US)<sup>1</sup></b> <b>172,890 (EU)<sup>4</sup></b>	 <b>51,400 (US)<sup>2</sup></b> <b>34,578 (EU)<sup>4</sup></b>	 <b>610,000 (US)</b> <b>255,000 (EU)</b>	 <b>270,000 (US)</b> <b>110,000 (EU)</b>	 <b>193,055 (US)<sup>3</sup></b> <b>318,327 (EU)<sup>5</sup></b>	 <b>NA</b>
Market size (US, Europe, Japan) <sup>5</sup>	USD 400-700m / y	USD 150-300m / y	USD 1,000-1,500m / y			USD 50-100m / CDx
Nr. of studies / partnerships	<b>11</b>	<b>3</b>	<b>5</b>			<b>Pipeline: 18</b>
Stage of development	<b>Commercial</b>	<b>Clinical development</b>	<b>Clinical development</b>			<b>Ongoing</b>

Sources: 1. Breastcancer.org, 2. Cancer.net, 3. European Commission 4. Europadonna.org 5. Globocan 2020



# Pharma Collaborations / CDx

continues its strong progress with new agreements signed Q1 FY23/24



From FY22/23 YoY revenue **+65% up**  
Q1 revenue: **+200% up**

# Recent news

- ⊕ 2023-09-28: DiviTum® TKa to pursue Gap-fill process for CMS pricing decision
- ⊕ 2023-09-25: Biovica signs second agreement with leading US healthcare provider
- ⊕ 2023-09-19: Biovica signs US agreement with leading healthcare provider in Arizona
- ⊕ 2023-07-31: Biovica signs US commercial agreement with Occum Health
- ⊕ 2023-07-21: Biovica achieves PLA code for Medicare
- ⊕ 2023-06-10: Biovica signs provider contract with provider network Contigo Health ConfigureNet™
- ⊕ 2023-06-01: DiviTum® TKa results to be presented at ASCO
- ⊕ 2023-05-17: Biovica signs the first commercial agreement for DiviTum® TKa in US
- ⊕ 2023-04-04: Biovica establishes DiviTum® TKa commercialization partnership in Italy
- ⊕ 2023-03-28: Biovica signs DiviTum® TKa commercial partner agreement for Dutch and Polish markets
- ⊕ 2023-02-08: Biovica receives CLIA certification
- ⊕ 2023-01-31: DiviTum® TKa clinical validation data published in Biomarkers
- ⊕ 2022-12-07: Biovica International announces outcome of the rights issue
- ⊕ 2022-12-01: Biovica establishes experienced US sales team

# Board of Directors



**Lars Holmqvist**  
*Chairman*

Holdings:  
659,436 B-shares,  
100,000 warrants



**Marie Louise Fjällskog**  
*Board Member*

Holdings:  
45,000 warrants



**Jarl Ulf Jungnelius**  
*Board Member*

Holdings:  
75,000 warrants



**Maria Holmlund**  
*Board Member*

Holdings:  
15,600 B-shares,  
75,000 warrants



**Annika Carlsson Berg**  
*Board Member*

Holdings:  
50,000 warrants



**Anders Rylander**  
*Board Member & CEO*

Holdings:  
3,575,640 A-shares,  
1,562,074 B-shares,  
90,000 warrants



**Jesper Söderqvist**  
*Board Member*

Holdings:  
41,085 A-shares,  
61,120 B-shares,  
75,000 warrants

# Management Team



**Anders Rylander**  
*CEO*  
Holdings:  
3,575,640 A-shares,  
1,562,074 B-shares,  
90,000 warrants



**Anders Morén**  
*CFO*  
Holdings:  
23,000 B-shares



**Helle Fisker**  
*VP Commercial Europe*  
Holdings:  
18,700 B-shares,  
20.000 warrants



**Warren Cresswell**  
*President Americas*  
Holdings:  
100.000 warrants



**Hanna Ritzén**  
*COO*  
Holdings:  
1,500 B-shares



**Henrik Winther, Ph.D.**  
*SVP Business Development*  
Holdings:  
32.000 B-shares,  
20,000 warrants



**Joakim Arwidson**  
*VP Regulatory & QA*  
Holdings:  
1,020 B-shares,  
20.000 warrants

# Shareholders, financials & financial calendar

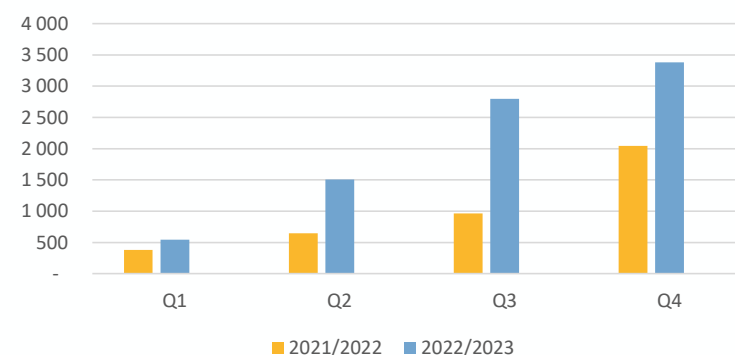
## Shareholder list as of August 2023

Name	Nr. of shares	Capital	Votes
Anders Rylander	5,137,714	11.23%	21.08%
Avanza Pension	3,491,203	7.63%	5.99%
Gunnar Rylander	2,085,225	4.56%	6.77%
Nordnet Pension Insurance	1,243,756	2.72%	2.13%
Mattias Sesemann	1,050,000	2.30%	1.80%
Max Mitteregger	865,000	1.89%	1.48%
Henrik Osvald	739,714	1.62%	1.27%
Lars Holmqvist	659,436	1.44%	1.13%
Gunvald Berger	543,428	1.19%	0.93%
Mats Danielsson	533,948	1.17%	0.92%
<b>Total 10</b>	<b>16,349,424</b>	<b>35.74%</b>	<b>43.52%</b>
Others	29,391,970	64.26%	56.48%
<b>Total number of shares</b>	<b>45,741,394</b>	<b>100%</b>	<b>100%</b>

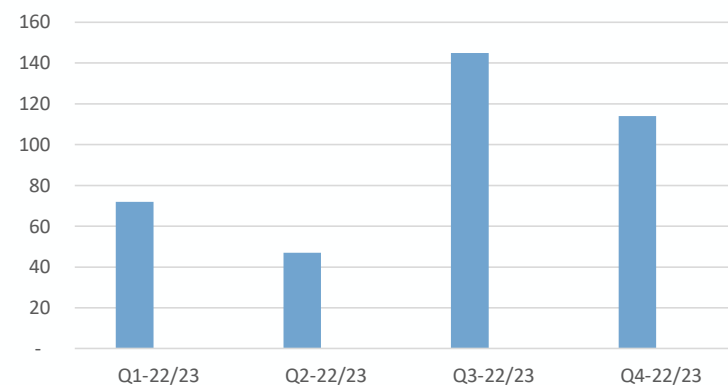
## Financial calendar

Interim Report Q1 2023/2024	6 September 2023
Interim Report Q2 2023/2024	15 December 2023
Interim Report Q3 2023/2024	14 March 2024
Interim Report Q4 2023/2024	18 June 2024

## Accumulated Net Sales SEK 000

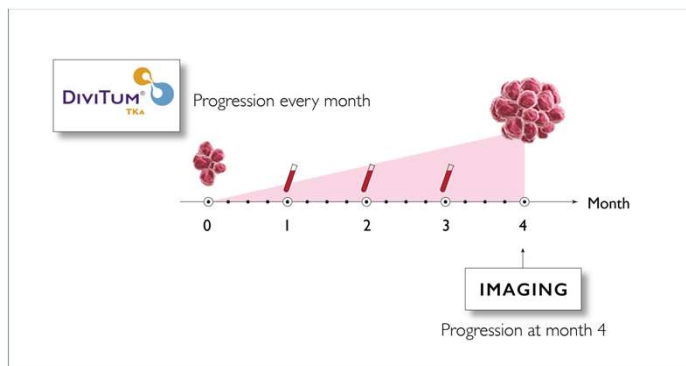


## Cash balance SEK Millions



# Summary & Milestones

- ⊕ Measures cell proliferation from a simple blood sample
- ⊕ DiviTum® TKa addresses an important clinical unmet need
- ⊕ DiviTum® TKa is supported by cancer KOL's and scientific collaborators globally
- ⊕ Market potential > \$2 billion for monitoring of metastatic cancer (key indications on key markets)



## Upcoming Milestones:

- ⊕ **US milestones**
  - ⊕ **2023:** CLIA Lab Certification ✓, PLA Code ✓ & agreements with payers ✓ & US hospitals ✓
  - ⊕ **2024:** Medicare reimbursement specific code & price
  - ⊕ **2026:** 15% of market potential realized
- ⊕ **Europe milestones**
  - ⊕ **2023:** First agreement ✓, additional to come
  - ⊕ **2023-25:** Agreement(s) in rest EU-5 + Nordics
  - ⊕ **2026:** 15% of market potential realized (three years after launch)
- ⊕ **Pharma Services /CDx**
  - ⊕ **FY2023-24:** Significant revenue growth
  - ⊕ Agreements/projects beyond the current 18
  - ⊕ **Contract development:** establish first CDx development contract





# Biovica® Overview

- ⊕ Founded in 2009, based on research from Uppsala University
- ⊕ IPO 2017, traded on Nasdaq First North Premier (Ticker: BIOVIC B)
- ⊕ HQ in Uppsala, CLIA lab and offices in San Diego
- ⊕ Regulatory: ISO 13485 certified
- ⊕ DiviTum® TKa CE marked & FDA 510(k) cleared





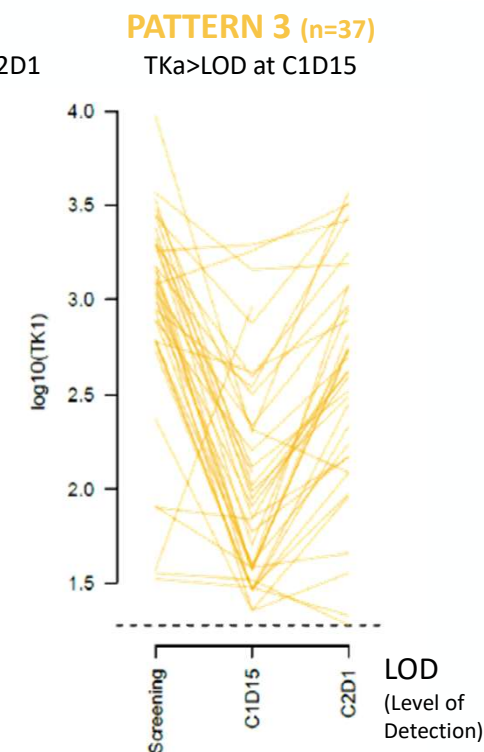
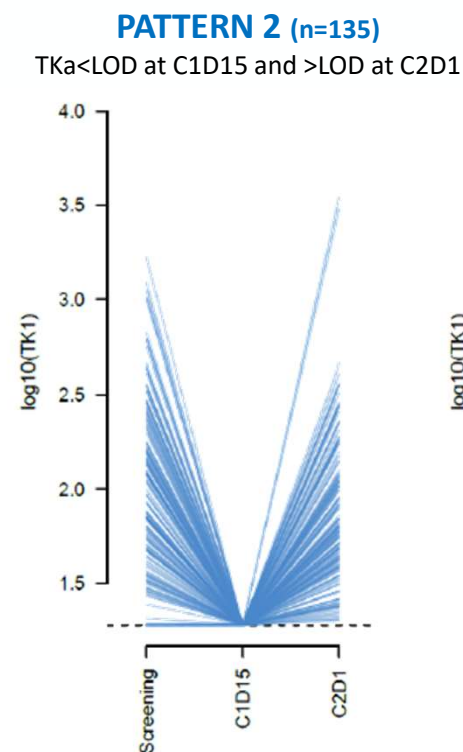
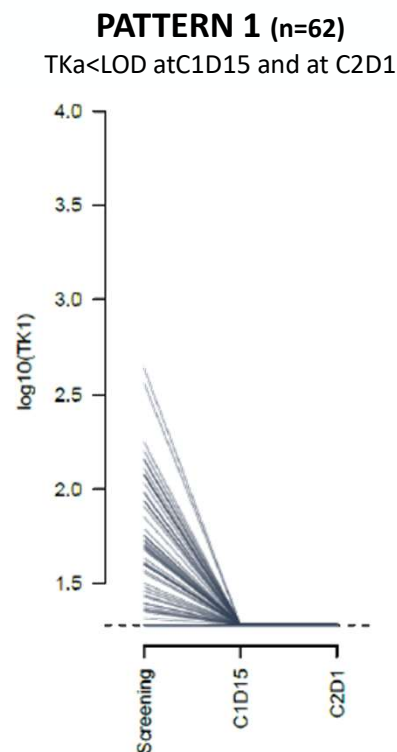
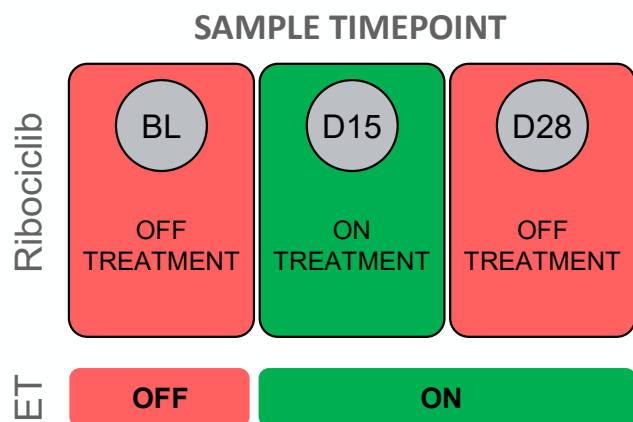


## Appendix



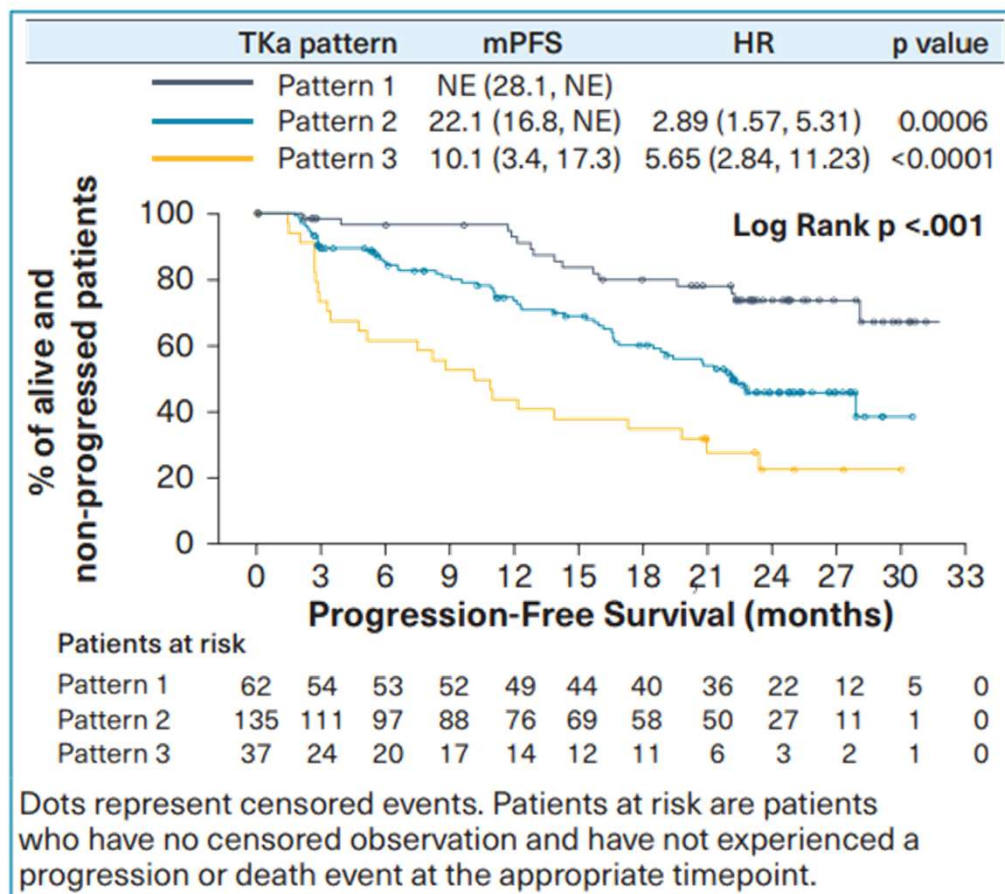
# BioltaLEE Data Shows 3 Distinct TKa Patterns

- 287 HR+ Her2- mBC patients
- 1<sup>st</sup> line therapy with ribociclib + letrozole
- TKa analyzed at BL, C1D15, C2D1, the on-treatment TKa values were used to identify patterns



Malorni et al, ESMO 2021 poster 292P

# TKa Patterns Correlate with Patient Outcome



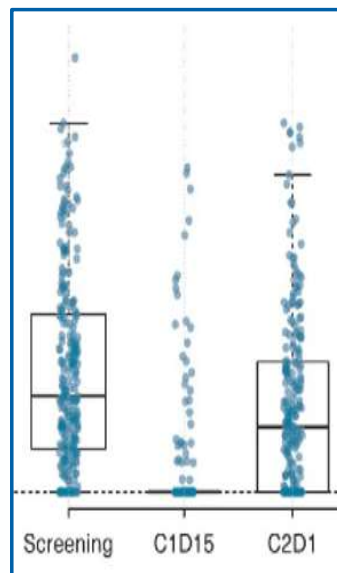
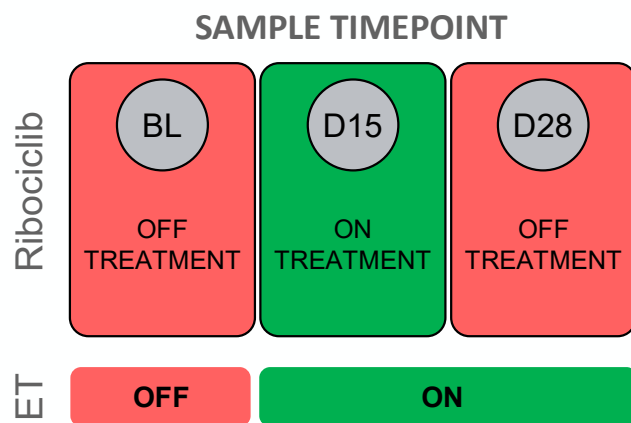
Pattern 1: TKa <LOD at D15 and C2D1

Pattern 2: TKa <LOD at D15 and >LOD at C2D1

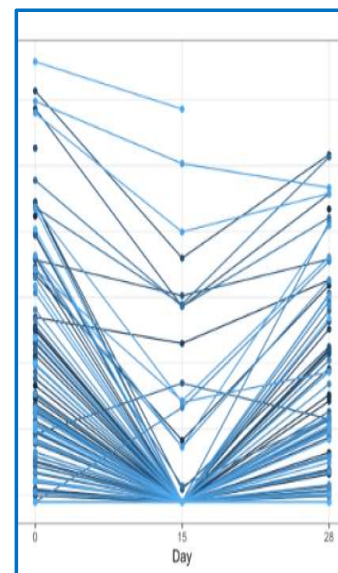
Pattern 3: TKa >LOD at D15 and C2D1

# Consistent TKa patterns across trials

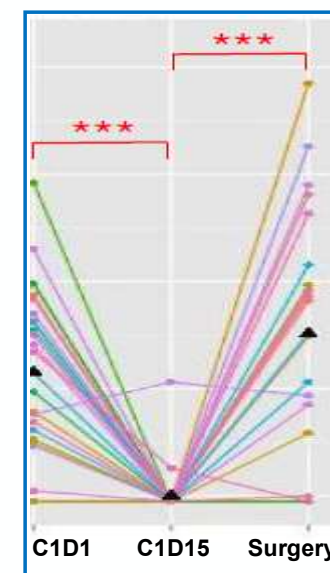
	BioltaLEE (n=287)	PYTHIA (n=108)	NeoPalAna (n=43)
% BELOW LOD on C1D15	85%	83%	86%
NO REBOUND on D28	31%	45%	32%
REBOUND on D28	69%	55%	68%



Malorni, ESMO 2021 poster 292P



Malorni, EJC 164: 39-51, 2022

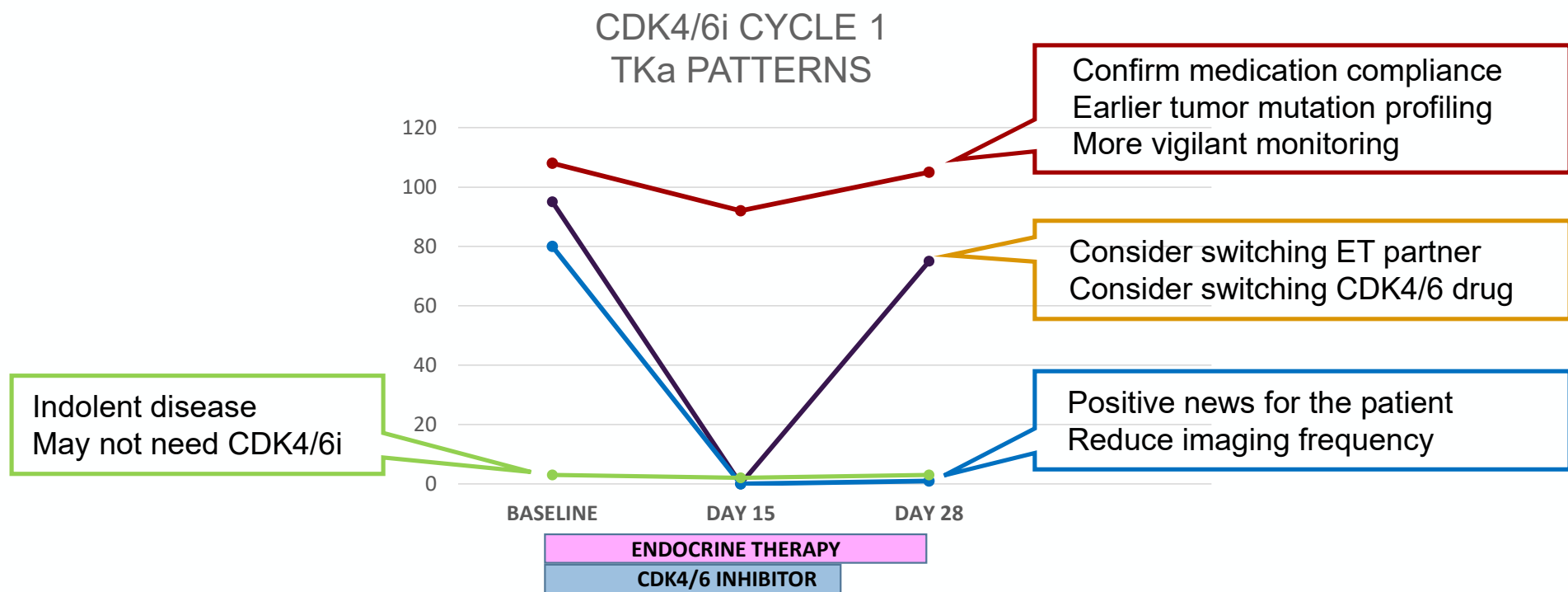


Bagegni, BCR (2017) 19:123



# Utility of DiviTum-TKa in Clinical Practice

Prediction of CDK4/6i response based on cycle 1 TKa pattern





**BI+VICA®**  
TREATMENT DECISIONS WITH GREATER CONFIDENCE™

A decorative graphic consisting of numerous small circles, each containing a plus sign (+). These circles are arranged in a sparse, non-uniform pattern across the entire slide, with a higher concentration on the left and right sides. One circle in the upper left quadrant is highlighted with a blue border and a white plus sign, while all other circles have a light gray border and a gray plus sign.

# Treatment Decisions With Greater Confidence™

**Blood-based test measures cell proliferation reflecting  
cancer progression**