

A microscopic image of cells, likely cancer cells, is visible in the background. The cells are shown in various stages of division and are characterized by their irregular, textured surfaces and fibrous structures. The image is in grayscale and has a soft, out-of-focus appearance, serving as a background for the text.

BIOVICA

Treatment Decisions With Greater Confidence

2022-06-20--21

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.

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About us

Anders Rylander, CEO & Board Member

- Main shareholder in Biovica
- Co-founder of Axholmen AB
- CTO at ICA AB
- Senior Manager at Accenture



Cecilia Driving, EVP CFO

- Board member & chair audit committee Ovzon AB
- CEO RISE Research Institutes of Sweden AB
- CFO MedCap AB
- CFO Diamyd Medical
- CFO & Legal Mando AB



Agenda

1. Company & Product Overview
2. Clinical Evidence & Collaborations
3. Market
4. Team
5. Summary

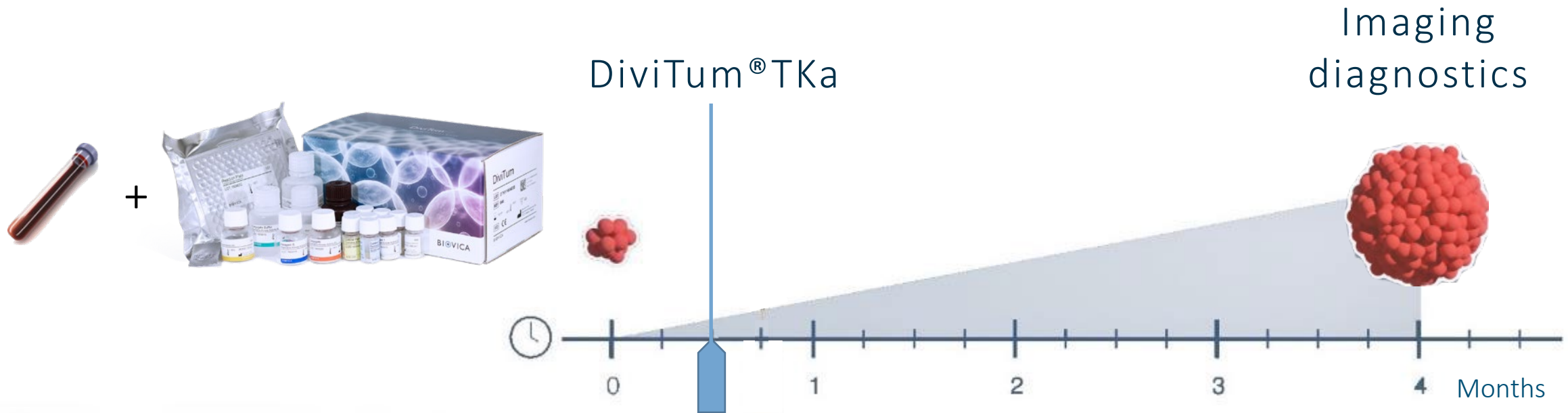


Biovica Overview

- Founded 2009, based on research performed at Uppsala University
- IPO 2017, traded on Nasdaq First North Premier
- HQ in Uppsala, lab in San Diego
- Regulatory: ISO 13485 certified and DiviTum® TKa CE labeled
- FDA 510(k) submission Q3 2020



DiviTum®TKa Provides Early Response Indicator of the Effectiveness of Treatment For Cancer Patients



DiviTum®TKa measures cell proliferation rate for faster evaluation of cancer treatment efficacy.






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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



Collaborations with Key Opinion Leaders

- selected from ongoing or completed clinical trials



Matthew P. Goetz

*M.D , Professor
Mayo Clinic*



Daniel F. Hayes

*M.D, Professor
University of Michigan
Ex. ASCO President
SWOG Transl. Med.*



Cynthia X. Ma

*M.D, Professor
Washington University*



Geoffrey Shapiro

*M.D, Ph.D , Professor
Dana-Farber Cancer
Institute*



Matthew J. Ellis

*M.D, Professor
Baylor Collage*



Gabriel N. Hortobagyi

*MD, FACP, Professor
MD Anderson Cancer Center
Ex ASCO President*



Luca Malorni

*M.D, Ass. Professor
Hospital of Prato
Baylor Collage*



Jonas Bergh

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



Thomas Hatschek

*M.D, PhD
Karolinska Institutet*



Martine J. Piccart

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



Sacha Howell

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



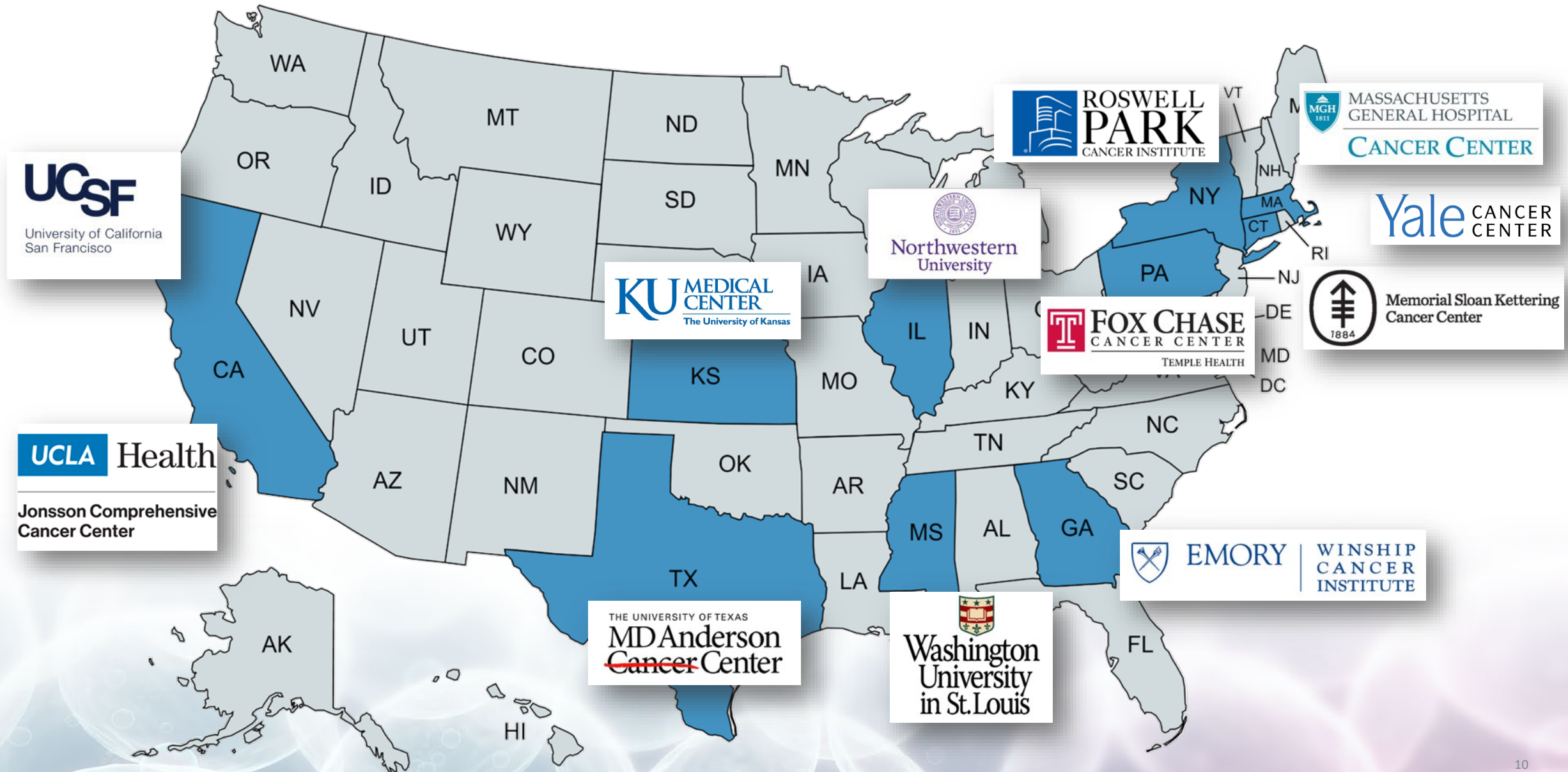
Amelia McCartney

*BSc BA (Hons) MBBS FRACP
Hospital of Prato
Monash Health, Melbourne*

Support from leading KOL's is a critical success factor for clinical acceptance!

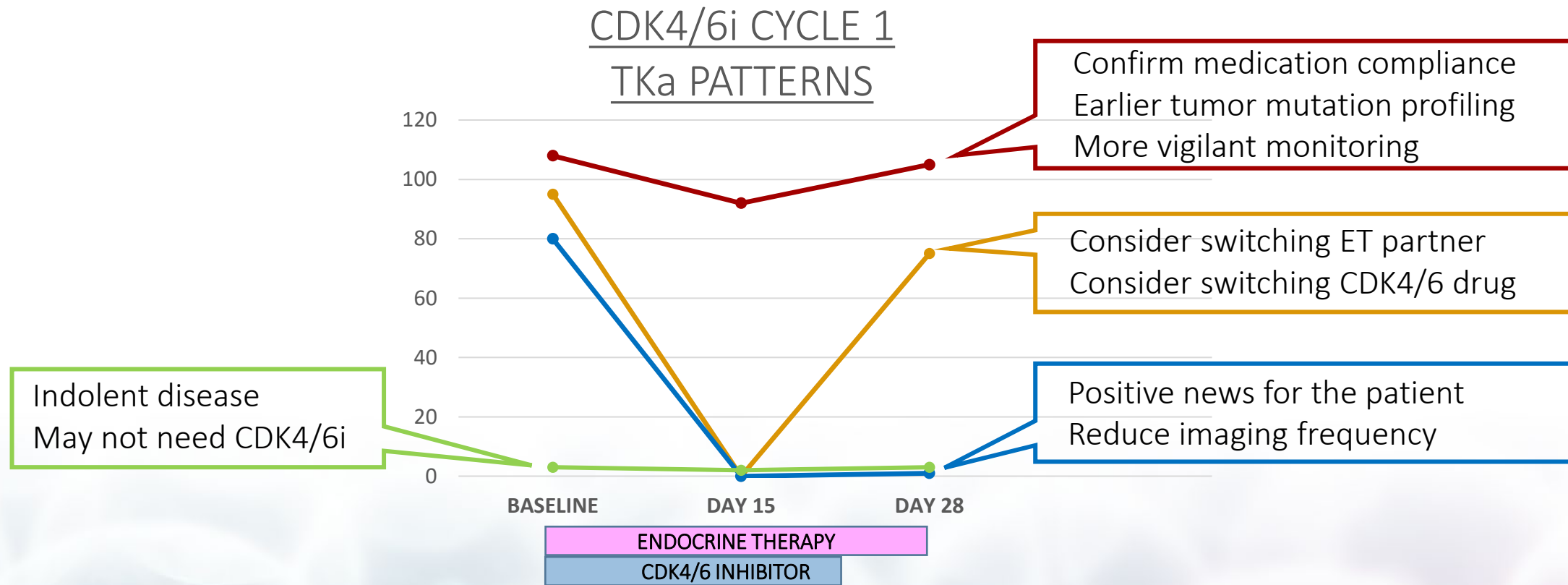
Scientific Advisory Boards (USA) during 2021

BI+VICA



Utility of DiviTum-TKa in Clinical Practice

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



DiviTum®TKa results from PYTHIA published in EJC

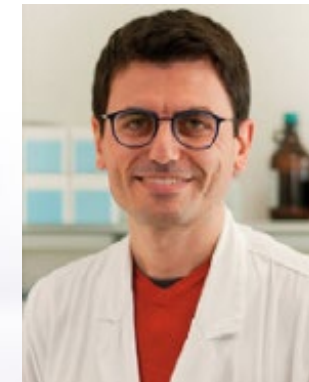
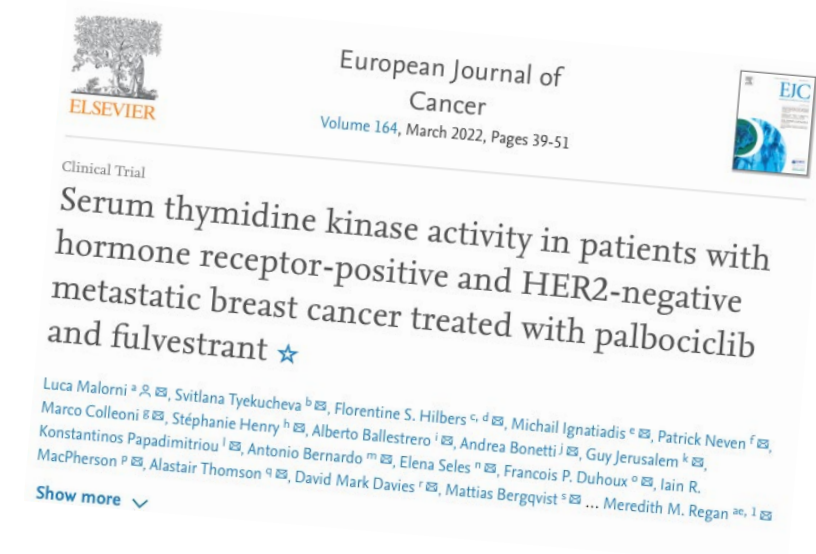
Summary:

- 122 patients, metastatic breast cancer, CDK4/6i treatment
- Patients that had low DiviTum®TKa-result two weeks into treatment, had significantly better progression free survival after six months (85% vs 17%)
- DiviTum® may be used as a novel biomarker to select patients for alternative treatment modalities.

“The results support that serum TK activity can be a biomarker to identify those patients who will have an adverse outcome to the treatment with fulvestrant in combination with palbociclib, which represents the most current and active treatment standard for patients with metastatic, endocrine resistant estrogen receptor positive and HER2 negative breast cancer.

TK activity measured after only two weeks of therapy gives us a strong indication on the clinical outcome independently from other clinical parameters. Even though further investigation in prospective comparative trials is warranted, these results are highly encouraging and highlight the potential of DiviTum®TKa to evaluate treatment efficacy already during the first weeks of therapy, and afterwards to monitor the disease.”

Luca Malorni, Principal Investigator of the study at Prato Hospital, Italy



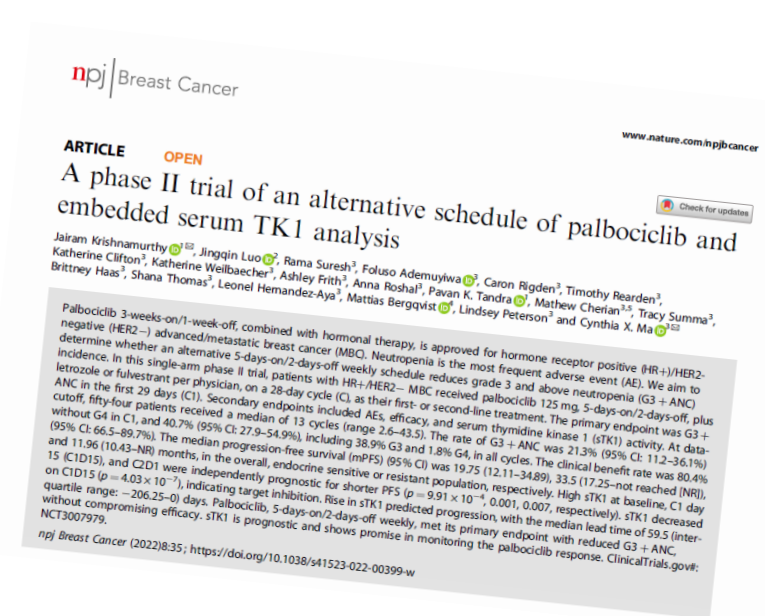
Positive DiviTum®TKa results published in npj Breast Cancer (a Nature publication)

Summary:

- 51 patients, metastatic breast cancer, CDK4/6i treatment
- Responders had significantly lower baseline Tka
- DiviTum®TKa predicted disease progression 83 days in median ahead of imaging

“The results from our study support using DiviTum®TKa to monitor efficacy during treatment and predict response to palbociclib, a standard therapy for women with metastatic breast cancer. It is interesting to learn that DiviTum®TKa can identify progression many months ahead of imaging”

Jairam Krishnamurthy, Principal Investigator of the study at Division of Oncology/Hematology, University of Nebraska Medical Center.





Circulating tumor DNA and serum thymidine kinase 1 activity matched dynamics in patients with hormone receptor–positive, human epidermal growth factor receptor 2–negative advanced breast cancer treated in first-line with ribociclib and letrozole in the BioltaLEE trial

Grazia Arpino¹, Giampaolo Bianchini², Luca Malorni³, Alberto Zambelli⁴, Fabio Puglisi⁵, Lucia Del Mastro⁶, Marco Colleoni⁷, Filippo Montemurro⁸, Giulia Valeria Bianchi⁹, Ida Paris¹⁰, Giacomo Allegrini¹¹, Stefano Tamberi¹², Marina Elena Cazzaniga¹³, Michele Orditura¹⁴, Claudio Zamagni¹⁵, Donatella Grasso¹⁶, Matteo Benelli¹⁷, Maurizio Callari¹⁸, Antonina Benfante¹⁶, Michelino De Laurentiis¹⁹

¹Department of Medical Clinics and Surgery, Università Federico II, Napoli, Italy; ²Department of Medical Oncology, Ospedale San Raffaele, Milano, Italy; ³Department of Oncology and Translational Research Unit "Sandro Pitigliani", Ospedale di Prato, Azienda USL Toscana Centro, Prato, Italy; ⁴U.S.C. Oncologia, Presidio Ospedaliero Papa Giovanni XXIII, Bergamo, Italy; ⁵S.O.C. Oncologia Medica e Prevenzione Oncologica, IRCCS, Centro di Riferimento Oncologico, Aviano, Italy; ⁶U.O.S.D. Breast Unit, IRCCS Ospedale Policlinico San Martino, Genoa, Italy; ⁷Senologia Medica, IEO, Istituto Europeo di Oncologia, IRCCS, Milano, Italy; ⁸Istituto di Candiolo, FPO, IRCCS, Candiolo, Torino, Italy; ⁹SC Oncologia Medica 1, Fondazione IRCCS Istituto Nazionale Tumori Milano, Milan, Italy; ¹⁰Department of Woman and Child Sciences, Fondazione Policlinico Universitario Agostino Gemelli, IRCCS, Rome, Italy; ¹¹U.O.C. Oncologia Medica, Presidio Ospedaliero Livorno, Livorno, Italy; ¹²U.O. Oncologia, P.O. Ospedale degli Infermi – AUSL, Ravenna, Italy; ¹³Phase 1 Research Unit & Oncology Unit, Azienda Socio Sanitaria Territoriale Monza & Milano Bicocca School of Medicine and Surgery, Monza, Italy; ¹⁴U.O.C. Oncologia Medica e Ematologia, A.O.U. Università Degli Studi L. Vanvitelli, Napoli, Italy; ¹⁵IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy; ¹⁶Oncology, Novartis Farma SpA, Origgio, Italy; ¹⁷Department of Oncology and Bioinformatics Unit, Ospedale di Prato, Azienda USL Toscana Centro, Prato, Italy; ¹⁸CRUK Cambridge Institute, University of Cambridge Li Ka Shing Centre, Cambridge, United Kingdom; ¹⁹IRCCS Istituto Nazionale Tumori Fondazione G Pascale, Napoli, Italy

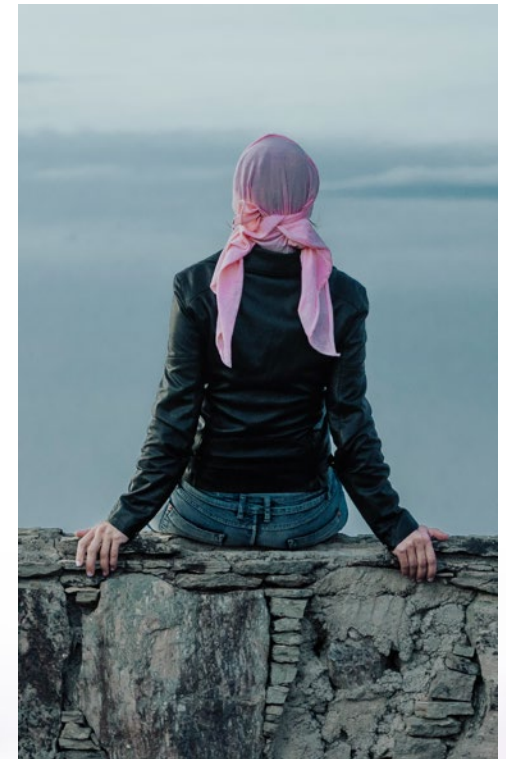
TKa and ctDNA were the Chosen Blood-based Biomarkers for the BioltaLEE Study Design

- Phase IIIb single treatment study sponsored by Novartis and conducted at 47 Italian cancer centers
- 287 patients enrolled (241 patients with blood samples)
- HR+ metastatic breast cancer patients were treated with 1st line ribociclib + letrozole
- Goal of the study was to identify blood-based biomarkers that can predict how well a patient will do when treated with ribociclib
- Blood samples were drawn at baseline, day 15, and cycle 2 day 1
- Two biomarkers were analyzed independently by Novartis and the study investigators
 - ctDNA using a 533-amplicon Custom AmpliSeq HD Panel (39 BC-related genes) by Illumina
 - TK activity analyzed by DiviTum®TKa

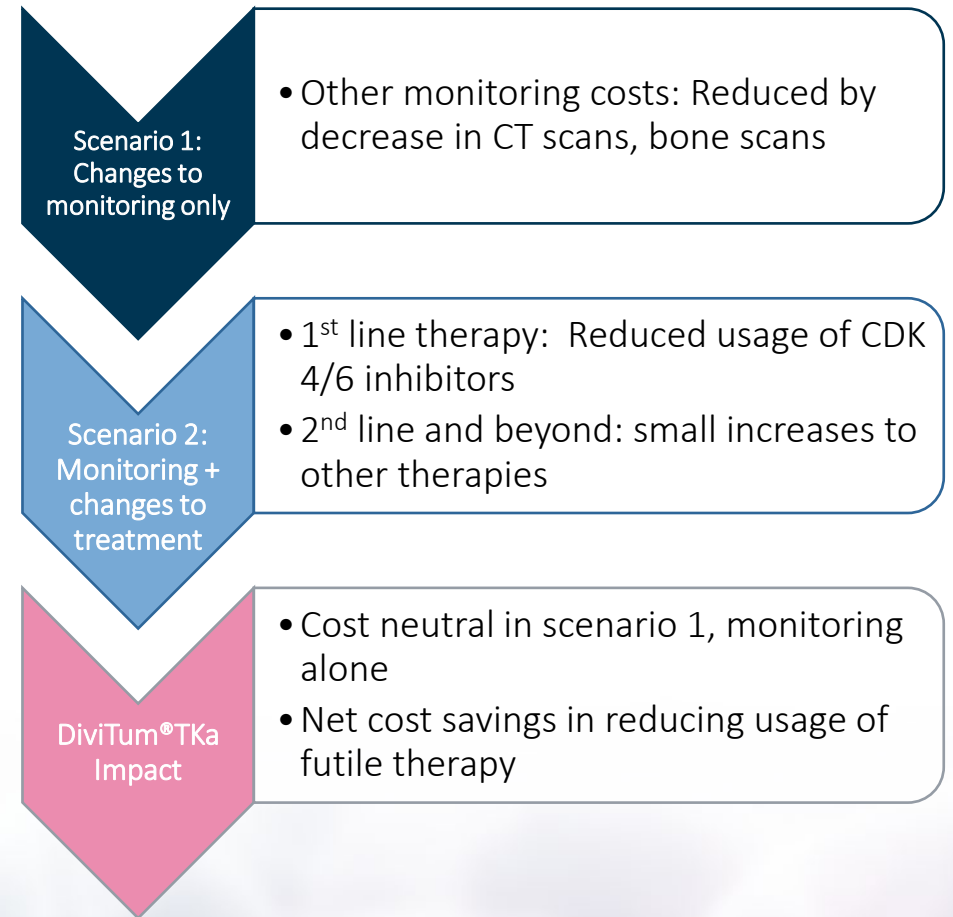
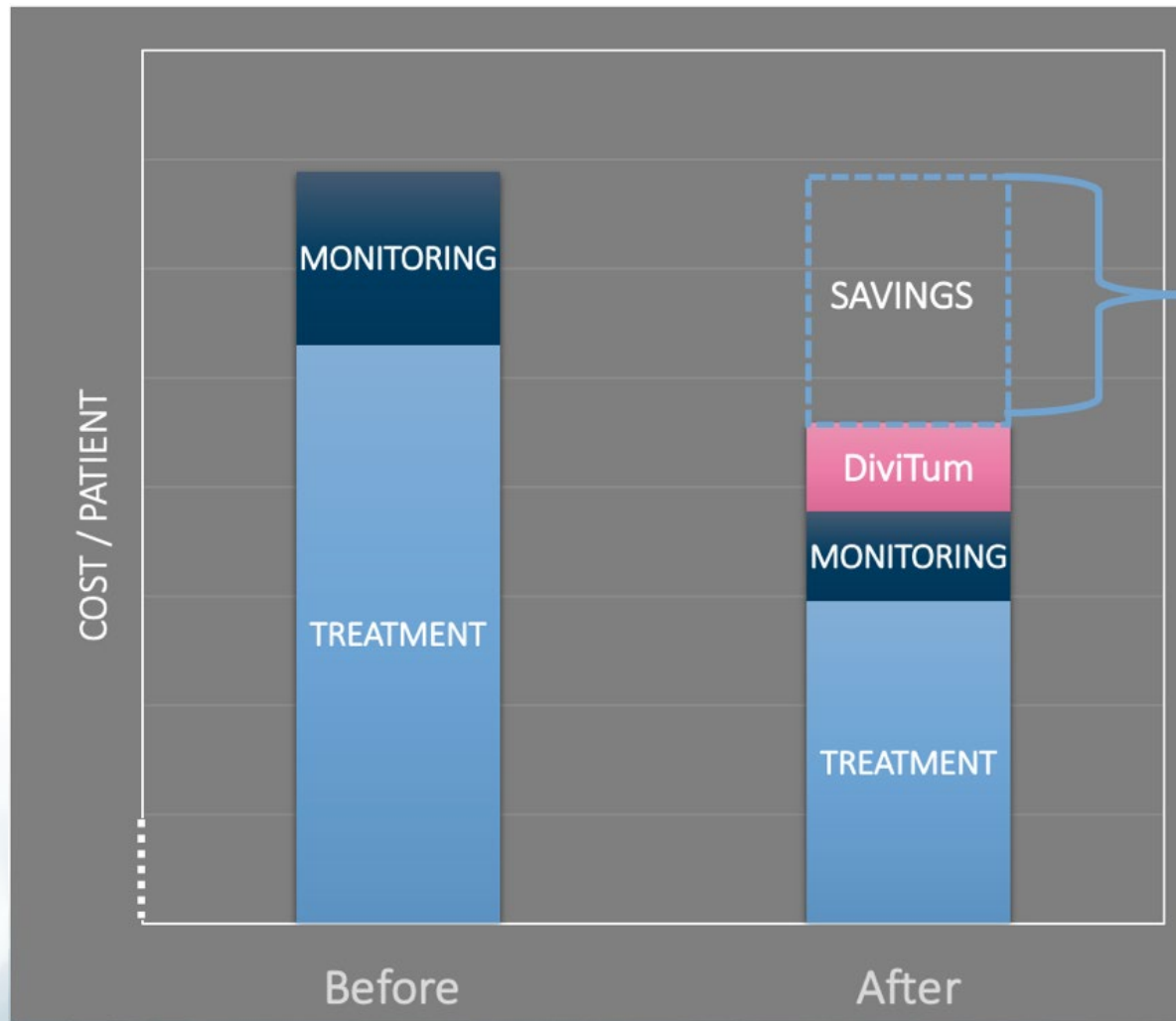


Conclusions

- Baseline samples:
 - ctDNA and TKa are independently able to predict outcome for ribociclib + letrozole patients equally well
- On-treatment samples:
 - TKa dynamic patterns were better able to stratify patients according to outcome versus ctDNA dynamic patterns alone
- Combined on-treatment samples analysis:
 - TKa and ctDNA combined data show better correlation with outcome in patients not likely to respond to ribociclib + letrozole versus either biomarker alone
- This further strengthens the evidence for DiviTum®TKa as a valuable biomarker for prediction and monitoring of CDK4/6i treatment response for metastatic breast cancer patients!



Budget Impact Model Results: Addition of DiviTum®TKa to Care Would Lead to Net Savings of 3x the Spend



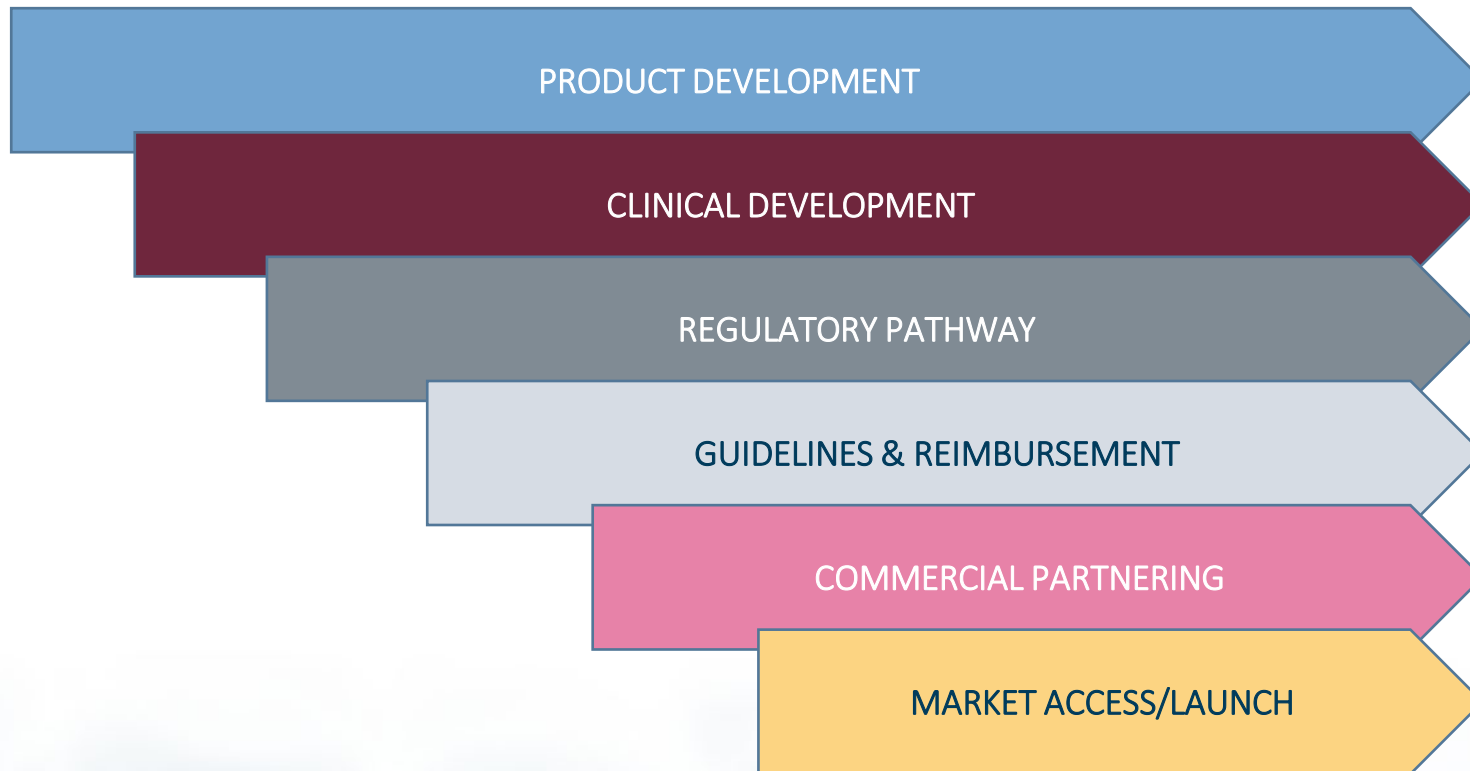
Strongly positive health economics for DiviTum®TKa with pricing modelled at \$400/test

Agenda

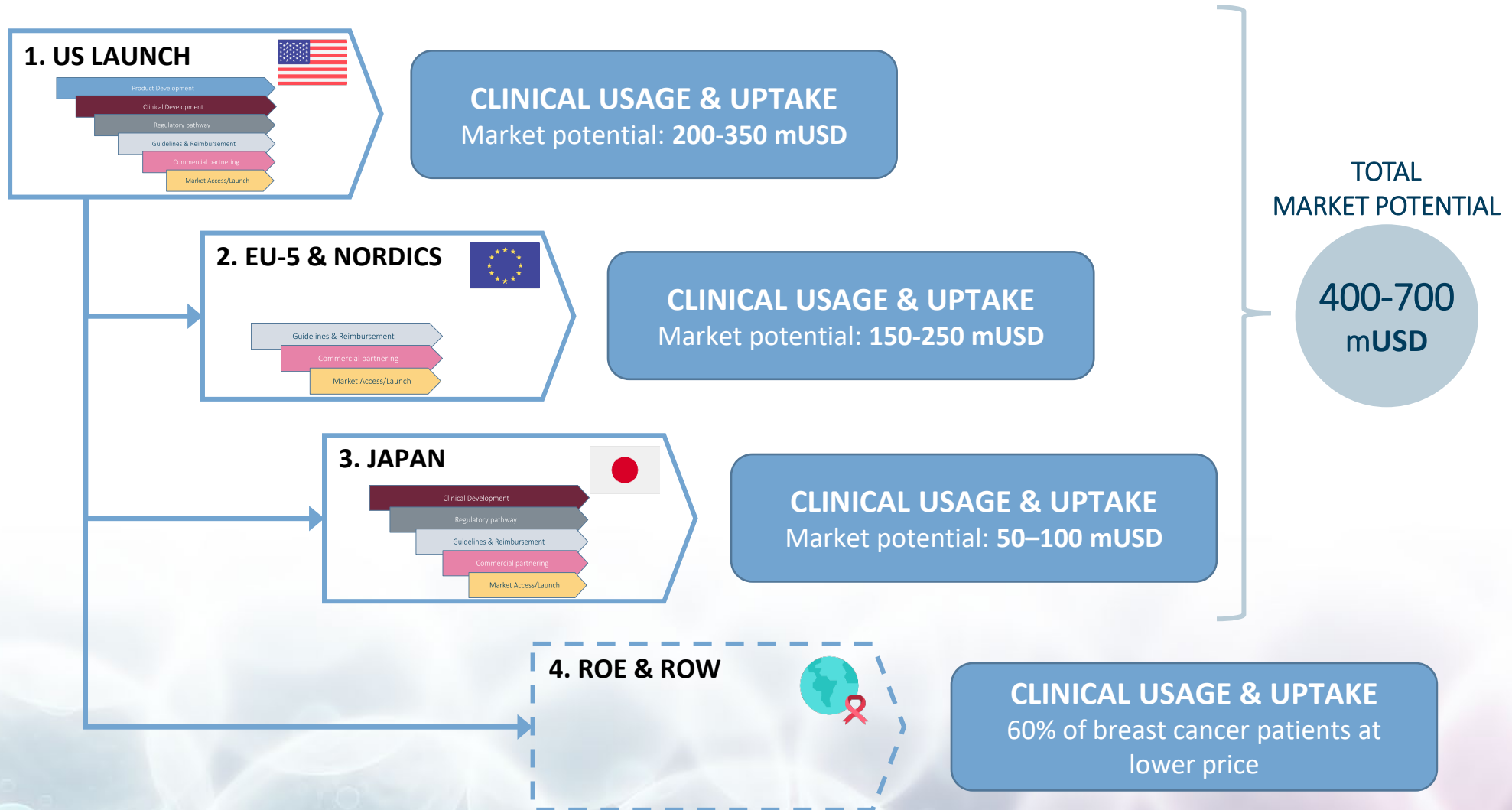
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DiviTum®TKa – Key Commercialization Activities



Geographical Roll-out Plan & Market Potential for DiviTum®TKa in Metastatic Breast Cancer



Biovica Commercial Roadmap

Legend

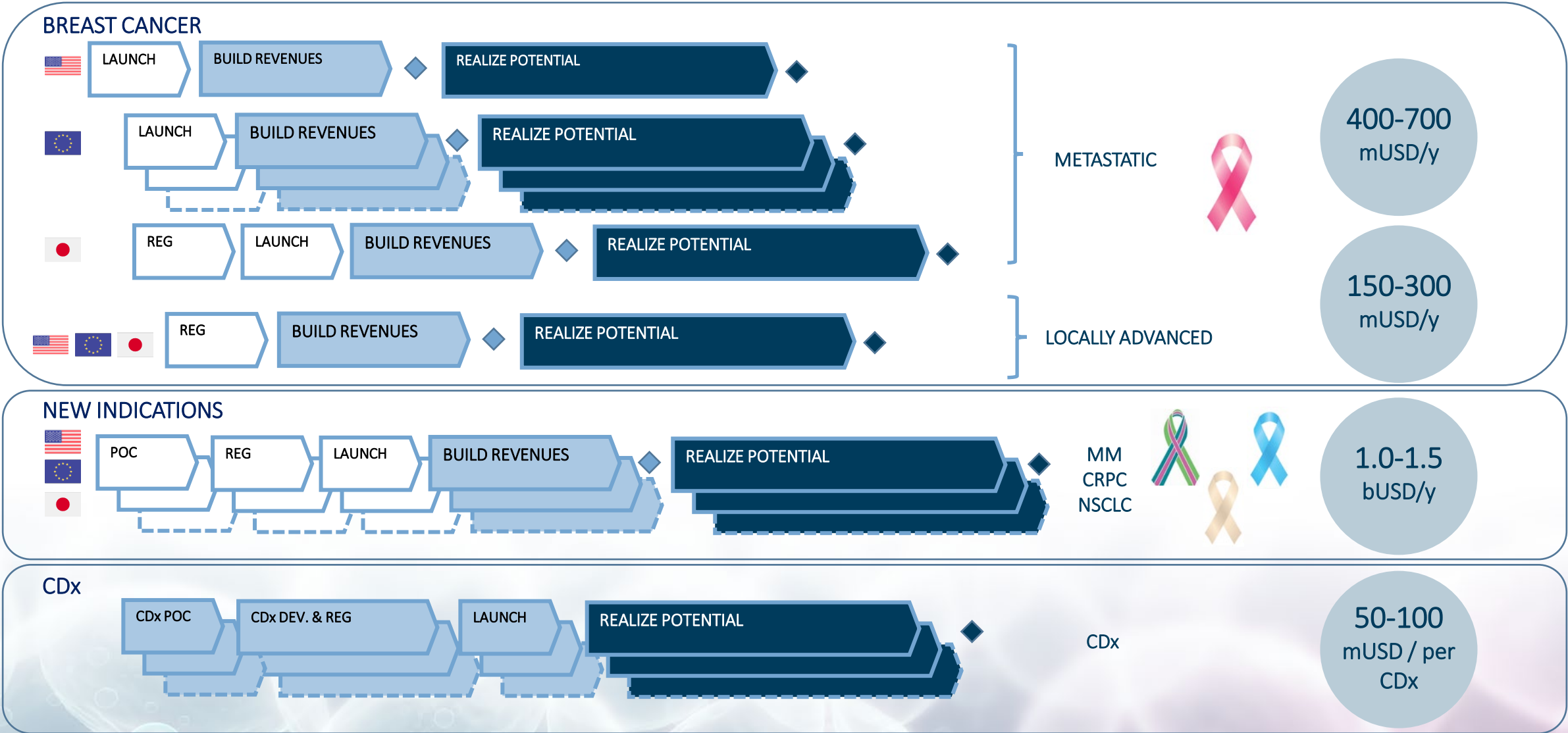
◆

 15% of market potential

◆

 50% of market potential

MARKET POTENTIAL



Pharma Have Identified TKa as a Highly Relevant Tool for the Development of Cell Proliferation Inhibitor Drugs

Pharma-partner	Indication(s)	Drug (Rx)	Rx Study Phase	Agreement
1. TIER-2 ² pharma (EU)	mBC (HR+, HER2÷). Patients resistant to CDK4/6i treatment.	CDK-inhibitor.	Phase IIa. Phase IIb. FDA fast track designation.	TESA ³
2. TIER-2 ² pharma (US)	mBC (HR+)	CDK-inhibitor	Phase I/II. Dose-escalation.	TESA ³ → MSA ⁴
3. TIER-2 ² pharma (US)	mBC and other solid tumors	CDK-inhibitor	Phase I	MSA ⁴
4. TIER-2 ² pharma (US)	Solid tumors	CDK-inhibitor	Phase I	RSA ⁵ /MSA ⁴
5. TIER-2 ² pharma (US)	Solid tumors	Rx's targeting key drivers of cancer cell growth	Phase I	KSA ⁶ →
6. TIER-1 ¹ pharma (EU/US)	Breast, prostate and ovarian cancers	CDK-inhibitor	Phase I	KSA ⁶
7. TIER-2 ² pharma (US)	mBC (HR+), other solid tumors	CDK-inhibitor	Phase I/IIa	KSA ⁶

¹TIER-1: Large-sized Pharma; ²TIER-2: Mid-sized Pharma

³TESA: technical Evaluation Service Agreement; ⁴MSA: Master Service Agreement; ⁵RSA: Research Service Agreement; ⁶KSA: Kit Supply Agreement

Experienced US team in place for a successful commercialization in US!

Warren Cresswell

President of Biovica Americas

25-years of Diagnostic Experience in Medical Device (IVD 510(k) & PMA), CLIA Lab (LDT) Pharma.

Built Dx Orgs, Developed & Launched High Value Multi-Analyte Algorithm Based Dx Assays, and Implemented Effective Reimbursement Strategies.



Kendon Richards

Executive Director of Sales

25+ years of Pharmaceutical and Specialty Diagnostic Experience



Dan Kiser

Quality, Regulatory & Lab Operations

25-years Regulatory & Operations in CLIA, IVD, Medical Device & Pharma



Amy Williams, PhD

Head of Clinical Development & Medical Affairs

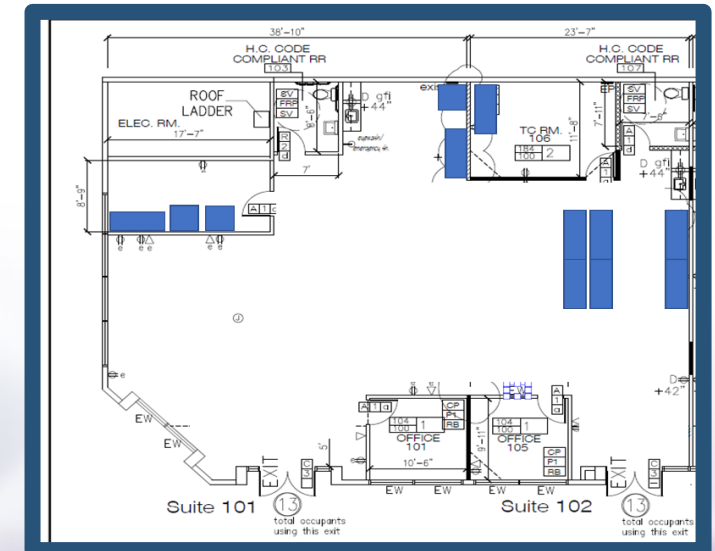
20+ years of experience in oncology drug development

CMD @ <https://biovica.com/investor-relations/events/>

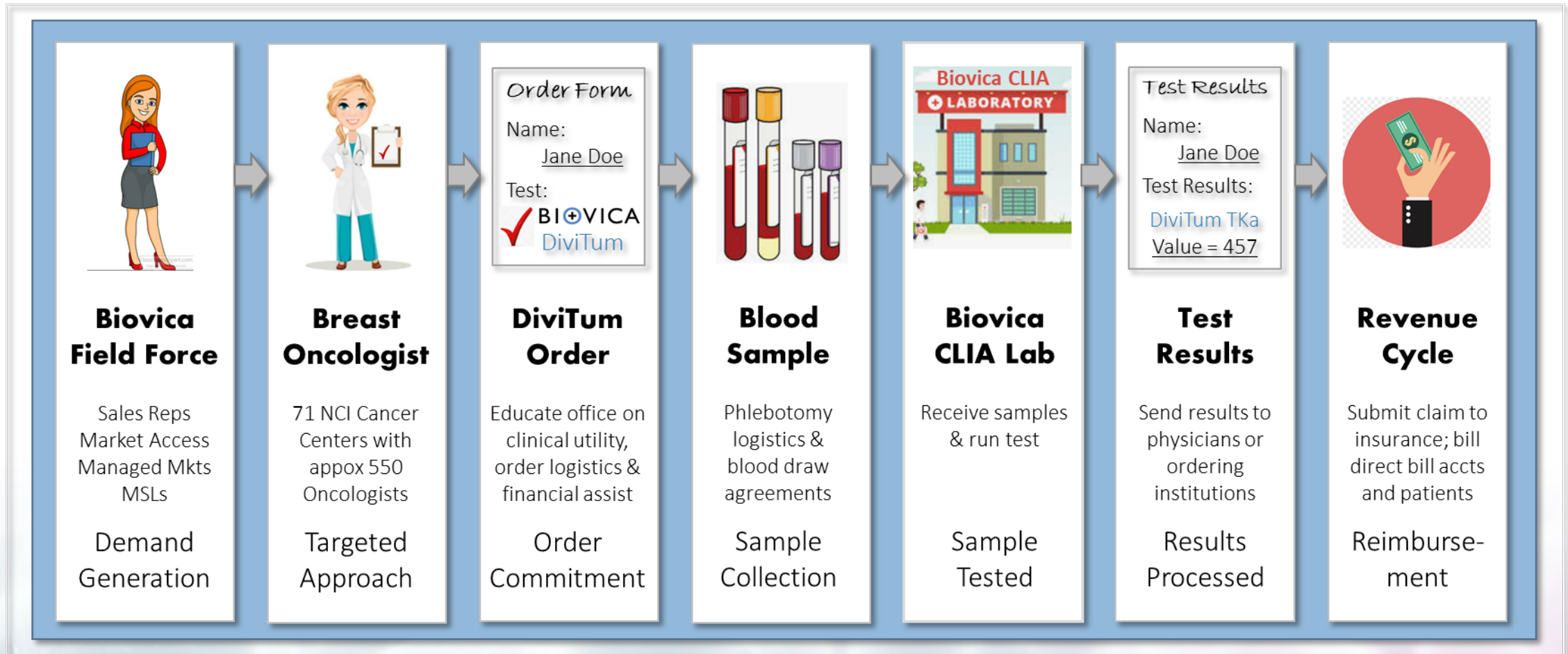
Successful High Value Dx Companies Follow the CLIA Lab Go-To-Market Strategy

Managing *critical success factors* position the company for long-term sustainable growth:

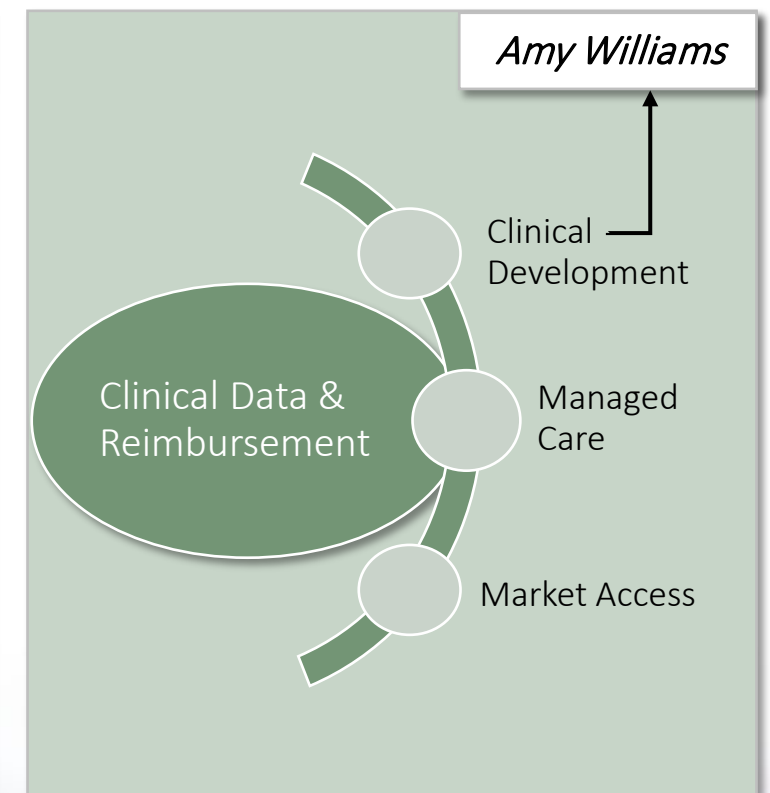
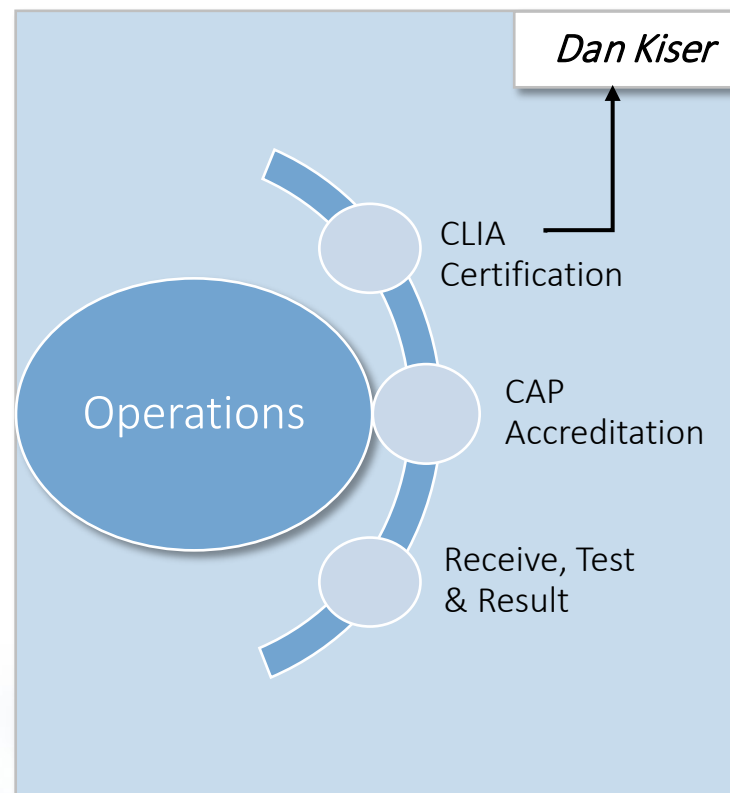
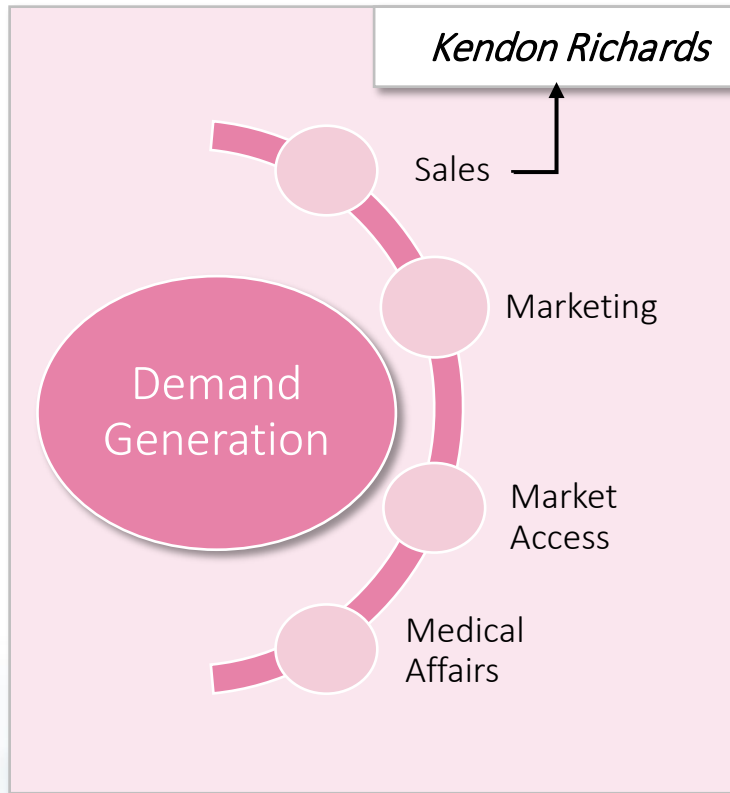
1. *Stakeholder Relationships* - patient, physician and payer
2. *Reimbursement* – insurance coverage, value and utilization
3. *Access* – availability to all patients
4. *Data Development & Mining* – understanding product utilization, utility & correlation
5. *Sample Biobank* – deep analysis and fuel pipeline development



The CLIA Lab Model Enables Management of the Entire Business Process

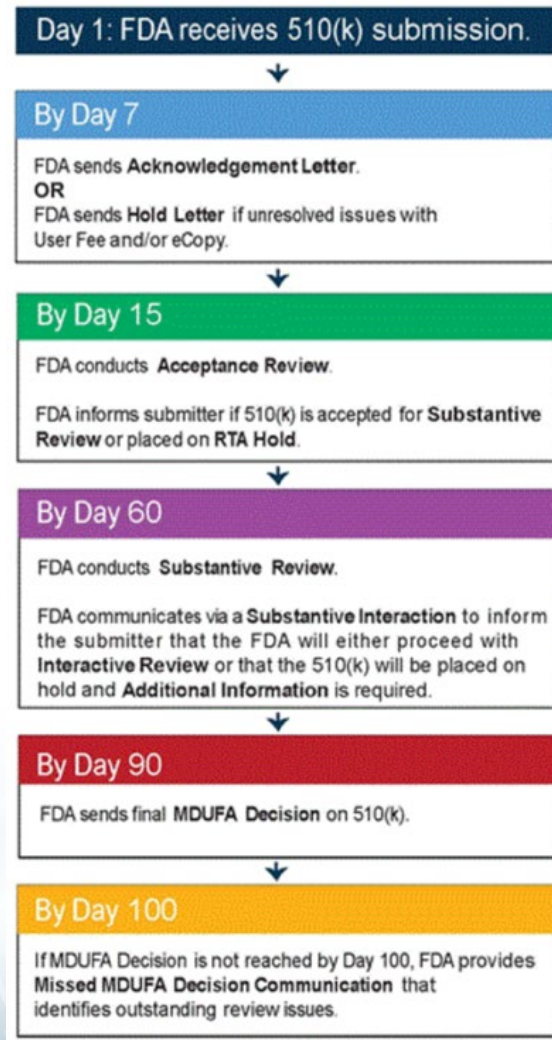


Our Immediate Focus



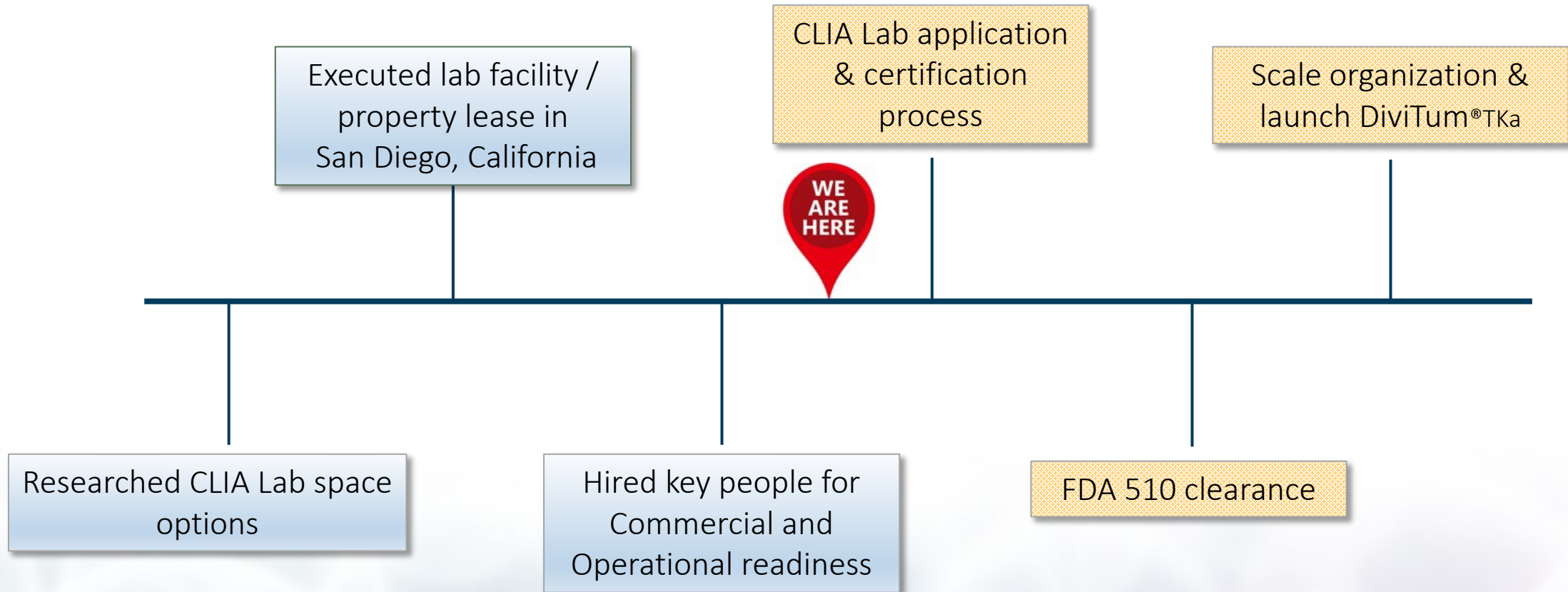
Highly experienced candidates have been identified for nearly every US-based position

FDA 510(k) Application



- FDA 510(k) submission Q3 2020
- Positive interactive process with FDA, feedback in February
- Updated application, addressing all raised questions, was submitted on the 28th of April
- FDA has started their final assessment in Substantive review process
- Next step, MDUFA decision, expected in Q3

US Operations Milestones



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Management Team & Key People



Anders Rylander

CEO

Holdings: 3,575,640 A-shares,
379,756 B-shares, 90,000 warrants



Cecilia Driving

EVP CFO

Holdings: 20,000 B-shares,
65,000 warrants



Helle Fisker

VP Commercial Europe

Holdings: 20.000 warrants



Tomas Andersson

VP Operations

Holdings: 40,000 warrants



Joakim Arwidson

VP Regulatory & QA

Holdings: 20.000 warrants



Henrik Winther, Ph.D.

SVP Business Development

Holdings: 20.000 B-shares, 20,000 warrants



Warren Cresswell

President Americas

Holdings: 100.000 warrants



Dan Kiser

Head RA&QA & Lab Operations

Holdings: None



Kendon Richards

Executive Sales Director

Holdings: 15.000 warrants



Amy Williams, Ph.D.

Head of Clinical Dev. & Medical Affairs

Holdings: 15.000 warrants

Board of Directors



Lars Holmqvist

Chairman
Holdings: 534,536 B-shares,
100,000 warrants



Annika Carlsson Berg

Board Member
Holdings: 50,000 warrants



Maria Holmlund

Board Member
Holdings: 9,750 B-shares,
75,000 warrants



Henrik Osvald

Board Member
Holdings: 624,106 B-shares,
50,000 warrants



Jesper Söderqvist

Board Member
Holdings: 41,085 A-shares,
38,200 B-shares, 75,000 warrants



Jarl Ulf Jungnelius

Board Member
Holdings: 75,000 warrants



Marie Louise Fjällskog

Board Member
Holdings: 45,000 warrants



Anders Rylander

Board Member & CEO
Holdings: 3,575,640 A-shares,
368,956 B-shares, 90,000 warrants

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Summary & Milestones

- DiviTum®TKa addresses an important clinical unmet need
- DiviTum®TKa is supported by cancer KOL's and scientific collaborators globally
- These collaborations has generated strong clinical data
- Pharma collaboration and sales are developing positively
- First clinical launch will be for metastatic breast cancer.

Upcoming milestones:

- Q3: 510(k) clearance
- Q4: US launch after 510(k) clearance
- 2023: Launch on 1st European market



Share price development and turn over



Financials Q4 2021/2022

- Net sales for the period amounted to SEK 1,082 (318) thousand. Fourth quarter sales are attributable to customers in the research market.
- Net sales for FY amounted to SEK 2,045 (2,077) thousand.
- Sales are only attributable to customers in the research market as product launch for clinical use in US are planned for later this year.



Financials Q4 2021/2022

- The closing amount for cash & cash equivalents on 30 April 2022 was SEK 89,792 (145,364) thousand.
- Operating cash-flow for the period was 16,6 (9,0) MSEK
- The company is well capitalized and with the current capital, we expect our current cash to last for more than 12 months of operations.

