

Pareto Securities Annual Healthcare Conference

3rd of September 2020

Anders Rylander, CEO



Unmet needs in Metastatic Breast Cancer

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



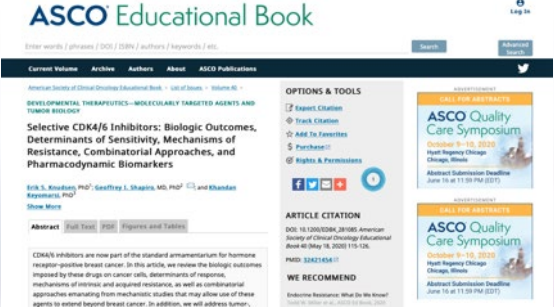
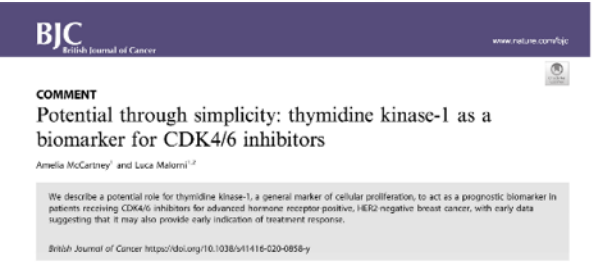
Unmet need & potential value of DiviTum® in clinical practice confirmed by articles in May 2020

“ 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. ”

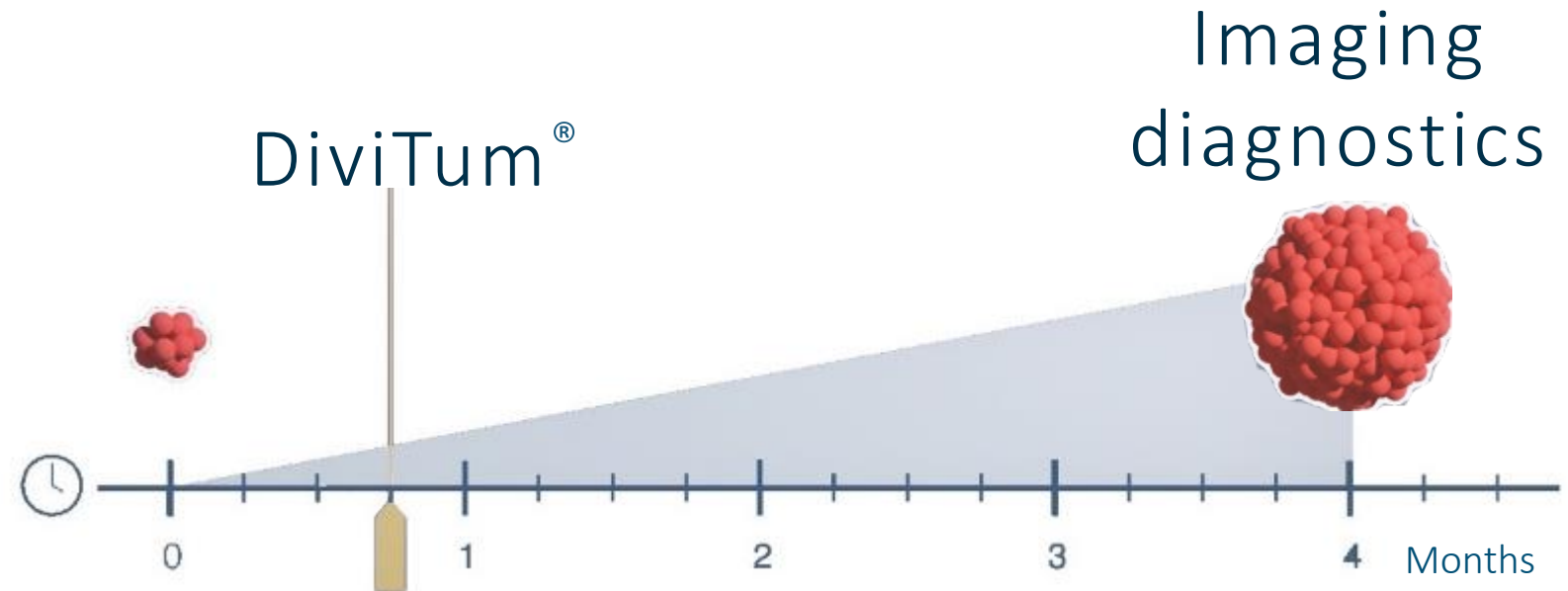
– Dr. Amelia McCartney, Prato Hospital, Italy

“ 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. ”

– Dr. Luca Malorni, Prato Hospital, Italy



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

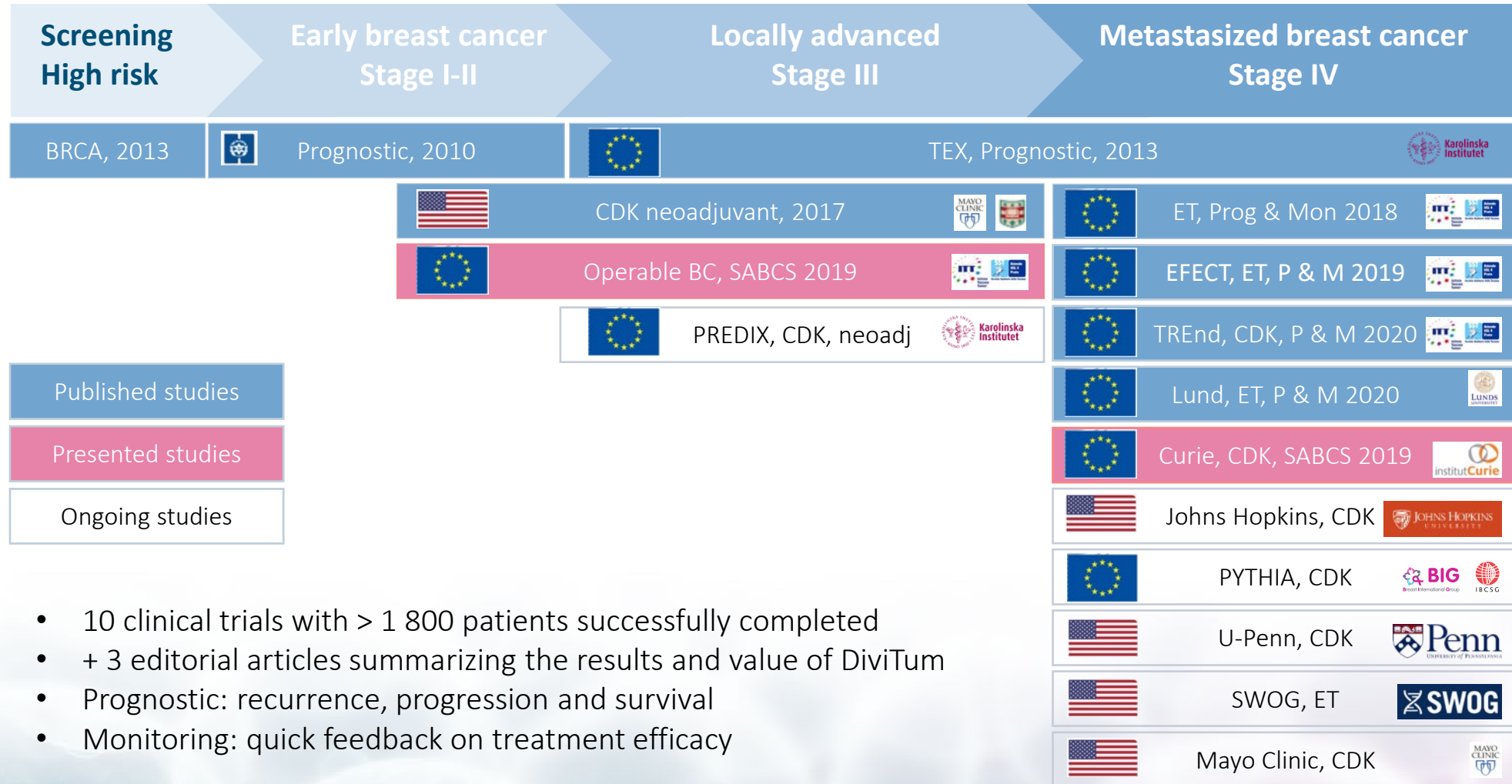
Strong clinical study results for DiviTum[®] peer-reviewed & published in oncology journals

- 22 published and peer-reviewed articles with DiviTum[®]
- 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	1,065	11
 Gastrointestinal	713	4
 Lung Cancer	281	2
 Blood Cancer	440	4
 Other	368	1
	2,867	22



DiviTum[®] – Extensive breast cancer study program



Broad key opinion leader support – key success factor for clinical acceptance



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

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Hospital of Prato
Baylor Collage*



Thomas Hatschek

*M.D, PhD
Karolinska Institutet*



Samuel Rotstein

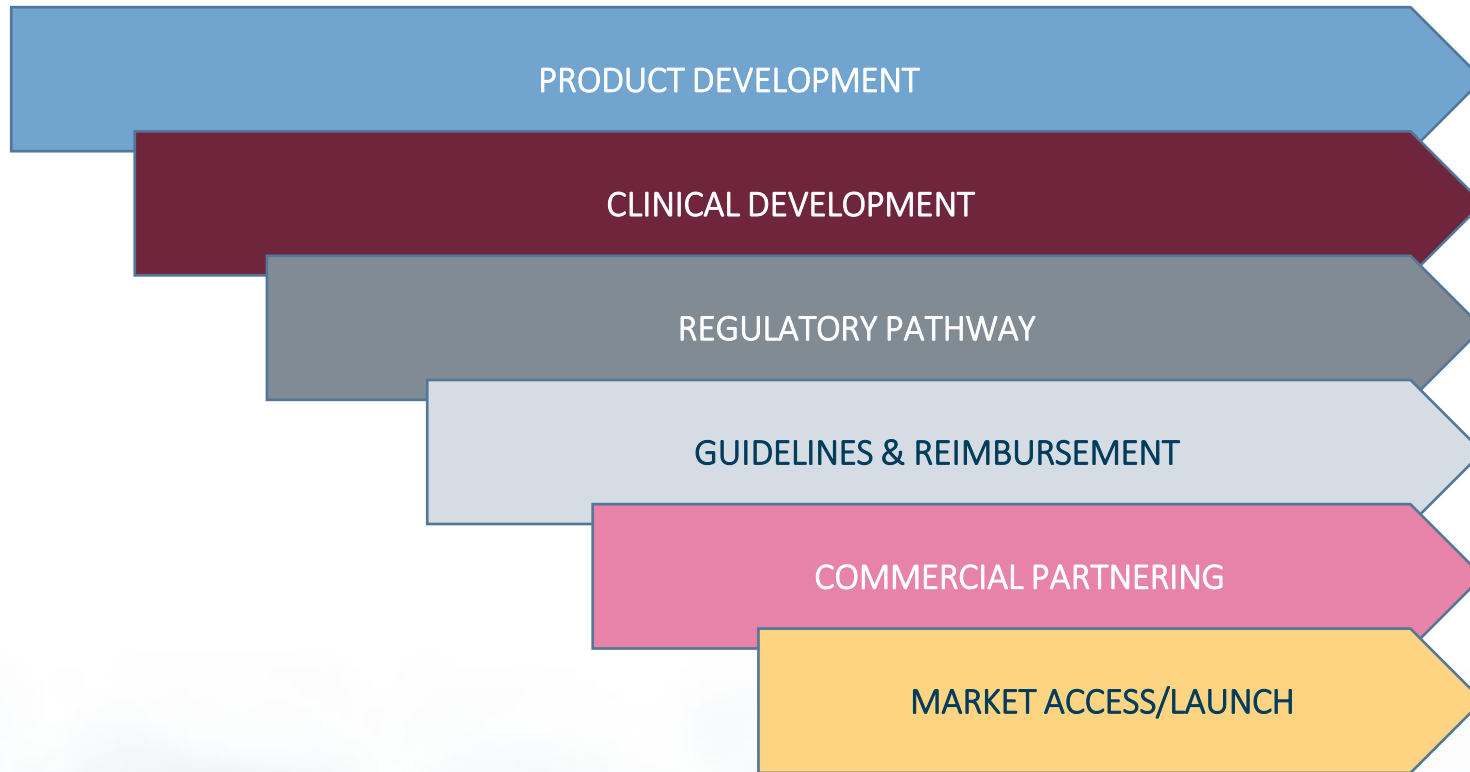
*M.D, PhD
Karolinska Sjukhuset*



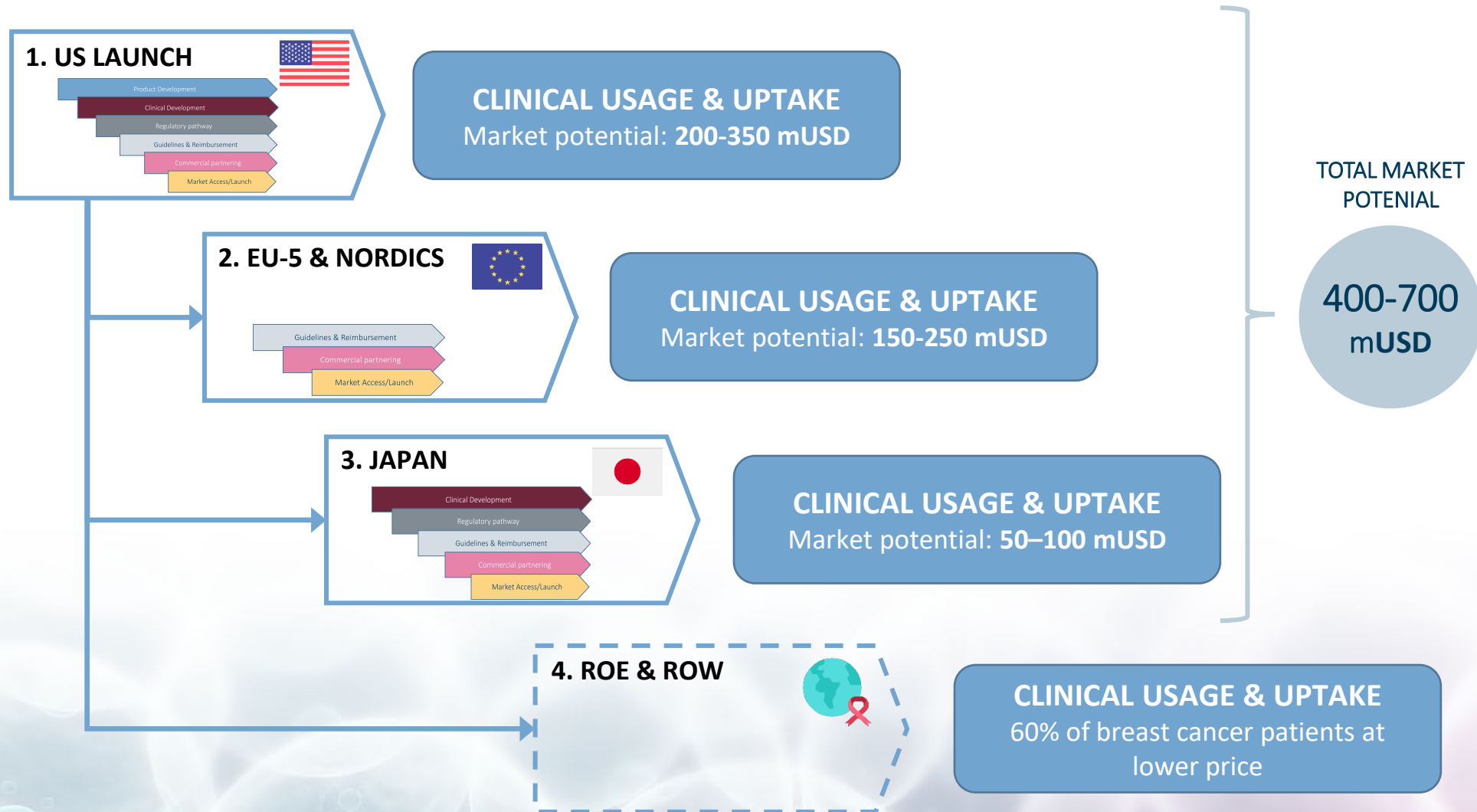
Henrik Lindman

*M.D, Ass. Professor
Uppsala Universitet
Vice Chairman SweBCG*

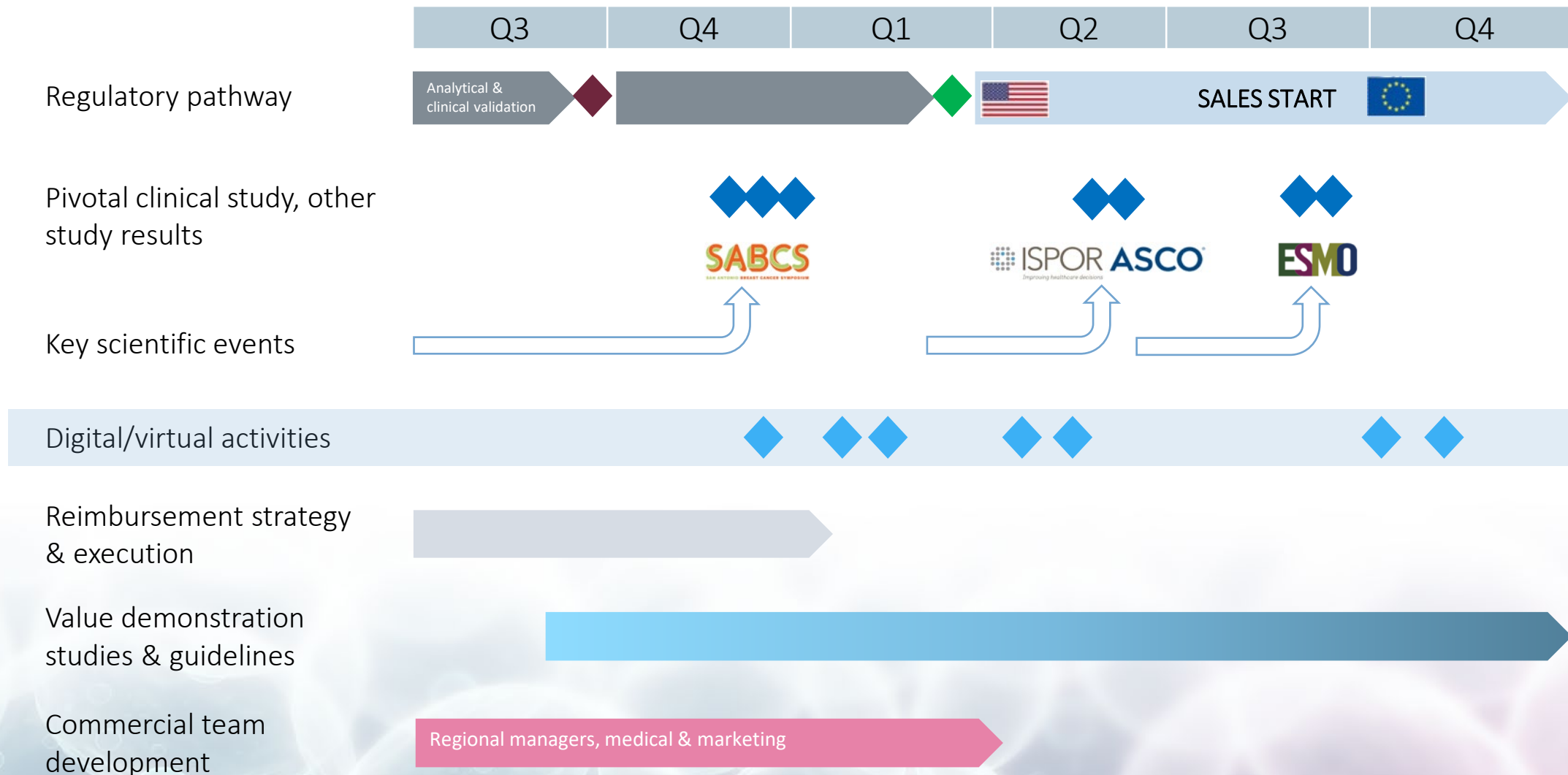
DiviTum[®] – Key commercialization activities



Geographical roll-out plan & market potential for DiviTum[®] in metastatic breast cancer

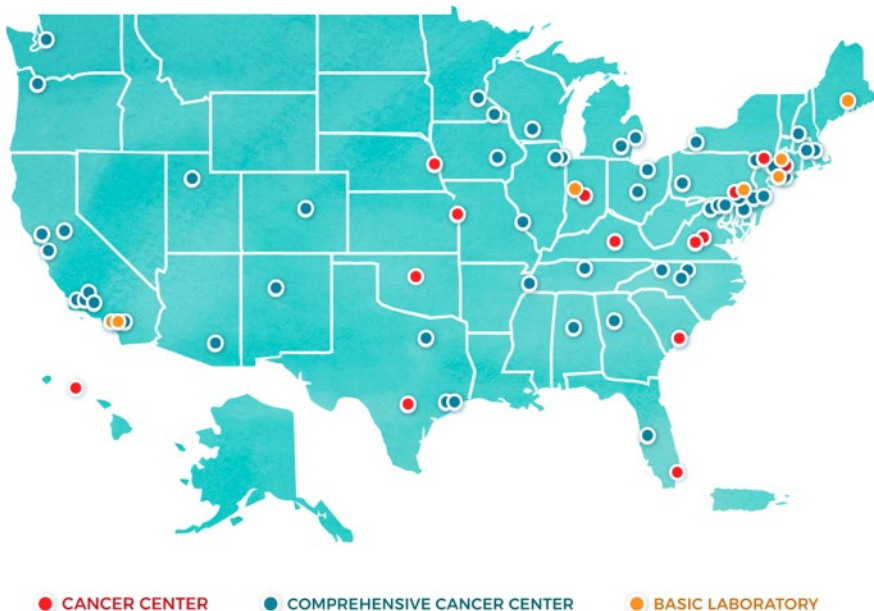


US Market Commercialization timeline 2020-2021



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
NEO GENOMICS	8	8
Cleveland Clinic Laboratories	1	1

IDNs/Payers



These will be customers and at the same time, partners

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%

European launches in MBC starting Q3/Q4 2021

- within EU-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 (EU-5 & Nordics) (Rest of Europe: 730,000 tests/year)

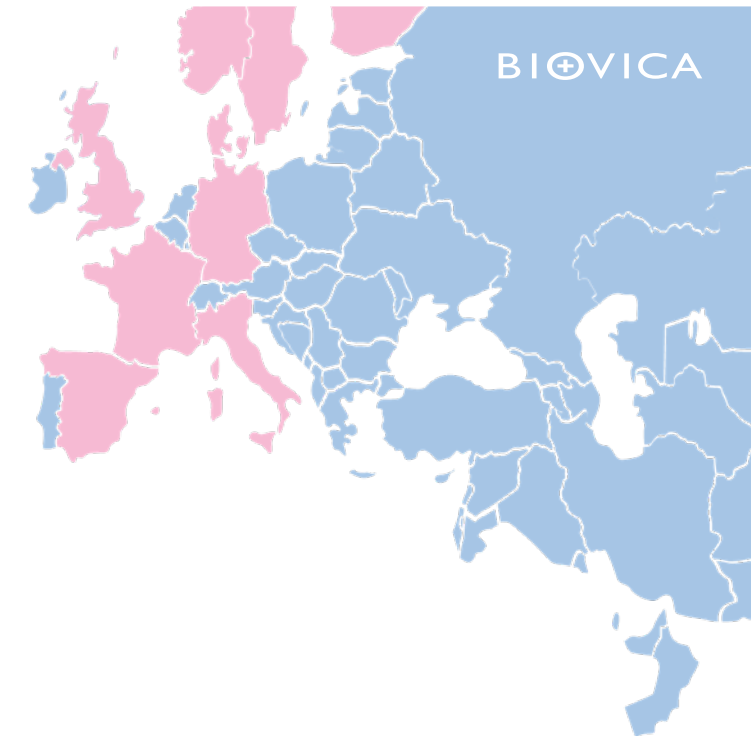
Launch strategy

- 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



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

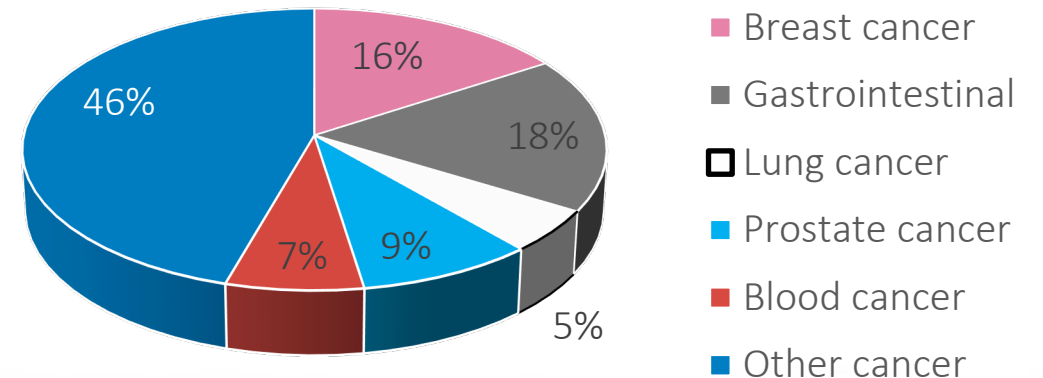
Medium term expansion:

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

Summary

- 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/>

