Biovica Capital Market Day

11th of May 2020

14:00-16:00 CET
Capital Market Day 11\textsuperscript{th} 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
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
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

Matthew P. Goetz
M.D, Professor
Mayo Clinic

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

Cynthia X. Ma
M.D, Professor
Washington University

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

Jonas Bergh
M.D, Professor
Karolinska Institutet
ESMO BC Award
Ex Chairman SweBCG

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Hospital of Prato
Baylor Collage

Matthew J. Ellis
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William Gradishar
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Northwestern Med.

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IBCG Exec. Committee
BIG against BC Exec Board
ESMO Lifetime Achievement

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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

<table>
<thead>
<tr>
<th>Cancer area</th>
<th>Patients</th>
<th>No of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer</td>
<td>1,065</td>
<td>11</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>713</td>
<td>4</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>281</td>
<td>2</td>
</tr>
<tr>
<td>Blood Cancer</td>
<td>440</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>368</td>
<td>1</td>
</tr>
</tbody>
</table>

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
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

Large potential to expand outside initial markets & applications!
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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

Screening

Self diagnosis

Triple-test diagnostics

Diagnosis

Benign (Healthy)

Early (Stage I & II)

Locally advanced (Stage III)

Metastatic (Stage IV)

Treatment Regimens
Adjuvant treatment

Disease-free
Recurrence

Pre surgery treatment

Surgery

Adjuvant treatment

Early
(Stage I)

Early
(Stage II)

Locally advanced
(Stage III)

1st line treatment
2nd line treatment
3rd line treatment
n line treatment
Palliative care

Metastatic
(Stage IV)
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

#### Screening
- High risk

#### Early breast cancer
- Stage I-II
  - BRCA, 2013
  - Prognostic, 2010

#### Locally advanced
- Stage III
  - TEX, Prognostic, 2013
  - CDK neoadjuvant, 2017
  - Operable BC, SABCS 2019
  - PREDIX, CDK, neoadj

#### Metastasized breast cancer
- Stage IV
  - ET, Prog & Mon 2018
  - EFECT, ET, P & M 2019
  - TREnd, CDK, 2020
  - Lund, Prog & Mon, 2020
  - Curie, CDK, SABCS 2019

#### Published studies
- Johns Hopkins, CDK
- PYTHIA, CDK
- U-Penn, CDK
- SWOG, ET
- Mayo Clinic, CDK4/6

#### Presented studies
-TEX, Prognostic, 2013

#### Ongoing studies
- SWOG, ET

- 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)

1\textsuperscript{st} ET
Median treatment 25 months

2\textsuperscript{nd} ET
Median treatment 10 months

3\textsuperscript{rd} 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

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

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
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<tr>
<td>Regulatory pathway</td>
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<tr>
<td>Pivotal clinical study</td>
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<tr>
<td>Key scientific events</td>
<td>ASCO</td>
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<tr>
<td>KOL inputs</td>
<td></td>
<td></td>
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<tr>
<td>Reimbursement strategy &amp; execution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial team development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value demonstration &amp; guidelines</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Focus on key cancer centers, reference labs, IDNs & payers

71 NCI-designated cancer centers

Major reference laboratories

<table>
<thead>
<tr>
<th>Company</th>
<th># of labs</th>
<th>Oncology labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>LabCorp</td>
<td>31</td>
<td>2</td>
</tr>
<tr>
<td>Quest Diagnostics</td>
<td>32</td>
<td>5</td>
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<tr>
<td>SONIC HEALTHCARE</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>BioReference</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>Mayo Clinic Lab</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>ARUP</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>NGS</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Cleveland Clinic</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

IDNs/Payers

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

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

### Factors defining DiviTum volume uptake

<table>
<thead>
<tr>
<th>Factor</th>
<th>Assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab coverage of the population</td>
<td>Rapid</td>
</tr>
<tr>
<td>Reimbursement timing &amp; coverage, risk sharing agreements</td>
<td>Dependent on price, test accuracy, clinical utility, price</td>
</tr>
<tr>
<td>Physician uptake</td>
<td>Dependent on accuracy and reimbursement coverage</td>
</tr>
<tr>
<td>Competitor share</td>
<td>Launching after DiviTum</td>
</tr>
<tr>
<td>Pricing</td>
<td>Preliminary research suggests $3-500/test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Share of test opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>~15%</td>
</tr>
<tr>
<td>10</td>
<td>~50%</td>
</tr>
</tbody>
</table>
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

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

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 resistance 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
- A SIMPLE BLOOD TEST
- CDx
- Pharma
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

Pharma needs monitoring CDx’s (MDx’s) - as a drug brand differentiator
Expanding the DiviTum® market potential - by adding more clinical utility

DiviTum® Classic Dx:

Broad cancer-diagnostic field:
- prognostic
- monitoring for disease progression

Revenue component:
1. **Product Sales** in chosen markets

DiviTum® CDx/MDx:

Cancer-drug field:
- monitoring the effect of specific drugs

Revenue components:
2. **FFS Development**
3. **CDx Products Sales**

Positive feedback loop

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

Product Sales in drug markets

Fee-for-Services based on time (hourly rate) and materials
Additional market potential for DiviTum® as a CDx/MDx-device

- Fee-for-Service Revenue and Product Sales

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

Fee-for-Service (FFS) Revenue

Product Sales Focus

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

<table>
<thead>
<tr>
<th>DRUG Mode-of-Action</th>
<th>Potential Collaborators</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDK 4/6 inhibitors</td>
<td>Pfizer; Novartis; Eli Lilly</td>
</tr>
<tr>
<td>MEK inhibitors</td>
<td>GSK; Roche; Pfizer; AZ</td>
</tr>
<tr>
<td>PI3K/TK inhibitors</td>
<td>Novartis; Gilead</td>
</tr>
<tr>
<td>SERD’s/SERM’s</td>
<td>AZ; GNE; Novartis</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

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/
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