Disruptive innovation
in molecular diagnostics

Hilde Windels | CEO Biocartis
25 March 2017

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One of the key innovations
in healthcare in the last decade

PERSONALISED MEDICINE

or HIGH PRECISION MEDICINE

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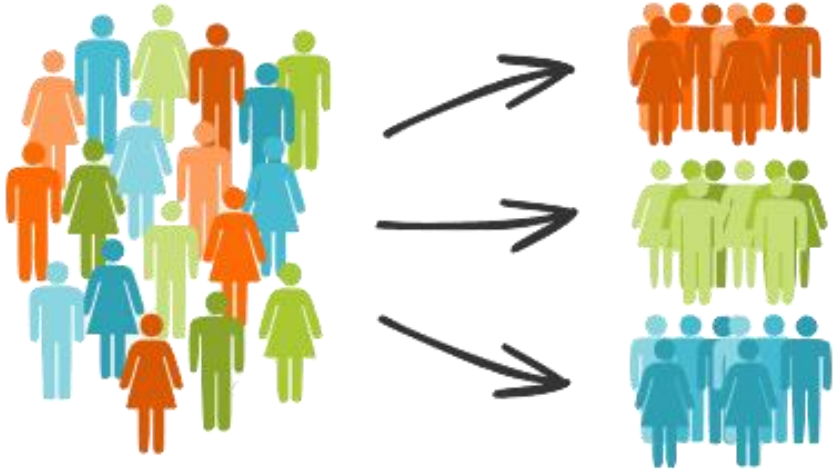
From symptoms to molecular gene signatures



Moving away from the one-drug-fits-all paradigm

Segmentation of patients

Targeted therapies
versus standard treatments such as chemotherapy.

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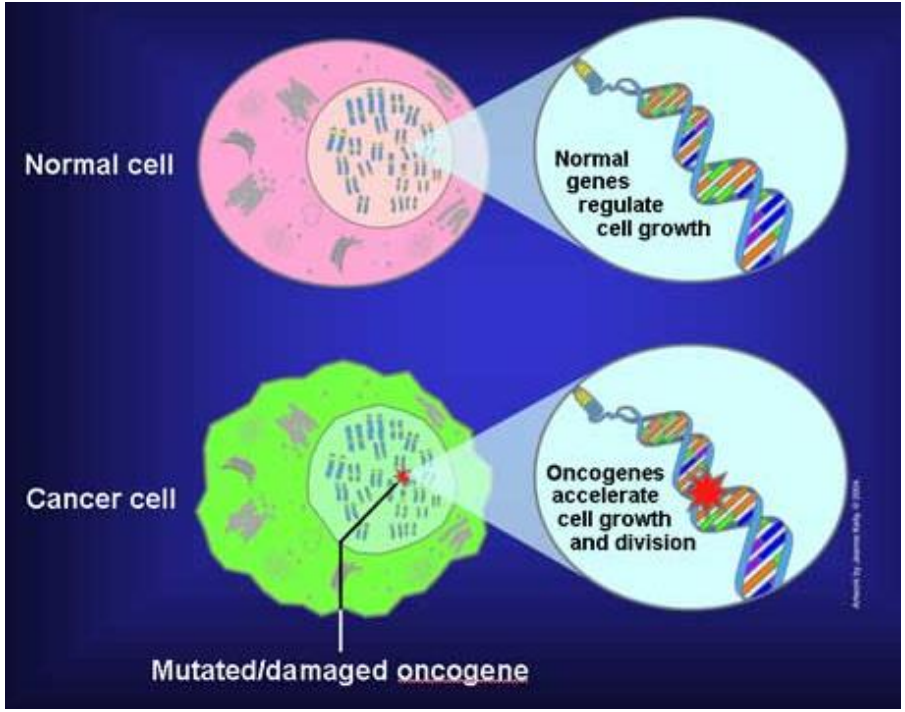
Targeting specific biomarkers - oncogenes

An **oncogene** is a gene that has the potential to cause cancer. In tumor cells, they are often mutated or expressed at high levels

Example:

BRAF mutations occur in ~50% of melanoma or skin cancers.



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Access to precision medicine

today

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Medtronic

Access to precision medicine

with Idylla™


idylla

Taking existing technologies to the next level

Polymerase Chain Reaction (PCR) technology

- Miniaturization: lab-in-a-box, all reagents inside
- Automation
- Sensitivity to the limits

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Any type of clinical sample

Fully automated sample to result

Access on demand

Speed and connectivity

Accurate results

Biocartis blinkt uit in opsporen longkanker

Op een belangrijke kankerconferentie in Kopenhagen is een longkankertest van het Vlaamse bedrijf Biocartis als beste uit de bus gekomen. Het apparaatje, Idylla genaamd, bleek erg handig in gebruik en veel sneller dan de toestellen van de concurrentie. 'We zijn enorm trots', zei Biocartis-topman Rudi Pauwels. De beurskoers van Biocartis steeg 11,2 procent naar 9 euro. **P15**

Biocartis - AstraZeneca's study highlights Idylla's superiority

KEMPEN & CO
Merchant Bank

11 October 2016, 08:35

BCART BB - Close: €8.10 (0.68%) - BUY, PT: €16.00

Biocartis has reported the presentation of the study conducted by AstraZeneca, comparing different diagnostic technologies for testing KRAS mutation and presented at ESMO yesterday. The results confirm our view that Biocartis' Idylla is the best technology for testing of oncologic mutations, providing the accuracy and mutation coverage of the best NGS systems with the convenience and simplicity of integrated PCR. Although incrementally positive, the study raises visibility

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Is the customer **buying** into innovation?

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Customer survey revealed customer delight

InSites Consulting

- Oncologists, pathologists, molecular biologists and lab technicians who have experience with Idylla™
- Six nationalities: UK, BE, IRE, SP, PORT, FR

"The number one argument for our setting is the short turn- around time. Patients' lives are affected if not treated quickly; some patients only have months to live. A result in 1.5 hours means decisions can be made quickly and these decisions are well informed."

Molecular biologist UK

"The Idylla™ platform is a real game changer."

Richard Sullivan, Division Manager IVD, Abacus (Australia and New Zealand)

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What was your reaction when you first heard about Idylla?

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Innovation is a verb

"Innovatie is een werkwoord"

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Business strategy & innovation tightly connected

- Solid tumor sample to result solutions
- Liquid biopsy testing on same platform
- Pushing sensitivity for superior performance data of Idylla™ tests
- Proprietary content for immuno-oncology Dx
- Gateway to Next-Generation Sequencing (NGS)

- Customers
  - Installed base and cartridge volume growth
  - Deployment Idylla platform in research and clinical performance studies
- Pharmaceutical/biotech companies
  - Commercial collaborations
  - Porting of proprietary assays to Idylla™
  - R&D collaborations
  - Companion diagnostics (CDx)

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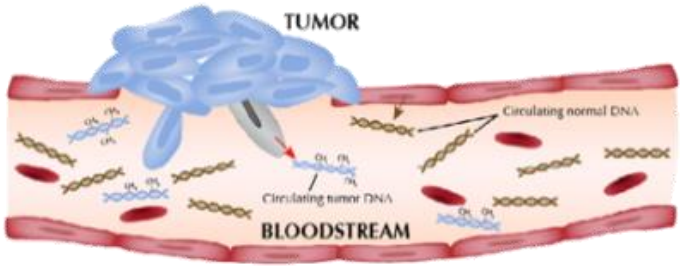
* FFPE = formalin fixed paraffin embedded
~ [add source]

Liquid biopsy assays, a promising extension of our menu



Cancerous tumors release cell-free circulating tumor ('ct') DNA fragments into the bloodstream

- Circulating blood biomarkers are a promising surrogate for solid tumor tissue-based biomarkers as this approach:
  - Allows for non-invasive sample taking
  - Does not require prior information of the tumor location
  - Is suitable for repeat sampling
- Promising market potential

- Combined offering of solid and liquid testing expected to deepen market adoption of Idylla™
- Focus for 2017 and beyond on liquid biopsies on lung, colon and breast cancers: easy diagnostic inclusion and monitoring of resistance to therapy

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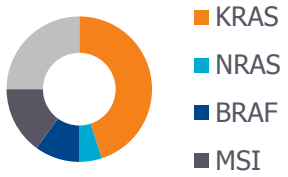
Teaming up with Next Gen Sequencing (NGS)

- **Enabling NGS**
  through standardization and automation of key sample and library prep steps

	• Isolate genomic material from clinical sample • Quantify genomic material via qPCR	• Target amplification via PCR • Indexing & tagging via PCR • Purification	• Pool libraries • Sequencing • Data analysis
Hands-on	**2.5h**	**3.5h**	
Total turn around time	**5h**	**7h**	

- **Complementing NGS**
  Idylla™ as first line testing for patients with most common alterations,
  NGS for detection of less common alterations

Melanoma**



Colon

** Source: Dienstmann, Salazar, and Tabernero ASCO EdBook 2015 and www.mycancergenome.org.

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Facts & figures

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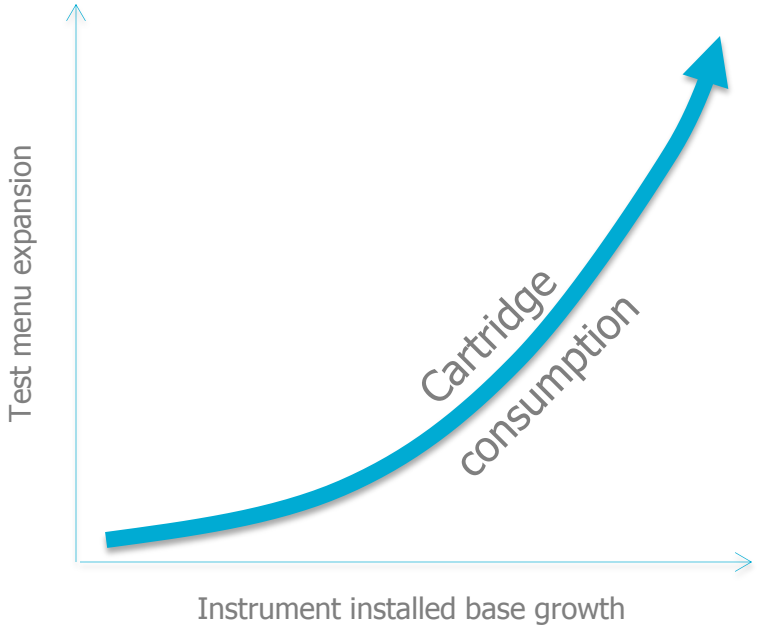
Idylla™ follows a razor-razorblade model



- Cartridge consumption on Idylla™ instruments is key value driver of Biocartis
- A broad installed base of Idylla™ instruments with expanding Idylla™ test menu facilitates cartridge consumption

An increasing installed base will:

- Grow consumption of existing Idylla™ tests
- Accelerate market adoption of new Idylla™ tests

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Executing on the promises

Installed base	Installed base Idylla™ instruments more than doubled in 2016 by adding a total of 224 instruments Total installed base year end was close to 390 instruments.
Cartridge consumption	Commercial cartridge volume in 2016 increased to over 25,000 cartridges which represents approx. 7.5 times the total commercial volume of 2015.
Menu	On market oncology menu expanded to 7 tests
Revenues	Product revenues in 2016 amounted to EUR 6.8m, representing +88% compared to 2015 Total 2016 operating income amounted to EUR 13.8m
Cash position	Cash and cash equivalents on 31 December 2016 amounted to EUR 83.2m

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What to expect?

Solid basis for exponential growth

250 - 275 expected installed base expansion in 2017

Forecasted total installed base of Idylla™ instruments around 640 by year-end

Commercial cartridge volume in 2017 to be at least three times 2016 volume

CE-marking of 4 existing tests (EGFR, NRAS, ct KRAS, ct NRAS-BRAF)

Launch Idylla™ ctEGFR Mutation Assay (RUO)

US FDA 510(k) approval of the Idylla™ platform in conjunction with Idylla™ IFV-RSV Panel Test

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Expanding in US

- Expected to account for **largest proportion of MDx market for oncology** (expected market size of $1.45B by 2020)*
- Requires more rigorous **product clearance efforts**, incl. Pre-Market Approvals (PMAs) for most oncology products
- Status:
  - US FDA 510(k) **premarket notification approval filed** for Idylla™ Instrument and Console, and for the Idylla™ Respiratory (IFV-RSV) Panel 2016
  - Idylla™ Instrument and Console **may gain exemption** from 510(k) requirements per the FDA Preliminary List of 510(K) Exempt Devices published 14Mar2017**. Final list of exempt devices anticipated to be published in July 2017

Phase 1: operational start H2 2017

Phase 2: Idylla™ platform supporting RUO oncology assays

Phase 3: PMAs for our oncology assays

* MarketsandMarkets, Molecular Diagnostics Market - Forecast To 2020

** https://www.federalregister.gov/documents/2017/03/14/2017-04938/medical-devices-exemptions-from-premarket-notification-class-ii-devices-request-for-comments

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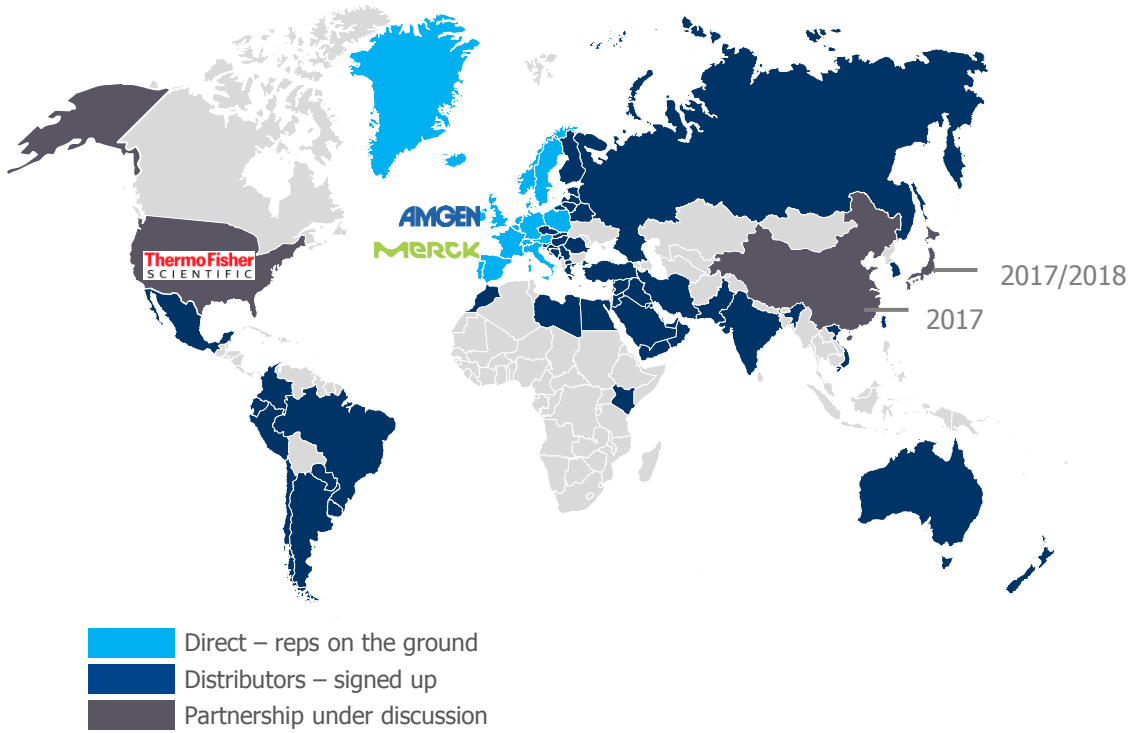
The world is our market

Over 60 countries covered through three sale channels*:

1. Direct sales force covering Western European countries

2. Distributor contracts in place covering approx. 45 countries
   - US commercialization partnership signed in November 2016
   - Announcement commercialization strategy China in 2017
   - Announcement commercialization strategy Japan in 2017/2018

3. Global pharma collaborations (e.g. Merck and Amgen)



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* Situation as per 31 December 2016

Q&A

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