

Biocartis

Corporate Presentation

3 December 2018

NOTICES AND WARNINGS

This presentation has been prepared by the management of Biocartis Group NV (the "Company"). It does not constitute or form part of, and should not be construed as, an offer, solicitation or invitation to subscribe for, underwrite or otherwise acquire, any securities of the Company or any member of its group nor should it or any part of it form the basis of, or be relied on in connection with, any contract to purchase or subscribe for any securities of the Company or any member of its group, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. It is not a prospectus or offering memorandum.

The information included in this presentation has been provided to you solely for your information and background and is subject to updating, completion, revision and amendment and such information may change materially. No person is under any obligation to update or keep current the information contained in this presentation and any opinions expressed in relation thereto are subject to change without notice. No representation or warranty, express or implied, is made as to the fairness, accuracy, reasonableness or completeness of the information contained herein. Neither the Company nor any other person accepts any liability for any loss howsoever arising, directly or indirectly, from this presentation or its contents.

This presentation includes forward-looking statements that reflect the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results, condition, performance, prospects, growth, strategies and the industry in which the Company operates. These forward-looking statements are subject to risks, uncertainties and assumptions and other factors that could cause the Company's actual results, condition, performance, prospects, growth or opportunities, as well as those of the markets it serves or intends to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. The Company cautions you that forward-looking statements are not guarantees of future performance and that its actual results and condition and the development of the industry in which the Company operates may differ materially from those made in or suggested by the forward-looking statements contained in this presentation. In addition, even if the Company's results, condition, and growth and the development of the industry in which the Company operates are consistent with the forward-looking statements contained in this presentation, those results or developments may not be indicative of results or developments in future periods. The Company and each of its directors, officers and employees expressly disclaim any obligation or undertaking to review, update or release any update of or revisions to any forward-looking statements in this presentation or any change in the Company's expectations or any change in events, conditions or circumstances on which these forward-looking statements are based, except as required by applicable law or regulation.

This document and any materials distributed in connection with this document are not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident or located in any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The distribution of this document in certain jurisdictions may be restricted by law and persons into whose possession this document comes should inform themselves about, and observe any such restrictions.

The Company's securities have not been and will not be registered under the US Securities Act of 1933 (the "Securities Act") and may not be offered or sold in the United States absent registration under the Securities Act or exemption from the registration requirement thereof.

Leader in oncology precision diagnostics

Differentiated technology

- Idylla™: first **fully automated** sample-to-result qPCR platform
- Superior and validated **performance** versus competition
- Enabling **global decentralization** of clinical molecular diagnostics (MDx)

Attractive market

- Global MDx market of USD 6.5bn; oncology fastest growing segment with **high double digit annual growth** rates
- Large, global customer base & opportunity to add new **customer segments**, e.g. labs that want to step into MDx testing

Focus on oncology

- Unique platform features bring strong **competitive advantage in oncology testing**
- Broad **test menu** (solid & liquid biopsies) for **therapy guidance**, later for patient monitoring & screening
- Validation via **partnerships** with pharma (e.g. Amgen, Merck KGaA, AstraZeneca) and content partners (e.g. Genomic Health)

Proven commercial strategy

- Installed base close to **800 instruments** as per 30 June 2018
- Present in **over 70 countries**
- Delivering **solid performance across markets**: Europe, US and RoW*

Performance first nine months 2018

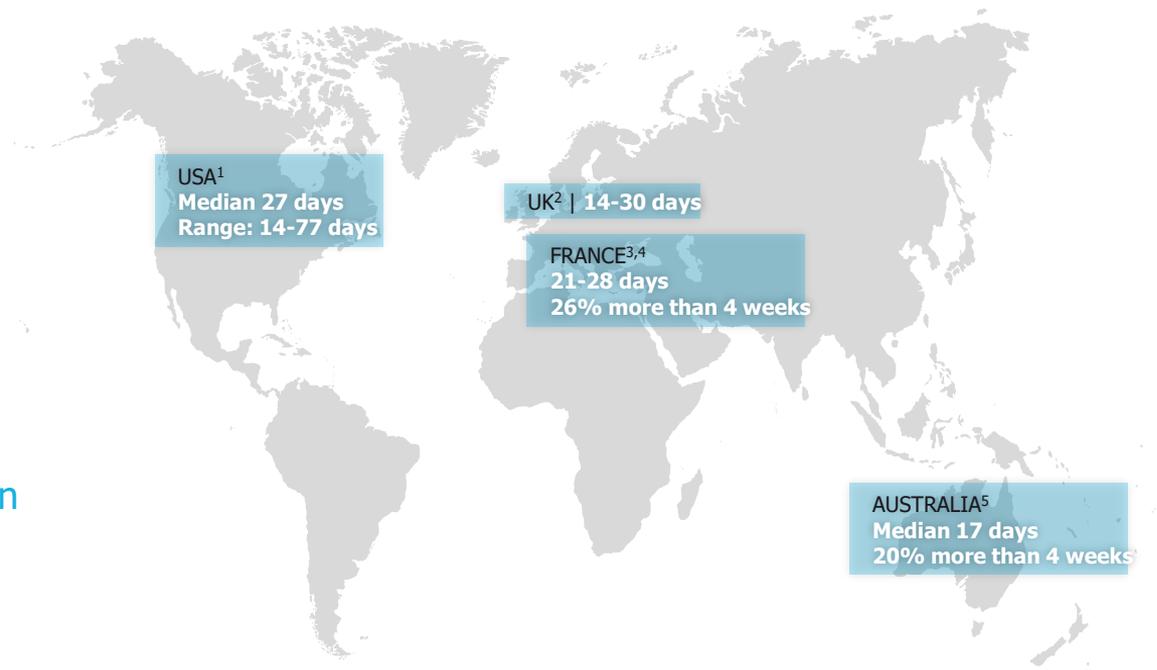
- **149 new Idylla™ instruments** placed in H1 2018, continued **strong installed base growth** in Q3 2018 of which the majority in the US
- Year-over-year **doubling of commercial cartridge volume** for the first nine months of 2018

Positioned for further growth

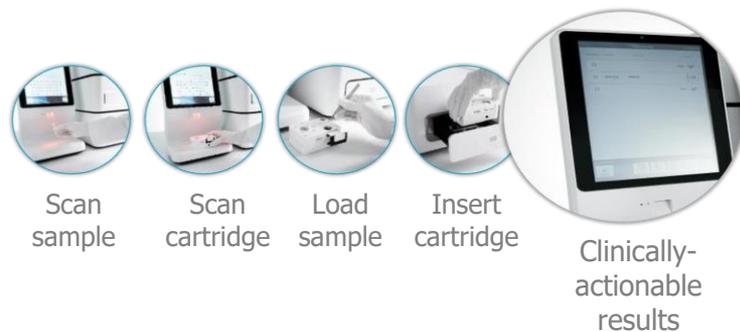
- Continued **global expansion**: strong cartridge consumption growth in **Europe**, fast growing **US** installed base, launch of the Idylla™ MSI Assay (RUO) also triggered European installed base growth, new market authorizations in **RoW*** geographies, 1st milestone achieved towards commercialization in **China** through joint venture with Wondfo
- Launch of the **Idylla™ MSI Assay** (Research Use Only) in Q3 2018, driving cartridge volume growth at existing and new clients
- Additional **highly automated second manufacturing line** operational by end 2018 supporting **volume** growth and **cost effectiveness**

Difficult access to molecular diagnostics information

- In the US, nearly **80%⁴** of cancer patients do **not have genetic mutation results available** at initial oncology consultation
- Up to **25%** of patients **begin treatment before receiving their results⁴**



Fully automated molecular testing with Idylla™



Superior sensitivity and ease-of-use, combined with sample to result turnaround time of 90 to 150* minutes

Enabling decentralized testing

	Idylla™ workflow	Traditional workflow*
Instruments needed		
Lab consumables needed		
Lab infrastructure (# rooms)	1	3
Workflow	<ul style="list-style-type: none"> Fully automated ('sample-to-result') and on demand 	<ul style="list-style-type: none"> Manual and batch-based testing, 1/week or biweekly
Turnaround time	<ul style="list-style-type: none"> < 2.5hrs turnaround time per test In 1-2 days to treatment initiation*** 	<ul style="list-style-type: none"> 1-4 days turnaround time per test On average 18 days** to treatment initiation***

Traditional workflow results in:

- **Centralized** testing (many labs send out samples) by specialized labs with experienced lab technicians
- **Poor reproducibility** of results (i.e. human errors)
- **Long turnaround** time (~ weeks)

Idylla™ enables:

- **Decentralized** testing by all labs (no geographical differences in quality)
- **'First-time-right'** results
- **Short turnaround** time (~ 'same-day-result')

Comparative studies confirm superior performance

Example study organized by AstraZeneca

Background

- Comparison of 13 different KRAS mutation detecting technologies:

6x NGS	
3x qPCR	
2x mass spec.	
1x ddPCR	
1x Sanger sequencing	

- Focused on detection of KRAS mutations in lung cancer based on **blinded samples**

Conclusions

Sensitivity

Technology	Overall sensitivity
Idylla™ KRAS	96%
Other qPCR (cobas/therascreen)	46-52%
Mass-spectrometry	58-92%
NGS	48-100%
ddPCR	52-60%

Ease-of-use

- Highest score for Idylla™ KRAS technology:
 - Lowest number of manual handling steps in sample preparation (1 to 2 steps versus 3 to > 20 steps)
 - Requires lowest level of expertise (1 versus 2-4 for others*)

TaT**

- Highest score for Idylla™ KRAS technology on total turnaround time (2 to 4 hours versus 1 day to 3 weeks)

Eight Idylla™ abstracts presented at AMP¹ 2018, US

Summary abstracts



Memorial Sloan Kettering
Cancer Center



Dartmouth-
Hitchcock

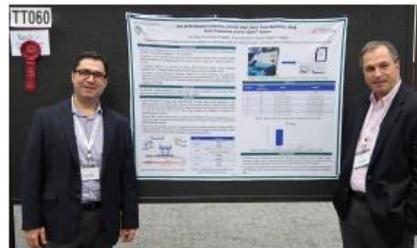


1. Rapid Assessment of Microsatellite Instability Status using the Idylla™ MSI Test⁴
2. Ultra-Rapid EGFR Mutation Assessment in Lung Adenocarcinoma without Prior DNA Extraction⁵
3. Detection of Microsatellite Instability in Endometrial Carcinoma Using the Novel Idylla™ MSI Assay^{2,6}
4. Biocartis Idylla™ Cartridge-based Microsatellite Instability Assay Shows High Concordance with Immunohistochemical Analysis for Mismatch Repair Status in Colorectal Cancer⁷
5. Stat EGFR Mutation Detection in Fresh Lung Cancer Tissue Specimens Using Touch Preparation and the Idylla™ System⁸
6. Rapid EGFR Mutation Testing in Lung Cancer Tissue Samples Using a Fully Automated System and Single-use Cartridge⁹
7. On the comparison of the Idylla™ EGFR Mutation Assay², based on 79 clinical FFPE tissue samples¹⁰
8. Validation of FFPE Tissue Punches for Detection of KRAS and BRAF Mutations with the Idylla™ PCR-based Molecular Diagnostics Assay¹¹

AMP¹ impressions



Biocartis Corporate workshop at AMP¹ with Key Opinion Leaders as speakers from Memorial Sloan Kettering Cancer Center and the Dartmouth-Hitchcock Medical Center attracted over 100 participants



Rabie Al-Turkmani (Dartmouth-Hitchcock Medical Center) received the AMP Young-Investigator-Award for his Idylla™ EGFR Touch-prep abstract

4-5 K. Nafa et al., Memorial Sloan Kettering Cancer Center, "Rapid Assessment of Microsatellite Instability Status using the Idylla™ MSI Test"; M.E. Arcila et al., Memorial Sloan Kettering Cancer Center, "Ultra-Rapid EGFR Mutation Assessment in Lung Adenocarcinoma without Prior DNA Extraction"
6-9 C.M. Nicksa et al., Dartmouth-Hitchcock Medical Center, "Detection of Microsatellite Instability in Endometrial Carcinoma Using the Novel Idylla™ MSI Assay"; N.S. Maloney et al., Dartmouth-Hitchcock Medical Center, "Biocartis Idylla™ Cartridge-based Microsatellite Instability Assay Shows High Concordance with Immunohistochemical Analysis for Mismatch Repair Status in Colorectal Cancer"; M. Rabie Al-Turkmani et al., Dartmouth-Hitchcock Medical Center, "Stat EGFR Mutation Detection in Fresh Lung Cancer Tissue Specimens Using Touch Preparation and the Idylla™ System"; M. Rabie Al-Turkmani et al., Dartmouth-Hitchcock Medical Center, "Rapid EGFR Mutation Testing in Lung Cancer Tissue Samples Using a Fully Automated System and Single-use Cartridge"
10 M. Kohlman et al., AstraZeneca, on the comparison of the Idylla™ EGFR Mutation Assay based on 79 clinical FFPE tissue samples
11 D. Morlote et al., "Validation of FFPE Tissue Punches for Detection of KRAS and BRAF Mutations with the Idylla™ PCR-based Molecular Diagnostics Assay"

1 AMP: Association for Molecular Pathology
2 Research Use Only, not for use in diagnostic procedures
3 All abstracts are available on [https://jmd.ampjpathol.org/article/S1525-1578\(18\)30401-X/pdf](https://jmd.ampjpathol.org/article/S1525-1578(18)30401-X/pdf)

Oncology, an attractive market segment

Fast growing market

Oncology MDx market

- Represents 19% of the USD 6.5bn total MDx market in 2016¹
- Fastest growing segment in MDx, expected to grow 26% per annum (doubling of market) to 2020²

Key growth drivers

- Growing global prevalence of cancer: ca. 2.5% per annum³
- Growth of MDx testing:
 - Clinical pipeline targeted therapies: in 2015, > 800 cancer treatments were in development in the US⁴ of which 73% have the potential to be personalized medicines⁵
 - Availability of targeted therapies: increasing adoption in Western world; roll-out in developing countries due to patent expirations
- Growth of decentralized market

Significant underpenetrated customer potential

- Around 16,000 pathology laboratories worldwide⁶
- Significant number of hospitals not performing MDx today, table below shows situation in US⁷:

Hospital Segment	Number	Performing MDx (total)	%
Small	3816	382	10%
Medium	988	632	64%
Large	420	353	84%

Sales approach:

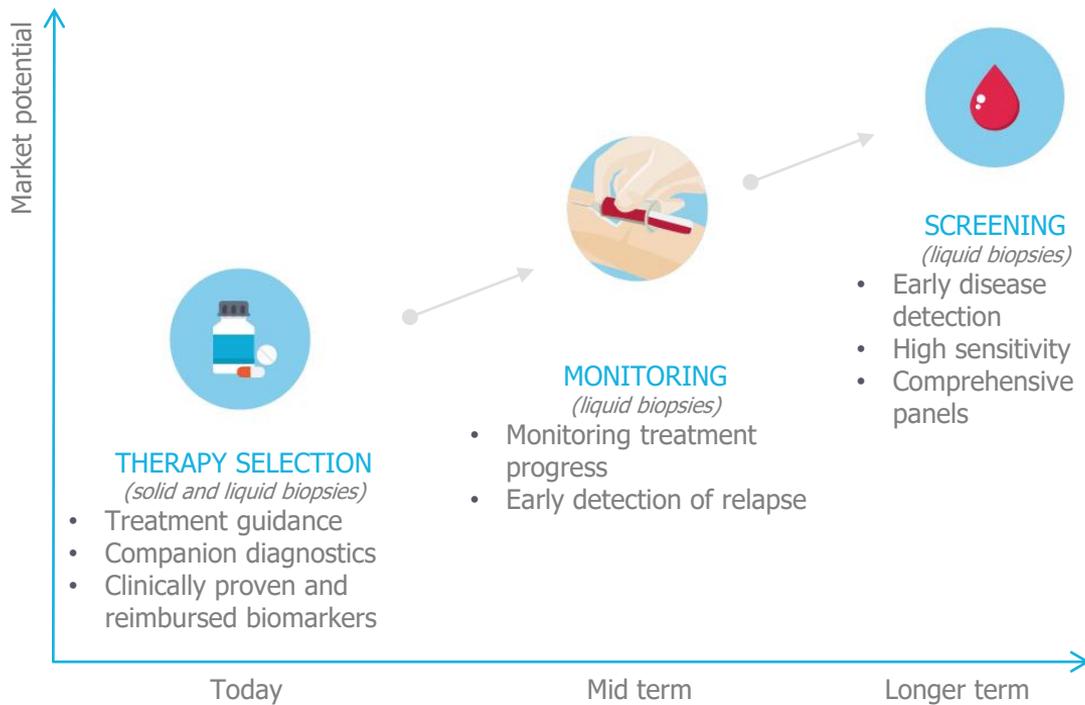
- Initial focus on labs offering MDx testing (= **existing** market)
- Second phase focused on targeting labs that want to step into MDx testing (= **new** market)

Menu focus on Oncology

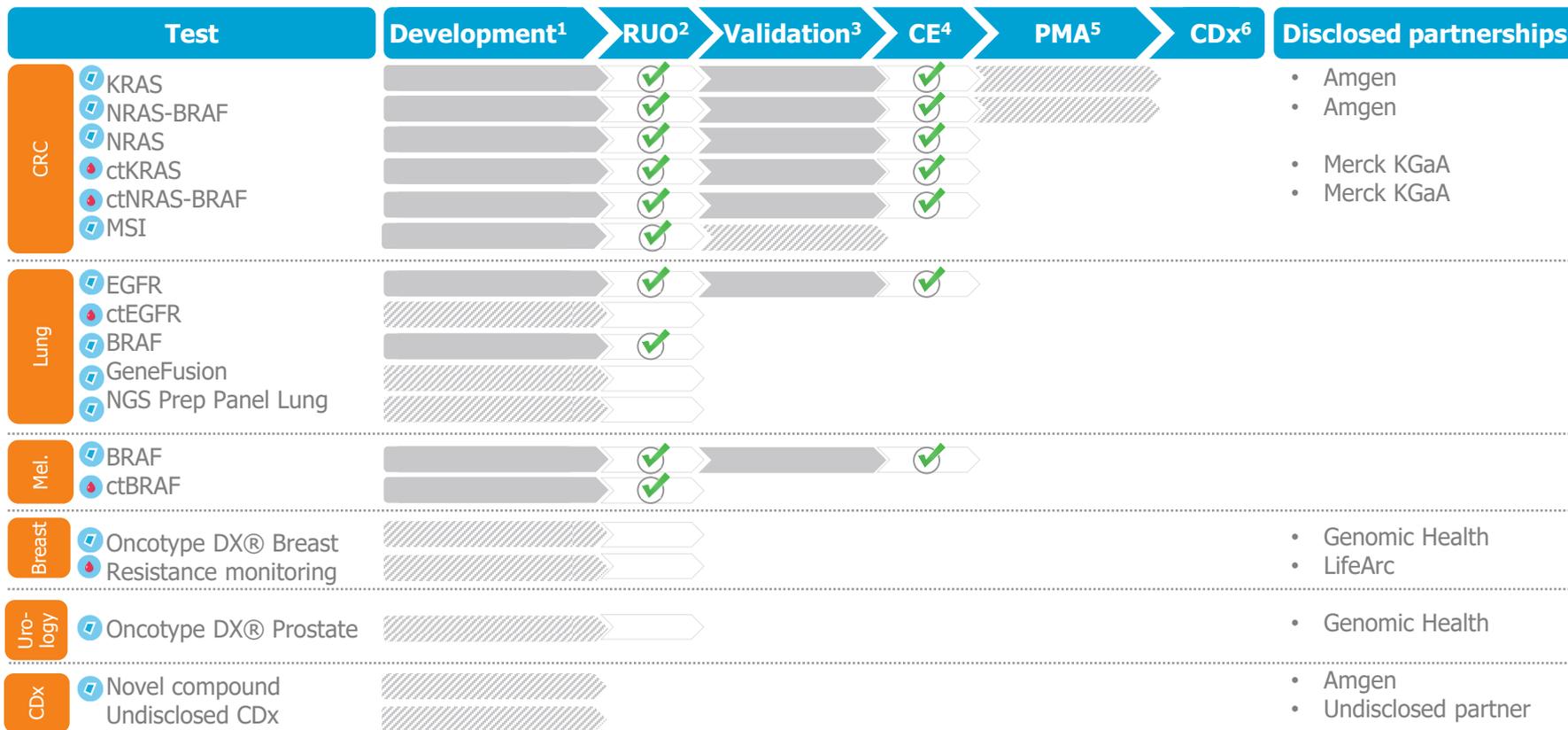
Idylla™ oncology Unique Selling Points

- 1 Ability to combine advantages of point-of-care testing with **performance** of lab reference testing (i.e. enabling oncology MDx in virtually any lab setting)
- 2 Reduction of **time-to-result** from weeks to **hours**
- 3 **Sample-to-result** (i.e. full automation) capabilities for:
 - o **Solid biopsies:** FFPE-slices* and tumor tissue
 - o **Liquid biopsies:** blood, plasma and urine

Expansion of the MDx application areas



Rapidly expanding Idylla™ test menu (1/2)



completed
ongoing
◻ = solid biopsy
 ◻ = liquid biopsy

1. Generally includes analytical validation. 2. Research Use Only 3. Clinical validation. 4. CE-IVD. 5. Premarket approval process with US FDA. 6. Companion Diagnostic.
 Overview is subject to change in amongst others prioritization of test development by Biocartis and/or partners driven by commercial, partnering and operational considerations.

Rapidly expanding Idylla™ test menu (2/2)

Further expansion oncology menu

- Continued menu expansion through own developments and partnerships:
 - 1 Menu expansion within current cancer areas focused on, e.g.:
 - Complementary **novel assays** (including NGS Prep Panels)
 - **Companion Diagnostics** of existing and novel tests
 - (Exclusive) **third party diagnostic content**
 - 2 Into additional:
 - Cancer indications (e.g. **bladder** and **prostate cancer**)
 - Treatment options (e.g. **immuno-oncology**)

Infectious disease menu

- **On market tests:**
 - Idylla™ IFV-RSV Panel (CE-IVD, RUO¹ and 510k²)
 - Ebola (EUA³)
- **Sepsis host response** partnership with  **Immunexpress**
 - Aimed at development and commercialization of Immunexpress' SeptiCyte™ test⁴ for use on Idylla™
 - SeptiCyte™ LAB test, recently received 510(k) clearance for use on a manual PCR instrument
 - Parties will co-develop the SeptiCyte™ Idylla™ test
 - Immunexpress will take the lead in commercialization, initial focus on US and Europe
- Further menu expansion with focus on **syndromic panels** & **bloodstream infections tests** that are to be (co-)developed and commercialized through **partnerships**

Accelerated launch Idylla™ MSI Assay in July 2018

Background MSI

- MSI is the abbreviation of Micro Satellite Instability
- MSI is the result of inactivation of the body's so-called DNA mismatch repair (MMR) system. Consequently, errors that normally spontaneously occur during DNA replication are no longer corrected, contributing to tumor growth and evolution
- MSI testing is included in [international guidelines](#) for colorectal cancer, but is present in several other tumor types as well, such as gastric & endometrial cancer
- MSI is an independent factor that may predict a patient's response to certain [immunotherapies](#)

The Idylla™ MSI Assay¹



- Includes [novel set of 7 MSI biomarkers⁵](#), exclusively licensed to Biocartis² in 2013
- [Unique characteristics:](#)
 - Fast & reliable information on MSI status directly from FFPE tissue without the need for matched normal samples³
 - High concordance (> 95%) and lower failure rates compared to standard methods³
 - No control sample required
 - Provides accurate results for a variety of cancer types independent of ethnicities³
- Expected to overcome drawbacks of conventional MSI testing, making MSI testing available to a [larger patient population](#)

Once validated for diagnostic use, the Idylla™ MSI Assay¹ will further strengthen the colorectal cancer menu

1 The Idylla™ MSI Assay was launched as a RUO (Research Use Only) Assay, not for use in diagnostic procedures

2 From VIB, the life sciences research institute in Flanders (Belgium), and originated from the research of the group of Prof. Diether Lambrechts (VIB-KU Leuven, Belgium)

3 Maertens G. et al. Annals of Oncology (2017) 28 (suppl_5): v22-v42; De Craene B. et al. Annals of Oncology (2017) 28 (suppl_5): v209-v268; De Craene et al. J Clin Oncol 36, 2018 (suppl; abstr e15639)-

4 FFPE = formalin fixed, paraffin embedded

5 Consisting of short homopolymers located in the ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2 genes

Accelerated menu expansion with partners

	Pharma & biotech companies	Content partners	Development partners
Focus	<ul style="list-style-type: none"> (Joint) development of CDx¹ on Idylla™ platform 	<ul style="list-style-type: none"> Porting of proprietary biomarker panels developed and validated by third parties on Idylla™ platform 	<ul style="list-style-type: none"> Development Biocartis Idylla™ assays in partnership with research institutions
Benefit Biocartis	<ul style="list-style-type: none"> Faster commercial adoption, higher market shares 	<ul style="list-style-type: none"> Proprietary 3rd party content on Idylla™ platform 	<ul style="list-style-type: none"> Lowered menu development costs
Benefit partners	<ul style="list-style-type: none"> Better and faster selection of eligible patients for targeted therapies given faster TaT & high sensitivity: <ul style="list-style-type: none"> Fast TaT: reduces competition with therapies not requiring a biomarker High sensitivity: more patients detected with relevant biomarkers 	<ul style="list-style-type: none"> Accelerated global roll-out of content No platform education needed: focus on content education Realization of cost efficiencies 	<ul style="list-style-type: none"> Contribution to medical innovation Knowledge sharing and building
Partners			

1. CDx = Companion Diagnostics

2. On 15 June 2017, MRC Technology changed its name to LifeArc. LifeArc has been involved in helping deliver a number of therapies including Keytruda (pembrolizumab, marketed by MSD) which is an important immunotherapy treatment for various cancers

3. Partnership is with ETPL, the commercialization arm of A*STAR

Strategic collaboration with Genomic Health[®]

LIFE, CHANGING.

Background collaboration

- Focused on **exclusive test development** of proprietary Genomic Health tests on the Idylla™ platform
- Aimed at **accelerating** adoption and market access around the world of Genomic Health's tests
- First test to be developed on Idylla™ is the **Oncotype DX Breast Recurrence Score[®] test**, second test is the **Oncotype DX Genomic Prostate Score[®] Test**

Background Genomic Health

- A leading provider of genomic-based diagnostic tests in cancer with **revenues of USD 377m** in 2017
- Based in California (US) and listed on NASDAQ (GHDX) with a market cap of approx. USD **2.97bn**
- **On-market tests** for **breast**, **prostate** and **colon cancer**, currently offered through own service laboratories

Oncotype DX Breast Recurrence Score[®] Test

- Examines the activity of **21 genes** in a patient's breast tumor tissue to provide personalized information for tailoring treatment based on the biology of their individual disease.
- Only test proven to **predict chemotherapy benefit**
- Included **in all major cancer guidelines** worldwide and is now considered standard of care for early-stage breast cancer.

Oncotype DX Genomic Prostate Score[®] Test

- Examines the activity of **17 genes** in a patient's prostate biopsy sample to provide information on the aggressiveness of their individual disease
- Predicts risk of metastasis and helps to make better informed & more personalized treatment decisions
- Has been validated in **> 4,500 patients**, which is described in **18 publications**

Expansion of menu partnerships in H1 2018



- **Second CDx partnership** with Amgen announced in January 2018
- Aimed at the development of Idylla™ CDx biomarker tests for a **novel oncology compound** to be used in the treatment of certain solid tumors
- The **first CDx partnership with Amgen** announced on 4 December 2017 is aimed at registering Idylla™ RAS biomarker tests with US FDA as a companion diagnostic (CDx) test for Vectibix® (panitumumab¹)



- **Sepsis host response** partnership
- Aimed at development and commercialization of Immunexpress' SeptiCyte™ test for use on Idylla™
- This test aids in the differentiation of infection-positive (sepsis) from infection-negative (SIRS) systemic inflammation in critically ill patients
- SeptiCyte™ LAB test is 510(k) cleared for use on a manual PCR² instrument
- Parties will co-develop the SeptiCyte™ Idylla™ test
- Immunexpress will take the lead in commercialization, initial focus on US and Europe

Third pharma collaboration with AstraZeneca

aimed at faster lung cancer biomarker results

Background

- Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types¹.
- In total, 85% of lung cancers are non-small cell lung cancers (NSCLC)². Many lung cancers are driven by mutations in the epidermal growth factor receptor (EGFR), which occur in 10-15% of NSCLC patients in the US and the EU, and 30-40% of NSCLC patients in Asia³.
- Current molecular testing of lung cancer samples is complex, also because obtaining high quality tissue samples is difficult. Results can take up to several weeks⁴, often because many laboratories do not have the necessary infrastructure to perform complex tests and need to send out their samples.

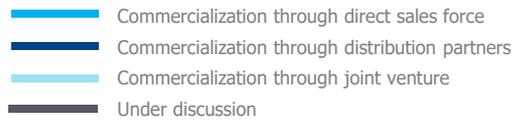
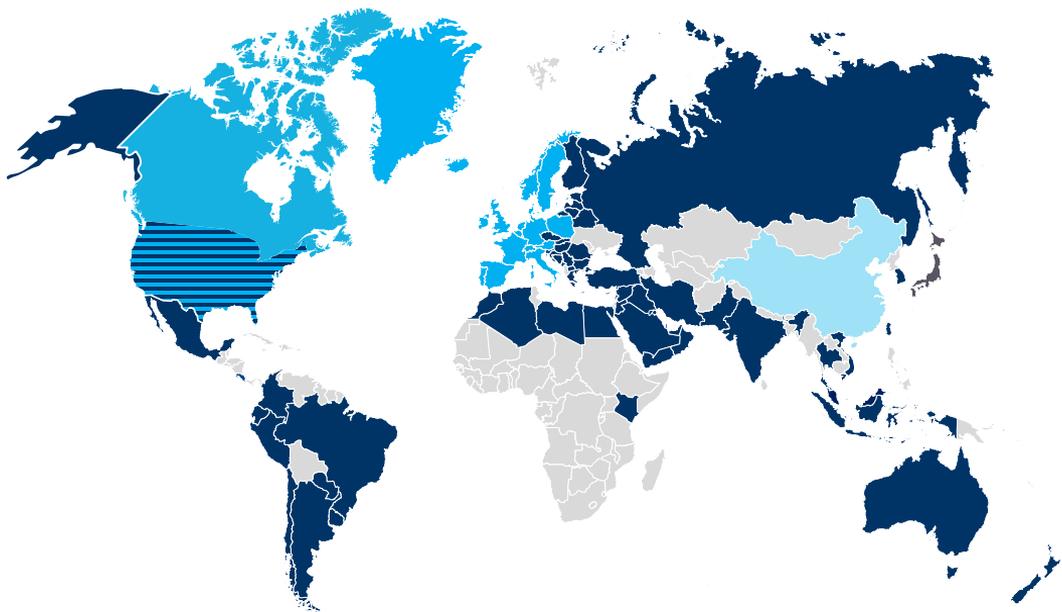
Partnership details

- AstraZeneca is a global science-led biopharmaceutical company (LON: AZN)
- Agreement announced on 29 November 2018
- A prospective lung cancer study with the Idylla™ EGFR Mutation Test (CE-IVD) will be conducted in selected European countries, aimed at demonstrating how the unique features of the Idylla™ platform can overcome the current complexity and long turnaround time for lung cancer patients by delivering accurate biomarker results faster and easier.
- The study will be initiated at more than a dozen sites in Belgium, France, Germany and Italy.

Continued expansion global commercial footprint¹

Over 70 countries covered through four sales channels:

- 1 **Direct sales force** covering Western European countries, US and Canada
- 2 **Distributor contracts** in place covering ~ 65 countries
 - Hybrid sales strategy in the **US** with own sales team & Fisher Healthcare² as commercialization partner
 - Discussion with potential distribution partners in **Japan** pending
- 3 Joint venture in **China** with Wondfo
- 4 **Global pharma collaborations** (e.g. Merck KGaA (Darmstadt, Germany) and Amgen) and **content partnerships** (e.g. Genomic Health, Immunexpress)



Joint venture with Wondfo for Chinese market (1/2)

Background Guangzhou Wondfo Biotech



- A **fast growing diagnostics leader** in China with a focus on POC¹ testing
- Listed on the **Shenzhen Exchange** (current market capitalization of USD ~1.7bn)
- Over **1,500 employees** and business activities in **over 100 countries** worldwide, serving more than 20,000 customers
- Revenues in 2017 of ~ USD 160m

Background Chinese market



- Chinese MDx market **one of the fastest growing** in the world and expected to reach a total value of USD 1.5bn by the end of 2022²
- Growth is driven by a **rising cancer incidence** in China, with over 4 million diagnosed cancer cases in 2015³
- **Lung cancer** is most frequent cancer with close to 800,000 patients being diagnosed every year⁴
- Number of **targeted and immuno-oncology therapies** prescribed based on MDx results growing; already over 500 immuno-oncology clinical trials in China in 2016⁵

Joint venture with Wondfo for Chinese market (2/2)

Deal structure

Ownership

- Joint Venture ('JV') based on a 50%-50% ownership structure

Short term focus

- Initial activities focused on local manufacturing, commercialization & registration with the Chinese Regulatory Authorities (CFDA) of existing Idylla™ oncology tests

Mid term focus

- In a future phase, the joint venture could develop new Idylla™ assays tailored to meet specific needs for the Chinese oncology market

Funding

- A total of EUR 14m of capital, over several tranches, is committed to the JV; split between the parties

License

- The joint venture will acquire from Biocartis a license to the Idylla™ platform

Launch

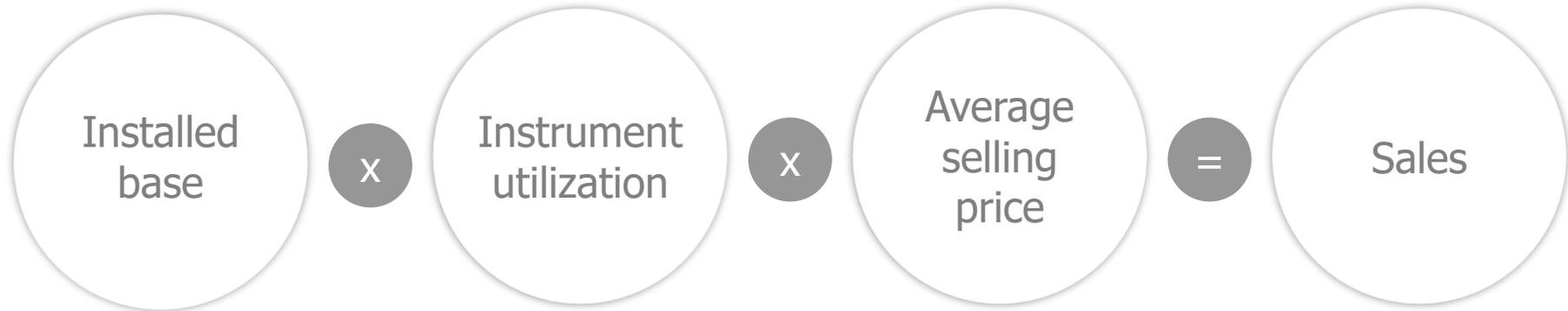
- JV is expected to launch its operational activities towards the end of 2018

High volume second cartridge manufacturing line operational by year end



- Located in Mechelen (Belgium), providing an additional **annual capacity of over 1,000,000 cartridges**
- Fully **automated** assembly workstations (versus a semi-automated on first line with an annual capacity of over 200k cartridges)
- Plastic parts manufactured with new **multi-cavity moulds** (versus single cavity on first line)
- Targeted to be operational by **end of 2018**
- Key driver in further **reduction of cartridge unit costs**

Platform and consumable driven business model



Key drivers

- Commercial footprint
- Commercialization partnerships

Key drivers

- Menu of tests
- Regulatory registrations

Key drivers

- Reimbursement
- Competitive advantage

Gross margin driven by

- Volume
- Manufacturing automation

Key messages H1 2018

Installed base	+149 added to installed base, ~800 Idylla™ instruments end H1 2018
Cartridge consumption	More than doubled year-over-year to ~58k cartridges
Product revenues	Increased year-over-year with 68% to EUR 8.6m
Total operating income	Increased year-over-year with 83% to EUR 12.7m
Cash position	EUR 91.3m as per end of June 2018 ¹
Test menu	Accelerated development of the Idylla™ MSI Assay (RUO ²)
New partnerships	Two new menu partnerships announced with Amgen and Immunexpress
Partnership pipeline	Advanced undisclosed pharma-sponsored feasibility projects
China	Finalized China strategy, resulting in a joint venture with Wondfo



¹ Biocartis' cash position at the end of Q3 2018 amounted to EUR 81m (unaudited figure)

² Research Use Only

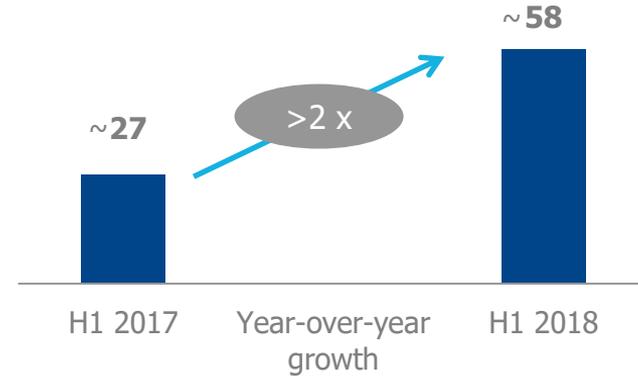
Strong continued placements & volume growth

Installed base (in # instruments)



- Increase H1 2018 driven by higher than expected growth in **Europe** and strong Idylla™ placements in the **US**
- Continued strong installed base growth in Q3 2018, **US** contributing to the **majority** of new Idylla™ placements

Commercial cartridge volume (x 1,000)



- **Europe** followed by **RoW**¹ contributed most to the growth in commercial cartridge volume in H1 2018
- Cartridge consumption for the first nine months of 2018 **doubled year-over-year**

Delivering solid performance across markets in Q3

Europe

- Successful continued efforts focused on **increased cartridge consumption** at existing clients helped fuel strong cartridge consumption growth on the existing European installed base
- Additional volume growth among existing clients was realized with the launch of the **Idylla™ MSI Assay (RUO¹)**
- The Idylla™ MSI Assay (RUO¹) triggered adoption of the Idylla™ platform with **new European clients**

US

- Continued **expansion of US direct sales team**, in combination with Fisher Healthcare sales team, and **new publications of US performance studies** supported a strong further growth of the US installed base in Q3 2018
- Feedback from **US Key Opinion Leaders (KOLs) on the Idylla™ MSI Assay (RUO¹)** has been very positive, making this test an important driver in the further near term US market adoption of the Idylla™ platform

RoW²

- Biocartis obtained **additional market authorizations** for its products in several Latin American, North African and Asian markets
- These new market authorizations, as well as the strategy to **focus** on those RoW² geographies that are of interest to pharmaceutical partners, enabled further **continued cartridge volume growth** in Q3 2018

Total operating income increased with 83% in H1 2018

Breakdown total operating income

In EUR 1,000	H1 2018	H1 2017
Product sales revenue	8,555	5,091
Collaboration revenue	3,535	716
Service revenue	251	104
Total revenue	12,341	5,912
Grants and other income	400	1,066
Total operating income	12,741	6,978

Breakdown product revenues (in EUR 1,000)

By product	H1 2018	H1 2017
Idylla™ System Sales	1,952	1,821
Cartridge Sales	6,603	3,270
Product sales revenue	8,555	5,092

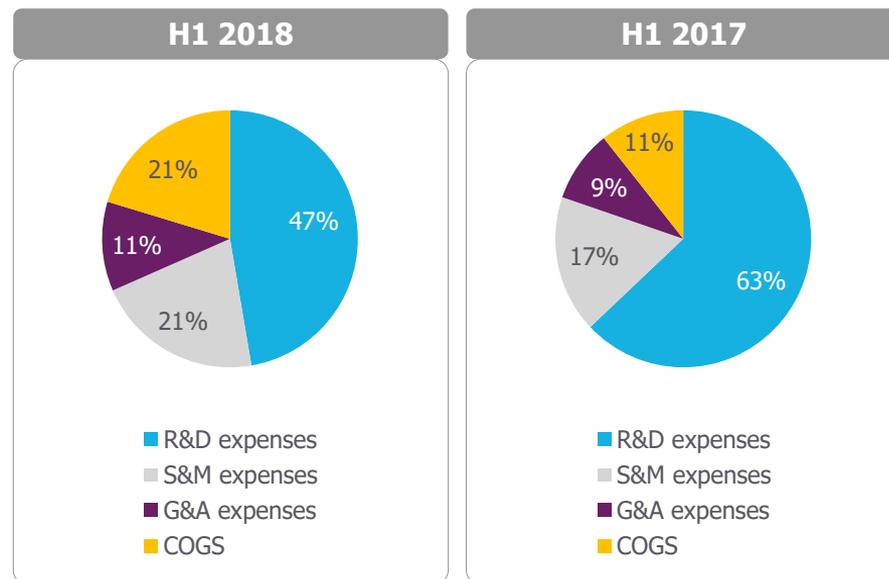
By type	H1 2018	H1 2017
Commercial revenue	7,950	5,024
R&D revenue	605	66
Product sales revenue	8,555	5,091

H1 2018 net result of EUR -21.8m

Condensed income statement

In EUR 1,000	H1 2018	H1 2017
Total operating income	12,741	6,978
COGS	(6,890)	(3,278)
R&D expenses	(16,029)	(19,320)
S&M expenses	(7,028)	(5,308)
G&A expenses	(3,933)	(2,781)
Total operating expenses	(33,880)	(30,687)
Operating result	(21,139)	(23,709)
Net financial result	(691)	(729)
Income taxes	70	456
Net result	(21,760)	(23,982)

Breakdown operating expenses



Cash position of EUR 91m end of H1 2018

Condensed cash flow statement

In EUR 1,000	H1 2018	H1 2017
Result for the period	(21,760)	(23,982)
Depreciation and amortization	2,144	2,428
Working capital changes	(1,725)	(848)
Other adjustments	1,006	230
CF operating activities	(20,335)	(22,172)
CF investing activities	(2,301)	(1,531)
CF financing activities	1,251	(1,531)
Total net cash flow¹	(21,385)	(24,182)
Cash and cash equivalents²	91,269	59,042
Financial debt	38,145	35,388

1. Excludes effects of exchange rate changes on the balance of cash held in foreign currencies

2. Including EUR 1.2 million restricted cash related to KBC Lease financing

Remarks

- **Cash flow from operating activities** improved year-over-year as the result of:
 - An improved result for the period
 - Non-cash expenses for share based payments
 - Partially offset by higher investments in working capital
- **Cash flow from investing activities** in H1 2018:
 - Mainly related to capitalized Idylla™ systems placed with customers under (reagent) rental agreements and Idylla™ systems used for assay development needs
 - Note: investments for cartridge manufacturing expansion were directly paid for via lease financing
- **Cash flow from financing activities** in H1 2018 mainly related to the net proceeds from warrants exercises, partially offset by repayments of borrowings
- Total net cash flow in H1 2018 of EUR -21.4m, resulting in a **cash position** per end of June 2018 of **EUR 91.3m**. Note: no drawdowns made on the multiple purpose credit facility and facility from the EIB

2018 Outlook

Guidance 2018



Guidance on **new Idylla™ instrument placements for 2018 now set at 300**, up from the previously communicated top end of the 250 – 275 range.



Guidance on year-over-year cartridge volume growth is narrowed to **130,000 – 135,000 commercial cartridges** (approx. 90% year-over-year growth), close to our ambitious guidance of doubling year-over-year.



Targeted year-end cash position **further narrowed to around EUR 55m**, excluding drawdowns on the Company's multiple purpose credit facility

Short term menu outlook (selection)

Area	Test	Timing	Partner
Colorectal cancer	<ul style="list-style-type: none">CE-marking of the Idylla™ MSI AssaySubmission of Idylla™ RAS PMA¹ documentation with the US FDA, subject to further feedback from US FDA interactions	<ul style="list-style-type: none">Q1 2019End 2019	
Lung cancer	<ul style="list-style-type: none">Launch of the Idylla™ ctEGFR Assay (RUO¹)	<ul style="list-style-type: none">H1 2019	
Breast cancer	<ul style="list-style-type: none">Launch of the Idylla™ Oncotype DXi IVD Breast Recurrence Score™ test in Europe	<ul style="list-style-type: none">H2 2019	

Shareholders, stock performance and coverage

Shareholder overview (as per 29 Oct 2018)

Shareholder >3% table	# shares	% shares
Johnson & Johnson Innovation	5,890,099	11.5%
OppenheimerFunds	4,830,389	9.4%
Debiopharm Innovation Fund	4,249,707	8.3%
Sycamore Asset Management	2,694,179	5.2%
Capfi Bank Delen Asset Management	2,501,777	4.9%
ParticipatieMaatschappij Vlaanderen NV (Flemish Region)	2,342,345	4.6%
Other institutional and retail investors	28,846,092	56.2%
Total outstanding shares (non-diluted)	51,354,588	100.0%

Note: see website Biocartis for more details

Stock facts

IPO date: 27 Apr 2015, Euronext Brussels

ISIN: BE0974281132

Ticker: BCART

Market cap: EUR 609m (as per 12 November 2018)

Share price performance*



Coverage



Financial calendar 2018

- 2018 full year results 28 February 2019
- Capital Markets Day 28 February 2019
- Publication 2018 annual report 4 April 2019

Appendix

Fewer erroneous results due to **standardized** cartridge

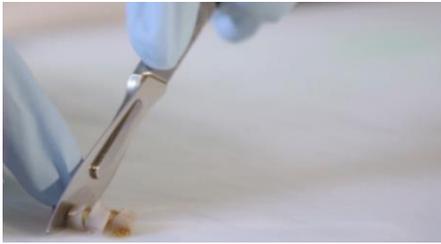
- Virtually any sample type
- No sample pre-treatment
- All reagents on board
- No PCR lab infrastructure
- No cold chain
- Stable at room temperature



Offering potential for CLIA waiver

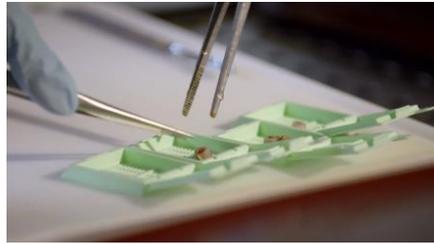
FFPE (formalin-fixed and paraffin-embedded) sample

Step 1: tissue macroscopy



- A laboratory technician cuts the tissue into smaller pieces

Step 2: formalin-fixing



- This incubate overnight in formalin for optimal conservation while maintaining the fixation of the morphology

Step 3: paraffin-embedding



- The next day, the tissue is embedded in fluid paraffin

Step 4: microtome cutting



- The paraffin block is then cut into thin slices (tissue sections), suitable for (microscopic) analysis

FFPE is the gold standard sample type within oncology

Powerful tests for lung cancer

Lung cancer testing

- Lung cancer is **most common cancer worldwide** accounting for 13% of all cancer types¹, 85% of lung cancers are non-small cell lung cancers (NSCLC)²
- Today, **EGFR mutation testing is recommended** in all patients with advanced NSCLC of a non-squamous subtype³
- Current molecular testing of lung cancer samples is a **complex** process:
 - Can take up to several weeks⁴
 - Samples are often small, with a limited amount of available lung tumor tissue
 - Laboratories send out samples for testing, causing long waiting times

Idylla™ EGFR Mutation Test



- Solid biopsy test
- CE-marked in June 2017
- Only on market fully automated CE-IVD test detecting all relevant EGFR mutations according to international guidelines

Idylla™ ctEGFR Mutation Assay



- Liquid biopsy test, under development
- Same panel as solid biopsy test (51 EGFR mutations)
- Operates directly from plasma

Idylla™ MSI: excellent concordance with reference methods



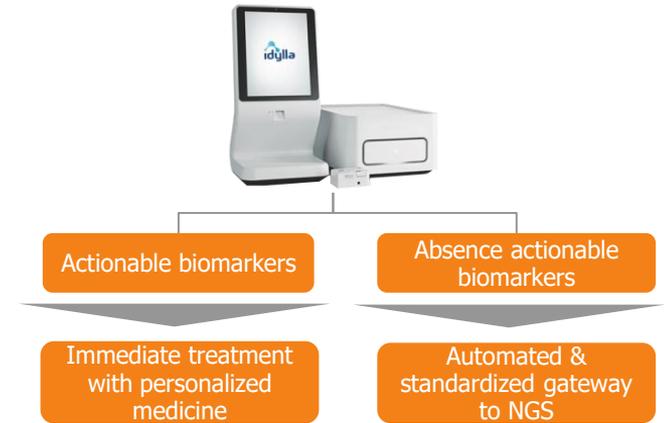
- Detects **7 novel biomarkers** in a **single cartridge**
- **Rapid** and **easy** to use: less than 2 minutes hands-on time; no manual deparaffinization; about 2.5 hours time-to-result
- **> 95% concordance** and **lower failure rates** compared to standard methods
- More than **1,400 clinical samples** included in studies

Study/Trial	Format	Cancer type	# Samples	Set-up	Validity	Overall agreement	Failure rate Idylla™ vs Promega
Claes B. et al. ASCO 2015	Abstract	CRC	N=70	- Comparison of 10 novel biomarkers, on Biorad (on-the-bench), to Promega MSI	N/A	98.3%	9% vs 16%
De Craene B. et al. ESMO 2017	Poster	Gastric Cancer	N=150 N=85	- Validity of 10 novel biomarkers - Comparison to Promega MSI	10% MSI-H reported	100%	0% vs 10.6%
Maertens G. et al. ESMO 2017	Poster	CRC	N=870 N=201	- Validity of 8-10 novel biomarkers - Comparison to Promega MSI	17.6% MSI-H reported	93.6%	4% vs 11.9%
De Craene B. et al. ASCO 2018	Online Abstract	CRC	N=348	- Comparison to Promega MSI	N/A	96.1%	3.4% vs 3.4%

NGS Prep Panel Lung completes lung menu

Idylla™ lung menu	Application
EGFR	<ul style="list-style-type: none"> Panel of >50 EGFR mutations as included in clinical guidelines Solid and liquid biopsy version required as tumor tissue is often not available Clinical guidelines¹ recommend EGFR testing for all NSCLC patients¹
ctEGFR	
GeneFusion Panel ³	<ul style="list-style-type: none"> Clinical guidelines¹ recommend ALK and ROS1 testing for all NSCLC patients²
BRAF	<ul style="list-style-type: none"> Panel of 7 BRAF mutations Clinical guidelines¹ recommend BRAF testing for patients who are negative for EGFR, ALK and ROS1
NGS Prep Panel Lung	<ul style="list-style-type: none"> A multiplexed sequencing panel for additional/infrequent markers Becoming accepted by international societies and increasingly mentioned in guidelines¹

- **Complete menu** for lung cancer testing from clinically **actionable** to clinically **oriented** targets starting from a **minimal sample input**



- **Fastest time-to-therapy** for frequent 'actionable mutations' as recommended by clinical guidelines

NGS sample prep & target enrichment on Idylla™

Traditional NGS workflow



- Isolate genomic material from clinical sample
- Quantify genomic material via qPCR



- Target amplification via PCR



- Sample indexing and tagging
- Purification



- Pool libraries
- Sequencing
- Data analysis

Summary traditional workflow

4

#labs

6

#auxilliary devices

6h

Hands-on time¹

3

#PCR reactions

18

#samples/
batch

12h

Turnaround time¹



Idylla™ NGS Prep Panels:

- **Standardization** and **automation** of FFPE sample prep and target enrichment workflow
- **Compatible** with mainstream desktop sequencers
- **Minimization** of required amount **FFPE sample input**
- Maintains **sample pooling flexibility**
- Biocartis NGS panel design makes overall NGS workflow more **cost-effective**
- Offers **partnership possibilities** for third party NGS panel content and CDx



Increasing biomarker-based therapies requiring CDx tests

What is Companion Diagnostics (CDx)?

- A CDx Test is used as a **companion to a therapeutic drug**¹ that helps predict if a patient is likely to respond to a treatment or not²
- CDx are most useful in the field of **targeted therapy** and **immunotherapy**
- The Personalized Medicine Coalition counted **132 personalized medicines**³ or drugs that point to specific biomarker(s) in their labels to direct use, currently on the market
- Analysts estimate the market value for drugs reliant on CDx at **over \$25 billion in 2015**³
- A recent survey by the Tufts Center for the Study of Drug Development showed that **42 % of the drugs in the development pipeline** now include **biomarkers** in their R&D design³

Growing global market for CDx

The global companion diagnostic market is expected to reach USD **6.5 billion by 2022** from USD 2.6 Billion in 2017, at a **growth rate (CAGR⁴) of 20%**⁵

Rationale CDx partnerships for Biocartis

- **Increased number eligible patients** for their targeted therapies given faster TaT⁶ and high sensitivity of tests:
 - **Fast TaT**: less competition with therapies not requiring a biomarker
 - **High sensitivity**: more patients detected with relevant biomarkers

1. 'Companion Diagnostics' FDA. Retrieved 26 September 2016. ; 2. Duffy, MJ; Crown, J (October 2013). "Companion biomarkers: paving the pathway to personalized treatment for cancer.". Clinical chemistry. 59 (10): 1447–56. PMID 23656699; 3. "The Personalized Medicine Report", 2017, Opportunity, Challenges and the Future, The Personalized Medicine Coalition; 4. CAGR = Compound Annual Growth Rate; 5. MarketsandMarkets, 2016, "Companion Diagnostics Market by Technology (PCR, IHC, NGS, ISH), Indication (Breast cancer, NSCLC, Colorectal cancer, Neurological disorders, Infectious Diseases), End User (Pharmaceutical & Biopharmaceutical Companies, Reference Lab) - Global Forecast to 2022"; 6. TaT = Total Turnaround Time



Contact

Biocartis Investor Relations
Generaal de Wittelaan 11 B3
2800 Mechelen
Belgium

tel. +32 15 63 17 29
ir@biocartis.com

www.biocartis.com