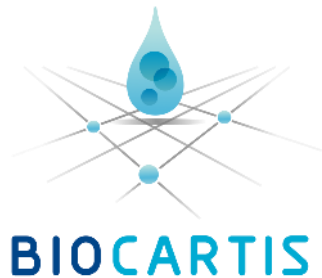


12 NOVEMBER 2020

# Biocartis Virtual Capital Markets Day 2020

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# TODAY'S PRESENTERS



**Gaëlle Boulet**  
Life Cycle Lead Idylla™ Menu  
Biocartis



**Benoit Devogelaere**  
Chief Technology Officer  
Biocartis



**Herman Verrelst**  
Chief Executive Officer  
Biocartis



**Dr. Tao Hong, MD, PhD**  
Chief of Microbiology & Molecular Diagnostics,  
Department of Pathology,  
Hackensack University Medical Center (US)



**Prof. Dr. Umberto Malapelle, PhD**  
Assistant Professor in Anatomic Pathology in School of  
Medicine and Chief Supervisor of Predictive Molecular  
Pathology Laboratory, Department of Public Health of  
University Federico II of Naples, Italy (EU)



**Dr. Rollie Carlson, PhD**  
Chief Executive Officer,  
Immunexpress (US)

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*Since the COVID-19 outbreak in December 2019, it has developed into a pandemic, causing significant disruptions to the global economy, including in certain countries in which the Company is operating its business. During H1 2020, the Company has experienced a slow down of its commercial activities and delays of certain partner projects as a result of various measures taken to contain the spreading of the virus. The extent to which the pandemic will continue to affect the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including but not limited to the duration of the pandemic, the severity and resistance of the virus and the actions taken to contain the virus or treat its impact. In particular, and although the Company currently expects that significant demand for its pandemic response products could mitigate the impact of COVID-19 on its oncology business, the continued spread of the virus could adversely impact its operations, including among others, the manufacturing and supply chain, sales and marketing and collaboration activities with partners, and could have an adverse impact on the Company's business and financial results.*

# AGENDA

15.00-15.15 **Introduction** by Herman Verrelst, CEO Biocartis

15.15-15.45 **Oncology strategy update**

15.45-16.15 **Infectious disease strategy update**

16.15-16.35 **Q&A**

**16.35-17.20 Testimonials by Idylla™ users**

16.35-16.50 *"The versatility of Idylla™ in oncology and infectious disease"* by Tao Hong, MD, PhD, Chief of Microbiology & Molecular Diagnostics Department of Pathology, Hackensack University Medical Center, US

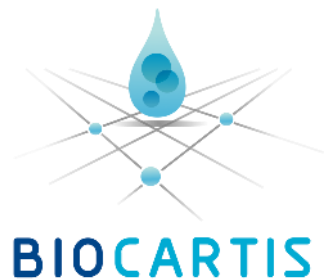
16.50-17.05 *"Predictive molecular pathology in the time of COVID-19"* by Umberto Malapelle, PhD, Chief Supervisor of Predictive Molecular Pathology Laboratory, University of Naples Federico II, Italy, EU

17.05-17.20 *"Partnering in Infectious Disease: Immunexpress"* by Rollie Carlson, PhD, CEO Immunexpress, US

17.20 **End**

# Introduction

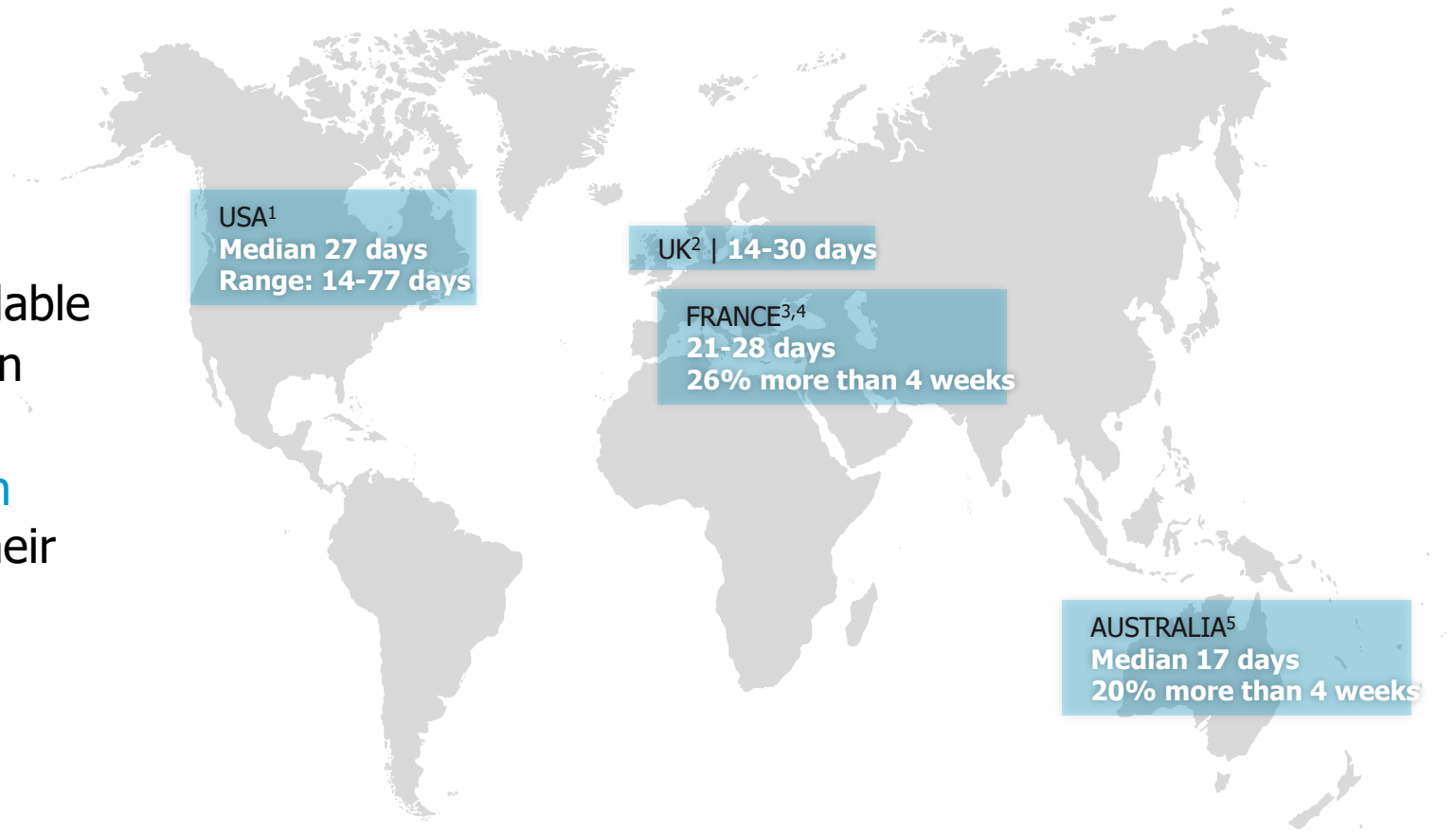
Herman Verrelst, CEO Biocartis



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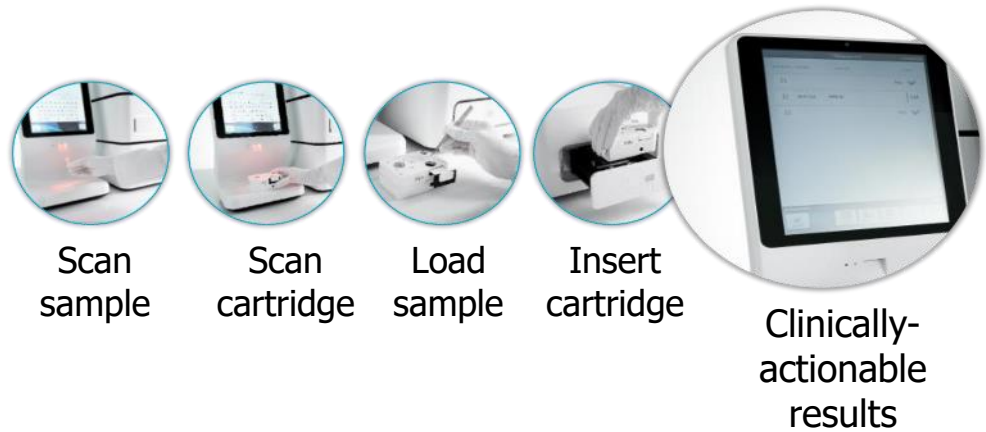
# DIFFICULT ACCESS TO MOLECULAR DIAGNOSTICS INFORMATION

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



# RAPID MOLECULAR TESTING ON THE FULLY AUTOMATED IDYLLA™

## UNIQUE PLATFORM FOR DUAL USE IN ONCOLOGY & INFECTIOUS DISEASE

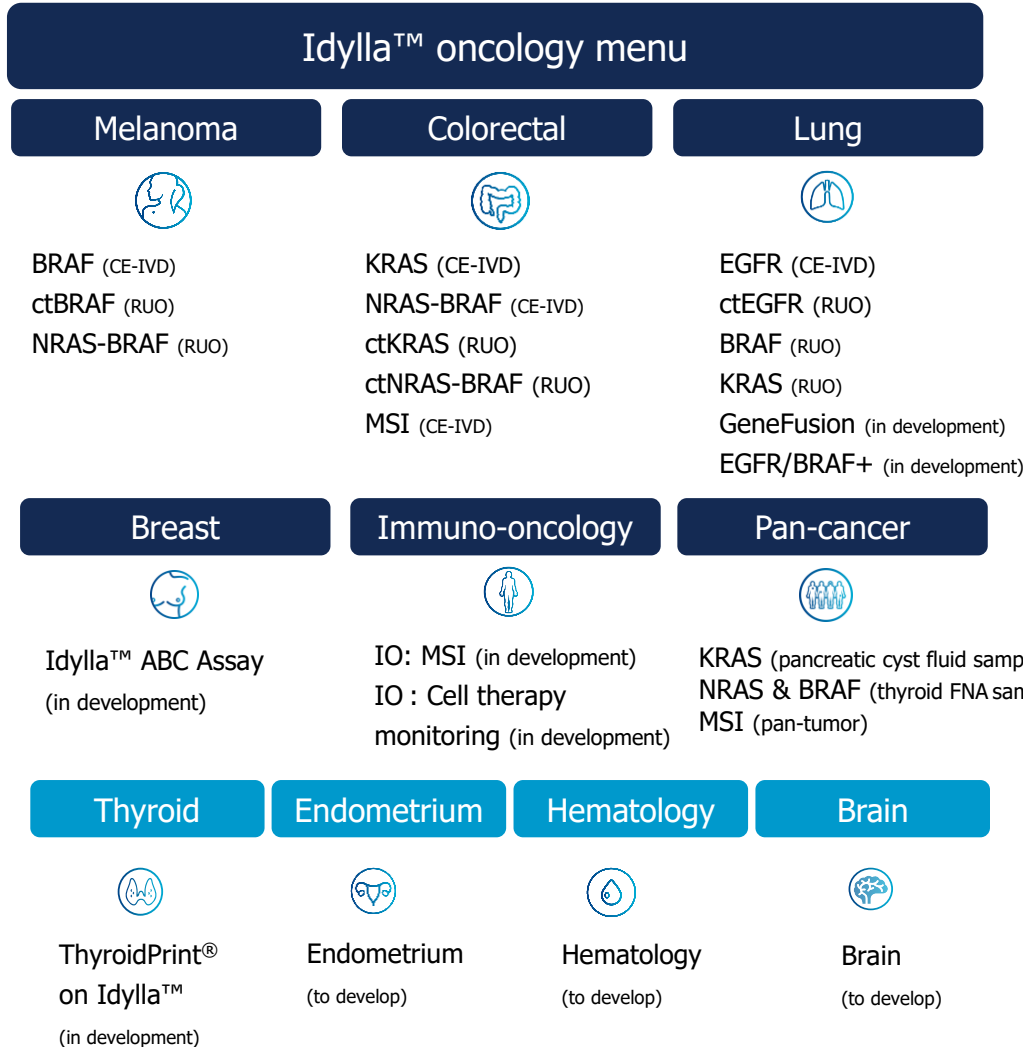


Superior **sensitivity** and **ease-of-use**,  
combined with **sample-to-result turnaround**  
**time of 65 to 160 minutes\***

Unique, versatile platform for **dual use** in  
**oncology and infectious disease**

\* Based on turnaround times of current on-market oncology tests

# DEVELOPMENTS IN IDYLLA™ ONCOLOGY MENU



## • Oncology focus:

- On market **Idylla™ oncology test menu** in colorectal, lung, melanoma, with ongoing developments in breast and thyroid cancer
- Selected opportunities to **broaden and deepen** in oncology
  - Pan-cancer opportunities
  - Improving with the **Idylla™ FLEX technology**
  - Expansion into **new areas**: endometrium, brain and hematological cancers

## • Expansion in infectious diseases:

- More **diversified** Idylla™ test menu to accelerate further installed base growth
- Driven by the current **pandemic testing needs**

NEW

Please see the Idylla™ oncology pipeline for all details on the development & regulatory status of assays. The Idylla™ oncology pipeline reflects the different cartridges and biomarkers in development, including cartridges that can be used for research applications. Please see [here](#) for more information about the respective studies, or to the specific product labeling for applicable intended use for each individual Biocartis product. All publications, abstracts & posters are available on [www.biocartis.com/publications](http://www.biocartis.com/publications). Overview is subject to change in amongst others prioritization of test development by Biocartis and/or partners driven by commercial, partnering & operational considerations. The Idylla™ GeneFusion Assay (RUO) & Idylla™ GeneFusion Panel (IVD) are currently under development. NTRK1-3 will be only available in the Idylla™ GeneFusion Assay (RUO). Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc.; ABC = Advanced Breast Cancer; IO = Immunology; FNA = Fine Needle Aspirates



# PARTNERSHIPS TO ACCELERATE MENU DEVELOPMENT

## Pharma & biotech partners

- **What:** (joint) development of CDx<sup>1</sup> on Idylla™ platform
- **For Biocartis:** faster commercial adoption, higher market shares
- **For partner:** better & faster selection of eligible patients for targeted therapies given faster TaT & high sensitivity. Fast TaT reduces competition with therapies not requiring a biomarker, high sensitivity means more patients detected with relevant biomarkers

## Content partners

- **What:** porting of proprietary biomarker panels developed & validated by 3rd parties on Idylla™ platform
- **For Biocartis:** proprietary 3rd party content on Idylla™ platform, expanded menu appealing to larger audience
- **For partner:** accelerated global roll-out of content, focus on content education since no platform education needed, cost efficiencies

## Development partners

- **What:** development of Idylla™ assays with IVD development companies and research institutes
- **For Biocartis:** lowered menu development costs
- **For partner:** contribution to medical innovation, knowledge sharing & building



AMGEN

MERCK

AstraZeneca

Bristol-Myers Squibb

Kite

COVANCE

Johnson & Johnson

ENDPOINT HEALTH

Immunexpress

GENEPRODX

LifeArc

UK based medical research charity<sup>2</sup>

a\*ccelerate

Singapore's Agency for Science, Technology and Research<sup>3</sup>

1. CDx = Companion Diagnostics; 2. On 15 June 2017, MRC Technology changed its name in 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. On 1 September 2020, Biocartis announced the expansion of the partnership with LifeArc in the field of infectious and immune related diseases; 3. Partnership is with ETPL, the commercialization arm of A\*STAR; 5. CAR = cartridges; 6. COGS = costs of goods sold

# KEY MESSAGES Q3 2020 BUSINESS UPDATE

## Commercial cartridge volume

- Growth **+ 61% year-on-year**: recovered from significant pandemic impact in Q2 2020
- Growth **+27% growth year-to-date**: on track for the targeted 30% growth for FY2020
- In **US**: returned to growth of commercial cartridge volumes in oncology, complemented by initial sales of Idylla™ SARS-CoV-2 Test
- In **EU**: consistent growth in oncology, fully in line with pre-pandemic expectations
- In **RoW**<sup>1</sup>: year-on-year Q3 2020 growth moderate, while year-to-date growth still stalling due to continued impact of pandemic

## Installed base

- During Q3 2020, installed base continued to **expand**
- The **US representing 50%** of all new Idylla™ placements
- Lingering impact of pandemic continued to slow down the Idylla™ instrument growth in **RoW markets**

## Partnerships

- Partnership with **GeneproDx**<sup>2</sup> for development of GeneproDx's novel genomic test ThyroidPrint® on Idylla™
- Partnership with **Endpoint Health**<sup>3</sup> for development and commercialization of a novel companion diagnostic<sup>4</sup> (CDx) test on Idylla™ for critically ill patients
- Partnership with **Genomic Health, Inc.** (a subsidiary of Exact Sciences Corporation): termination of collaboration driven by uncertain timing of a product market release because of pandemic
- Biocartis joined the COVID-19 Testing Industry Consortium led by **Bristol-Myers Squibb Company**

## Test menu

- Publication of **FACILITATE study** supported by AstraZeneca, showing that Idylla™ reduces EGFR mutation testing turnaround time by more than a week, allowing faster patient management decisions<sup>5</sup>
- EUR 1.2 million **grant from VLAIO** for the development of the **Idylla™ GeneFusion Assay**
- Successful market release in Europe of the CE-marked version of **SeptiCyte® RAPID on Idylla™**, in collaboration with Immunexpress
- Successful launch of CE-marked version of the **Idylla™ SARS-CoV-2 Test**

## Cash position

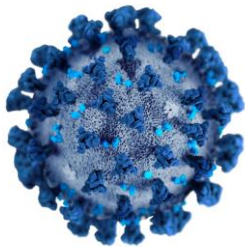
- Biocartis' cash position end Q3 2020 amounted to **EUR 137m** (unaudited figure)

<sup>1</sup> RoW = Rest of the World. RoW is defined as the world excluding European direct markets, US, China and Japan; <sup>2</sup> On 3 November 2020, Biocartis announced it had signed a license, development and commercialization agreement with GeneproDx, a molecular diagnostics company based in Santiago, Chile; <sup>3</sup> On 3 November 2020, Biocartis announced it has entered into a partnership agreement with Endpoint Health, a Palo Alto, CA (USA) based company developing personalized care solutions and targeted therapies for critically ill patients; <sup>4</sup> An IVD companion diagnostic device is an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Source: US FDA, last consulted on 6 November 2020; <sup>5</sup> It concerned a prospective, real-world data set study across 16 European sites in Belgium, France, Germany and Italy. The study aimed to prospectively test 100 paraffin-embedded biopsy or cytology tissue samples with ≥10% neoplastic cells per site, from patients with advanced NSCLC

# THE RIGHT MOMENT FOR A STRATEGIC REVISIT

## MARKET at a tidal shift due to pandemic

- A **new 'pandemic world'**: supports current step-up in infectious diseases
- A **unique opportunity**: speed and simplicity of Idylla™ addresses current and future rapid response testing needs
- Evolution of **testing needs**: unique combination of oncology and infectious disease testing on one single platform



**Idylla™ as a unique rapid, easy to use and highly accurate platform for dual use in both oncology & infectious disease testing**

## BIOCARTIS at an inflection point

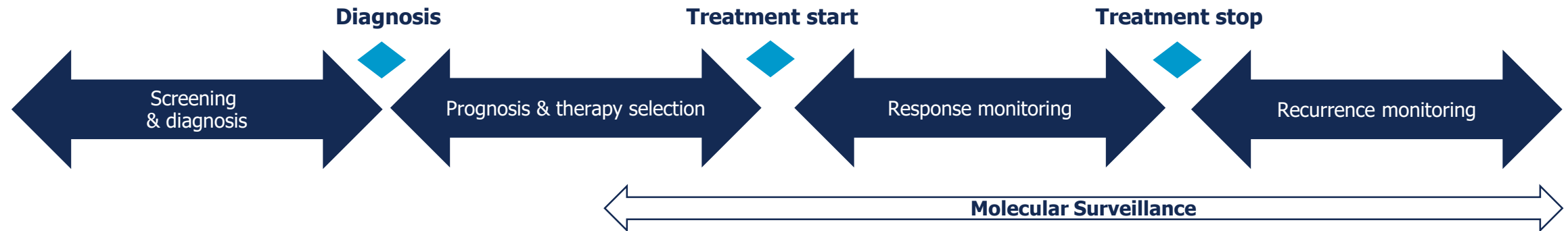
- Our **oncology customer base** and **franchise** is ready for further scaling:
  - Product excellence: demonstrated Idylla™ performance
  - Commercial: global market access and expanding installed base due to commercial network, growing regulatory approvals Idylla™ platform & tests
  - Operational footprint: growing manufacturing capacity while maintaining highest quality standards
  - R&D efficiencies: leaner development processes
- First expansions in **infectious diseases**:
  - Pandemic menu: Idylla™ SARS-CoV-2 and SeptiCyte® RAPID on Idylla™
  - First market access: sales force contracted premium accounts in EU & US
- Growing **partner business model**: optimizing partnering business model to accelerate core strategy

# Oncology strategy update

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# IDYLLA™ IN THE CANCER TREATMENT CONTINUUM



## Gene signatures

- MDx tests based on **RNA Gene Signatures** are used for e.g.:
  - Diagnosis
  - Prognosis
- Often **high value once validated** & clinical value demonstrated
- Examples
  - SeptiCyte® RAPID
  - ThyroidPrint®



## Targeted therapy

- MDx tests detecting **specific tumor mutations** used for therapy selection in a specific cancer type
- **Significant pharma pipeline** of new targeted therapies
- Examples
  - Zelboraf®<sup>1</sup> (BRAF)
  - Tagrisso®<sup>2</sup> (EGFR)
  - Erbitux®<sup>3</sup> (RAS)
  - Vectibix®<sup>4</sup> (RAS)



## Pan-tumor

- **Pan-tumor application of tumor mutation tests** for therapies selected based on genetics rather than location of the tumor
- Allows therapy use across **multiple cancer types**
- Positive impact on underlying **test volumes**
- Examples
  - Vitrakvi®<sup>5</sup>
  - Keytruda®<sup>6</sup>
  - Rozlytrek®<sup>7</sup>



## Immuno-oncology

- MDx tests supporting **immuno-oncology cancer treatments**
- Consists of **many different therapies**, e.g.:
  - Immune checkpoint inhibitors
  - Cell and viral therapies
  - Vaccines
- **High unmet need** for underlying MDx testing



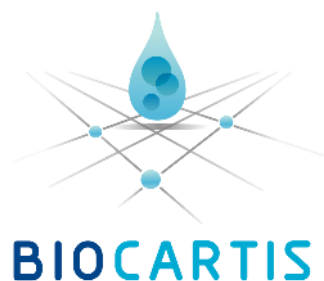
## Liquid biopsy

- MDx tests via **liquid samples**
- Use in **diagnosis, prognosis and Molecular Surveillance** (i.e. therapy selection, response and recurrence monitoring)
- Can be done through **off-the-shelf catalogue panels** as well as **tumor-informed, personalized panels**



































































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# THE IDYLLA™ TEST MENU 2.0:


GAËLLE BOULET, LIFE CYCLE LEAD IDYLLA™ MENU  
BIOCARTIS



# IDYLLA™ ONCOLOGY PIPELINE

Cartridge	Development	RUO	CE	USA	Japan	China
  KRAS  NRAS-BRAF  ctKRAS  ctNRAS-BRAF  MSI	Product update ongoing			PMA	Ongoing	Ongoing
	Product update ongoing			PMA	Ongoing	Ongoing
	Product update ongoing			510(k)	Ongoing	Ongoing
	Product update ongoing				Ongoing	Ongoing
	Ongoing					
  EGFR  ctEGFR  BRAF  KRAS  GeneFusion  EGFR/BRAF+	Product update ongoing				Ongoing	Ongoing
	Ongoing					
	Ongoing					
	Ongoing					
	Ongoing					
  BRAF  ctBRAF  NRAS-BRAF	Product update ongoing					
	Ongoing					
	Ongoing					
  Idylla™ ABC Assay	Ongoing					
	Ongoing			PMA	Ongoing	Ongoing
  IO: MSI  IO: Cell therapy monitoring	Ongoing					
	Ongoing					
 KRAS (pancreatic cyst fluid samples) NRAS & BRAF (thyroid FNA <sup>7</sup> samples) MSI (pan-tumor) <sup>4</sup>						
						
						
<b>NEW</b>   ThyroidPrint® on Idylla™	Ongoing					
<b>NEW</b>   Endometrium	 					
<b>NEW</b>   Hematology	  	 	Shared design & development project			
<b>NEW</b>   Brain						

### Legend

-  Product update ongoing
-  Ongoing
-  = on market
-  = FLEX product
-  = planned start
-  = solid biopsy
-  = liquid biopsy

RUO = Research Use Only, not for use in diagnostic procedures; CE = CE-marked IVD; Product updates = Product updates to ensure IVDR compliance and implementation of Post-Marketing Surveillance feedback; ABC = Advanced Breast Cancer; IO = Immuno-oncology; FNA = Fine Needle Aspirates; PMA = Pre-Market Approval; 510(k) notification = a premarket submission made to the US FDA. Source: US FDA website. All publications, abstracts & posters are available on [www.biocartis.com/publications](http://www.biocartis.com/publications). The Idylla™ GeneFusion Assay (RUO) & Idylla™ GeneFusion Panel (IVD) are currently under development. NTRK1-3 will be only available in the Idylla™ GeneFusion Assay (RUO). Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc. The Idylla™ development pipeline reflects the different cartridges and biomarkers in development, including cartridges that can be used for research applications. Please see [here](#) for more information about the respective studies, or to the specific product labeling for applicable intended use for each individual Biocartis product. Overview is subject to change in amongst others prioritization of test development by Biocartis and/or partners driven by commercial, partnering & operational considerations.



# CURRENT LUNG CANCER MENU ON IDYLLA™

## What is lung cancer?

- **Most common cancer worldwide:** 13% of all cancers<sup>1</sup>, 85% are non-small cell lung cancers (NSCLC)<sup>2</sup>
- EGFR mutation testing: **recommended in all patients with advanced NSCLC** of a non-squamous subtype<sup>3</sup>
- Current lung cancer molecular testing is **complex**:
  - Can take up to several weeks<sup>4</sup>, as labs often send out samples
  - Samples often small, with limited amount of available lung tumor tissue

## Idylla™ EGFR Mutation Test (CE-IVD)



- Fully automated, directly on **1 FFPE** tissue slice from metastatic NSCLC<sup>5</sup>
- Less than 2 minutes hands-on time
- Covers **51 mutations** in 1 single cartridge
- Approx. **150 minutes** sample-to-result
- Mutation detection for patient management assessment



## Existing testing in lung cancer

- Standard of care: **slow, complex, costly**
- **Combination of different techniques** (IHC, FISH & qPCR) to cover relevant biomarkers: many samples needed, time-consuming if tests are performed sequentially
- **Next-generation sequencing (NGS)**
  - Stringent sample requirements: low sample quality & quantity might lead to high invalid rates
  - Long turnaround time
  - BioIT complexity is major hurdle

## Idylla™ ctEGFR Mutation Assay (RUO)



- Fully automated, directly on **2 ml plasma**
- Approx. 2 minutes hands-on time
- Covers **51 mutations** in 1 single cartridge
- Approx. **160 minutes** sample-to-result





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# TOWARDS A COMPREHENSIVE LUNG CANCER WORKFLOW ON IDYLLA™

## TWO-STEP LUNG CANCER TESTING ON IDYLLA™



The Idylla™ EGFR/BRAF+ Mutation Assay & the Idylla™ GeneFusion Assay intend to cover the **vast majority** of the **actionable mutations** in NSCLC

### NEW: Idylla™ GeneFusion Panel\*



- Chromosomal translocations can produce gene fusions leading to **uncontrolled tyrosine kinase** activity
- Tyrosine kinase inhibitors are recommended by **international guidelines**<sup>1</sup> for NSCLC patients with a specific gene fusion
- Idylla™ GeneFusion Assay:
  - Fully automated testing of **ALK, ROS1, RET, MET exon 14, NTRK1-3** in **one single cartridge**<sup>2</sup>
  - Less than **2 minutes** hands-on time with turnaround time of **~180 min** using only **1 slice of FFPE**<sup>3</sup>

### NEW: Idylla™ EGFR/BRAF+ Mutation Test\*



- **>60 targets** in one single Idylla™ cartridge
- Detects vast majority of **actionable mutations in DNA**
- Targets include markers in **EGFR** and **BRAF**, as well as a.o. **KRAS G12C** which covers **~41%** of KRAS mutations in NSCLC<sup>4</sup>
- Completes the Idylla™ lung menu and extends partnering opportunities

The Idylla™ EGFR/BRAF+ Mutation Assay and the Idylla™ GeneFusion Assay can be used in a different sequential order. The Idylla™ EGFR/BRAF+ Mutation Assay and the Idylla™ GeneFusion Assay should be performed following international recommended guidelines.

\* The Idylla™ GeneFusion Assay and the Idylla™ EGFR/BRAF+ Mutation Assay will first be launched as RUO. The Idylla™ GeneFusion Assay (RUO) & Idylla™ GeneFusion Panel (IVD) are currently under development. NTRK1-3 will be only available in the Idylla™ GeneFusion Assay (RUO). Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc.; 1. NCCN Guidelines version 8.2020 Non-small Cell Lung Cancer; 2.; 3. FFPE = formalin fixed, paraffin embedded; 4. 25% of NSCLC are KRAS and 41% of KRAS mutations are G12C. Source: Molecular Diagnostics in Lung Cancer: A Review of Current and Emerging Diagnostic Tests.

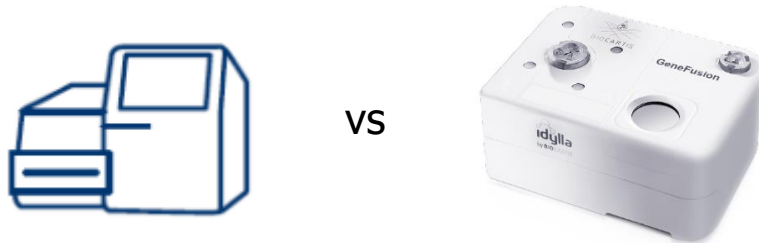


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# STRONG PERFORMANCE OF THE IDYLLA™ GENE FUSION ASSAY

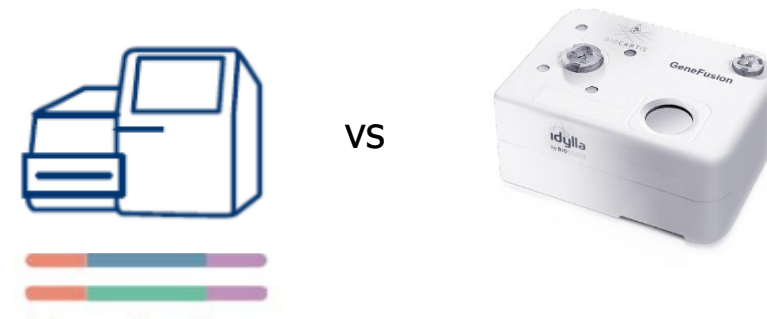
## Idylla™ vs comprehensive NGS panel

- Comparator: **comprehensive NGS** technology, optimized for detection of gene fusions
- **Strong agreement** across all markers:
  - Overall Percentage Agreement: 97-100%
  - Positive Percentage Agreement: 93-100%
  - Negative Percentage Agreement: 97-100%



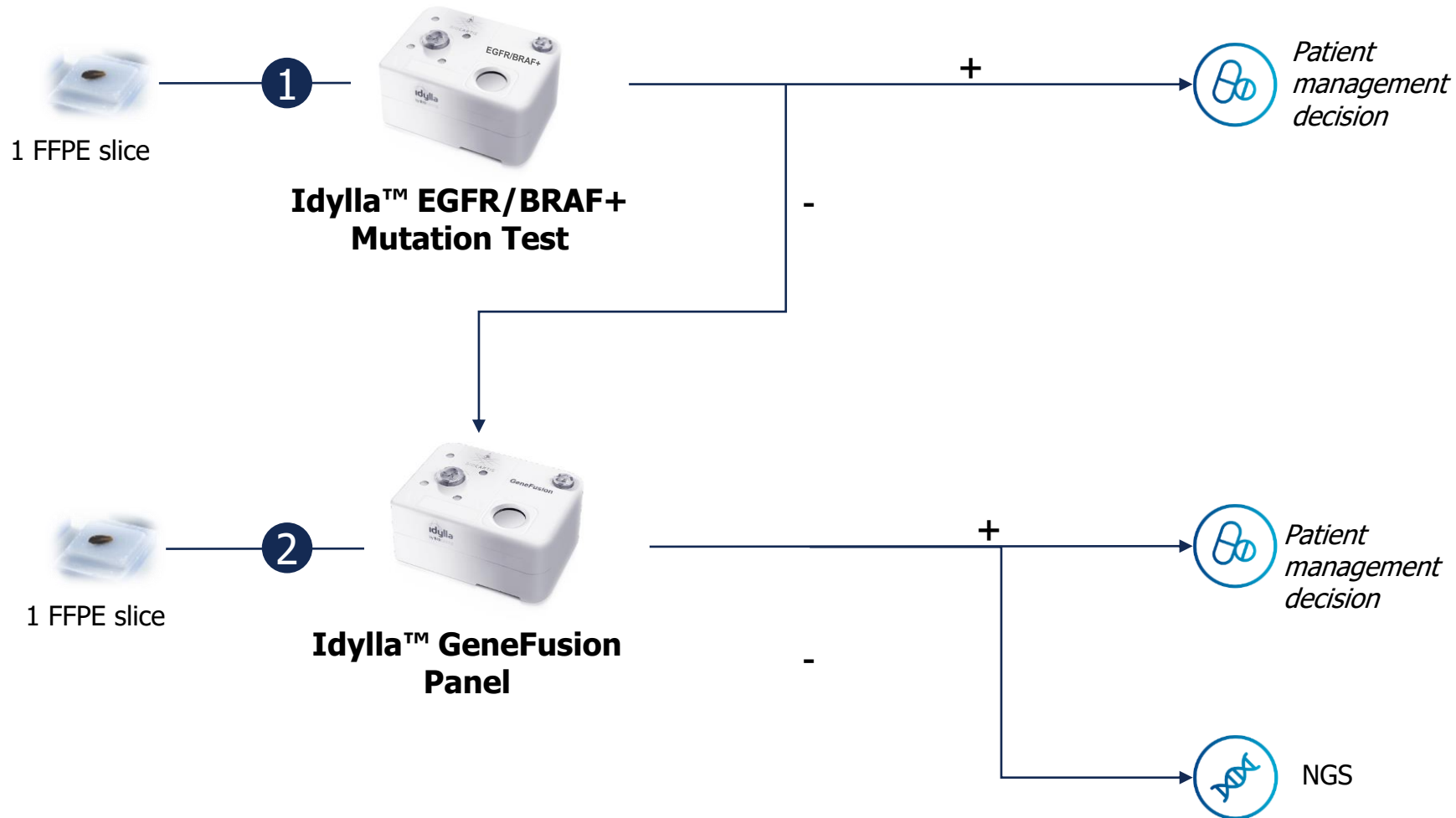
## Idylla™ vs amplicon-based NGS panel

- Comparator: **amplicon-based NGS** technology
- **Excellent agreement** across all markers:
  - Overall Percentage Agreement: 99-100%
  - Positive Percentage Agreement: 100%
  - Negative Percentage Agreement: 99-100%





# THE FUTURE IDYLLA™ LUNG DIAGNOSTIC WORKFLOW



**Idylla™ in lung diagnostics, complementary to NGS**

- Idylla™ as the go-to platform for fast results on actionable biomarkers, enabling rapid initiation of targeted therapy with minimal sample input and superior ease-of-use
- If no actionable biomarkers are detected with Idylla™, NGS can be performed to complete the profiling and support experimental therapies

# STUDIES DEMONSTRATE INCREASING PAN-TUMOR POTENTIAL

## What is pan-tumor?

- Pan-tumor implies that therapy selection is **driven by genetics rather than location of the tumor**
- Allows therapy use **across multiple cancer types**
- Also pharmaceutical **trials** based on pan-tumor testing
- Positive impact on underlying **test volumes**

## MSI data from papers published in peer-reviewed journals



Colorectal

Concordance: **93%-100%**  
Sample size: 683

Gilson et al. Sci Rep 2020; Mindiola-Romera et al. Exp Mol Path 2020; Malapelle et al Cells 2020; Pécriaux et al. JCP 2020; Zwaenepoel et al JMD 2020; Lee et al J Pat Trans Med 2019; Samasion et al JCP 2019; Li et al Clin Col Can 2019



Endometrial

Concordance: **97%**  
Sensitivity: 95%  
Specificity: 100%

Gilson et al. Sci Rep Oct 2020  
Pécriaux et al. JCP Jun 2020



Gastric

Concordance: **97%**  
Sensitivity: 96%  
Specificity: 100%

Farmkiss et al. JCP Oct 2020  
Pécriaux et al. JCP Jun 2020



Urinary tract

Concordance: **100%**  
Sensitivity: 94%  
Specificity: 100%

Pécriaux et al. JCP Jun 2020



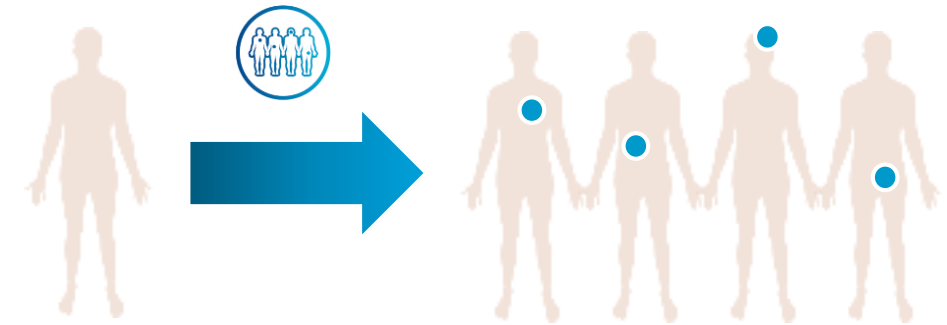
Duodenal  
pancreatic

Concordance: **100%**  
Sensitivity: 94%  
Specificity: 100%

Pécriaux et al. JCP Jun 2020

## Pan-cancer applications

- Idylla™ assays for **research in pan-tumor applications**



### Idylla™ cartridge

- KRAS/NRAS/BRAF
- MSI
- GeneFusion







### Select potential applications

- Lung, pancreas, breast
- Gastric, prostate, endometrial
- Gastro-intestinal, thyroid









Efficient access to pan-tumor setting:  
validation of existing products

# NEW HIGH GROWTH ONCOLOGY SEGMENTS

## Reinforcing **existing** oncology areas

Test	Use	Value proposition
<b>Idylla™ EGFR/BRAF+ Mutation Test</b>  	Detection of the vast majority of actionable mutations in FFPE samples from patients with NSCLC, including a.o. EGFR, BRAF and KRAS G12C	Fast time-to-result, ease-of-use, sample versatility
<b>Idylla™ GeneFusion Assay</b>  	Detection of the vast majority of actionable gene fusions in FFPE samples from patients with NSCLC, including a.o. ALK, ROS1, RET, METex14 and NTRK1-3	Fast time-to-result, ease-of-use, sample versatility
<b>Idylla™ Pan-tumor MSI Test</b>  	Detection of MSI status in FFPE samples from patients with different cancer types	Easy (automation, sample-to-result), fast molecular test next to IHC

## Entering **new** oncology areas




Test	Use	Value proposition
<b>Idylla™ Hematology Assay</b>  	Detection of mutations in samples from patients with certain hematological cancers	Fast time-to-result vs current batch-based methods, ease-of-use, standardization
<b>Idylla™ ABC Panel</b> <i>Collaboration with lifeArc</i>  	Detection of mutations in FFPE samples from patients with advanced breast cancer	Fast time-to-result, ease-of-use, sample versatility
<b>Idylla™ Brain Assay</b>  	Detection of mutations in samples from patients with brain cancer	Ease-of-use, sample versatility, fast time-to-result
<b>Idylla™ Endometrium Assay</b>  	Detection of mutations in samples from patients with endometrial cancer	Ease-of-use, sample versatility, fast time-to-result, cost-effectiveness

Names of Idylla™ Assays, Tests or Panels can be subject to change. Unless stated different, Idylla™ Assays are first launched as RUO assay.

Idylla™ GeneFusion Assay (RUO) & Idylla™ GeneFusion Panel (IVD) are currently under development. Not all markers may be present in the Idylla™ GeneFusion Panel. Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc

FFPE = formalin fixed, paraffin embedded; NSCLC = Non-small cell lung cancer; NGS = Next Generation Sequencing; IHC = Immunohistochemistry is a valuable tool for the identification and visualization of tissue antigens in biological research and clinical diagnostics. Source: ScienceDirect


## Background collaboration

- A [license, development and commercialization agreement](#) focused on the development of GeneproDx's novel genomic test  **ThyroidPrint®** on the Idylla™ platform
- GeneproDx will take the lead in the development of the Idylla™  **ThyroidPrint®** test
- Biocartis will be responsible for the distribution of the  **ThyroidPrint®** on Idylla™ through its [growing global commercial infrastructure](#) of Idylla™ instruments

## About thyroid testing

- [Thyroid nodules](#) are very common, often detected during routine medical exam or by patient self-assessment
- Only ca. [10% of FNA biopsy procedures](#)<sup>4</sup> reveal [malignant cells](#); approx. 70% confirm a benign diagnosis. The remaining 20% are indeterminate, meaning no certain diagnosis can be provided to physician and patients<sup>5</sup>
- Annually, [> 1.2 million](#) thyroid cytology evaluations are reported as [indeterminate](#)<sup>1</sup>. Here, diagnostic surgery of the thyroid gland is frequently recommended<sup>6</sup>
- Risk of malignancy in these indeterminate cases is est. between 15-35%, meaning that [surgical intervention is unnecessary](#) in up to 65-85%<sup>6</sup>

## Background GeneproDx

- A [molecular diagnostics company based in Santiago, Chile](#)
-  **ThyroidPrint®** was clinically validated in a multicenter trial in [Chile](#), after which it was launched in Latin America<sup>1</sup> in Sept 2018, and in a second independent multicenter, prospective trial in the [US](#) in Dec 2019<sup>2</sup>
- New [international validation study ongoing](#)<sup>3</sup> in leading academic sites in Europe, the US and Latin-America

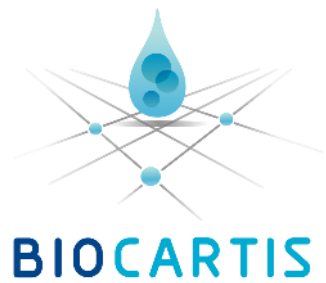
## About ThyroidPrint®

- A [qRT-PCR based mRNA-expression classifier](#)<sup>7</sup> test that helps determine if a thyroid nodule with indeterminate cytology result is benign or malignant<sup>8</sup>
- Benign test result<sup>9</sup> allows physicians to recommend watchful waiting as an alternative to diagnostic surgery
- This [prevents exposing patients to surgical risks & permanent thyroid hormone supplementation](#), and significantly [reduces health costs](#) due to unnecessary surgery<sup>1</sup>

1 S. Vargas-Salas et al., Genetic testing for indeterminate thyroid cytology: review and meta-analysis, 2018, Endocrine-Related Cancer, <https://erc.bioscientifica.com/>; 2 Demonstrating that ThyroidPrint® performs in the same manner in populations with different ethnicities and genetic backgrounds (M. Zafereo et al., A Thyroid Genetic Classifier Correctly predicts benign nodules with indeterminate cytology: two independent multicenter, prospective validation trials); 3 Results are expected end of October 2021; 4 FNA = fine needle aspirate. In FNA biopsy procedures, approximately 350,000 of which are performed annually in the US alone (Popoveniuc G, Jonklaas J. Thyroid nodules. Med Clin North Am. 2012;96(2):329-349. doi:10.1016/j.mcna.2012.02.002), cells are collected from the thyroid nodule for microscopic examination; 5 Faquin WC, Bongiovanni M, Sadow PM 2011 Update in thyroid fine needle aspiration. Endocrine pathology 22:178-183.; 6 To determine the true nature of the nodule as standard practice. Haugen BRM, Alexander EK, Bible KC, Doherty G, Mandel SJ, Nikiforov YE, Pacini F, Randolph G, Sawka A, Schlumberger M, Schuff KG, Sherman SI, Sosa JA, Steward D, Tuttle RMM, Wartofsky L 2015 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid: official journal of the American Thyroid Association; 7 Quantitative Reverse Transcription PCR. PCR or Polymerase chain reaction is an efficient and cost-effective way to copy (amplify) small segments of DNA or RNA. As such, millions of copies of a section of DNA are made in just a few hours, allowing further analysis for clinicians to diagnose and monitor diseases using a minimal amount of sample, such as blood or tissue. Source: www.genome.gov, last consulted on 22 October 2020; 8 This means that the probability of the nodule being malignant drops from 25% to less than 5%, allowing follow-up to be recommended as an alternative to surgery. Info and source: <https://thyroidprint.com/en/home-us/>, last consulted on 22 October 2020; 9 NPV (Negative Predictive Value) > 95%

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**THE IDYLLA™ TECHNOLOGY 2.0:**  
BENOIT DEVOGELAERE,  
CHIEF TECHNOLOGY OFFICER BIOCARDIS



# THE IDYLLA™ TECHNOLOGY: WHERE WE COME FROM

## 1st generation Idylla™ products: PERFORMANCE & VERSATILITY

### Purpose

Establish Idylla™ as the most versatile MDx testing platform



Superior ease-of-use with <2 min hands-on time



Fast turn-around-time delivering 10 days faster



Broad sample versatility gives results on 80% of samples that failed on NGS



Superior performance with >95 % concordance and <2 % invalids

### Technology

All basic building blocks for sample preparation, qPCR (DNA/RNA) and melting curve analysis are available



Solid biopsies (e.g. FFPE, cytological samples)



Liquid biopsies (e.g. plasma, urine)



Pathogens (e.g. swabs, viral transport medium)



Sepsis (e.g. blood)

### Applications

- Expanding Idylla™ menu



- Growing number of Idylla™ partnerships

AMGEN



MERCK

Immunexpress

AstraZeneca

ENDPOINT HEALTH

Bristol-Myers Squibb

GENEPRODX

Johnson & Johnson

lifeArc

COVANCE

a+ccelerate





# THE IDYLLA™ TECHNOLOGY: WHERE WE AIM TO GO

## 2nd generation Idylla™ products: FASTER & CHEAPER DEVELOPMENT

### Purpose

Develop **more** Idylla™ products **faster**, at a **lower cost**

- Eliminate in-line cartridge customization, to **reduce development lead times** and **cost**
- **Industrialize** and **accelerate** the **design** of reagents and software for new panels
- Enable efficient **customization** of the Idylla™ cartridge

### Technology

**Idylla™ FLEX technology** (in development), a new revolution under the hood of Idylla™

- Mass manufactured Idylla™ FLEX **cartridges** that can be used **across multiple panels**
- Panel-specific Idylla™ FLEX reagents for **off-line customization** of the cartridge
- Reagent and software design based on **proprietary Artificial Intelligence algorithms**

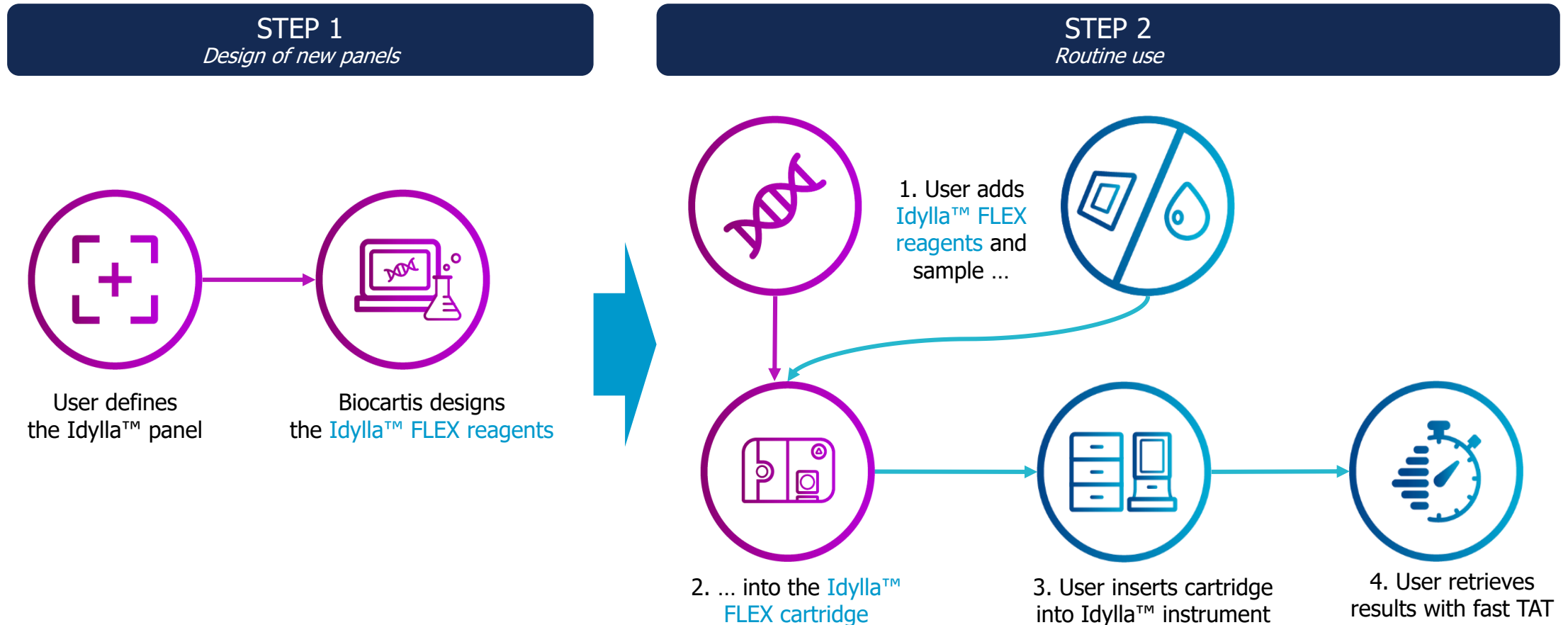
### Applications

Improved **development lead times**, **cost** and **scalability** enables:

- **Acceleration** of Idylla™ menu growth
- Further expansion into currently **unserved oncology markets**
- **Customized** Idylla™ panels



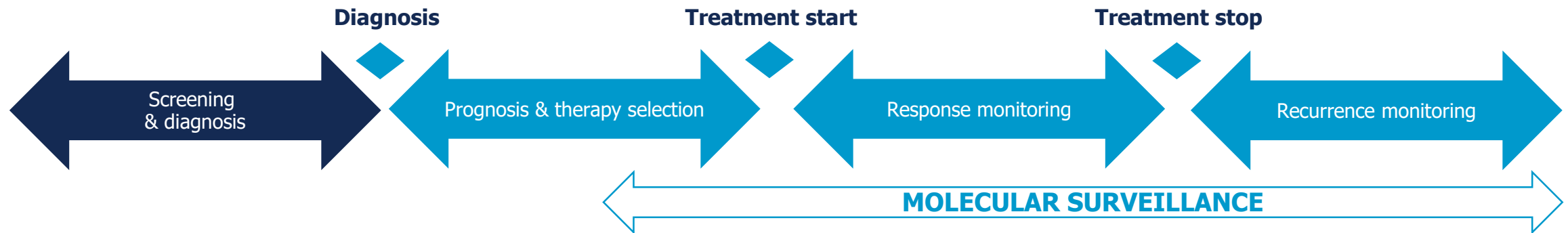
# THE IDYLLA™ FLEX TECHNOLOGY EXPLAINED



The Idylla™ FLEX technology complements the **core strengths of Idylla™** (ease-of-use, speed, performance and sample versatility) with **off-line customization**

# IDYLLA™ FLEX: 1 FASTER & CHEAPER DEVELOPMENT

# 2 ENABLING MOLECULAR SURVEILLANCE



## Gene signatures

- MDx tests based on RNA Gene Signatures are used for e.g.:
  - Diagnosis
  - Prognosis
- Often high value once validated & clinical value demonstrated
- Examples
  - SeptiCyte® RAPID
  - ThyroidPrint®



## Targeted therapy

- MDx tests detecting specific tumor mutations used for therapy selection in a specific cancer type
- Significant pharma pipeline of new targeted therapies
- Examples
  - Zelboraf®<sup>1</sup> (BRAF)
  - Tagrisso®<sup>2</sup> (EGFR)
  - Erbitux®<sup>3</sup> (RAS)
  - Vectibix®<sup>4</sup> (RAS)



## Pan-tumor

- Pan-tumor application of tumor mutation tests for therapies selected based on genetics rather than location of the tumor
- Allows therapy use across multiple cancer types
- Positive impact on underlying test volumes
- Examples
  - Vitrakvi®<sup>5</sup>
  - Keytruda®<sup>6</sup>
  - Rozlytrek®<sup>7</sup>



## Immuno-oncology

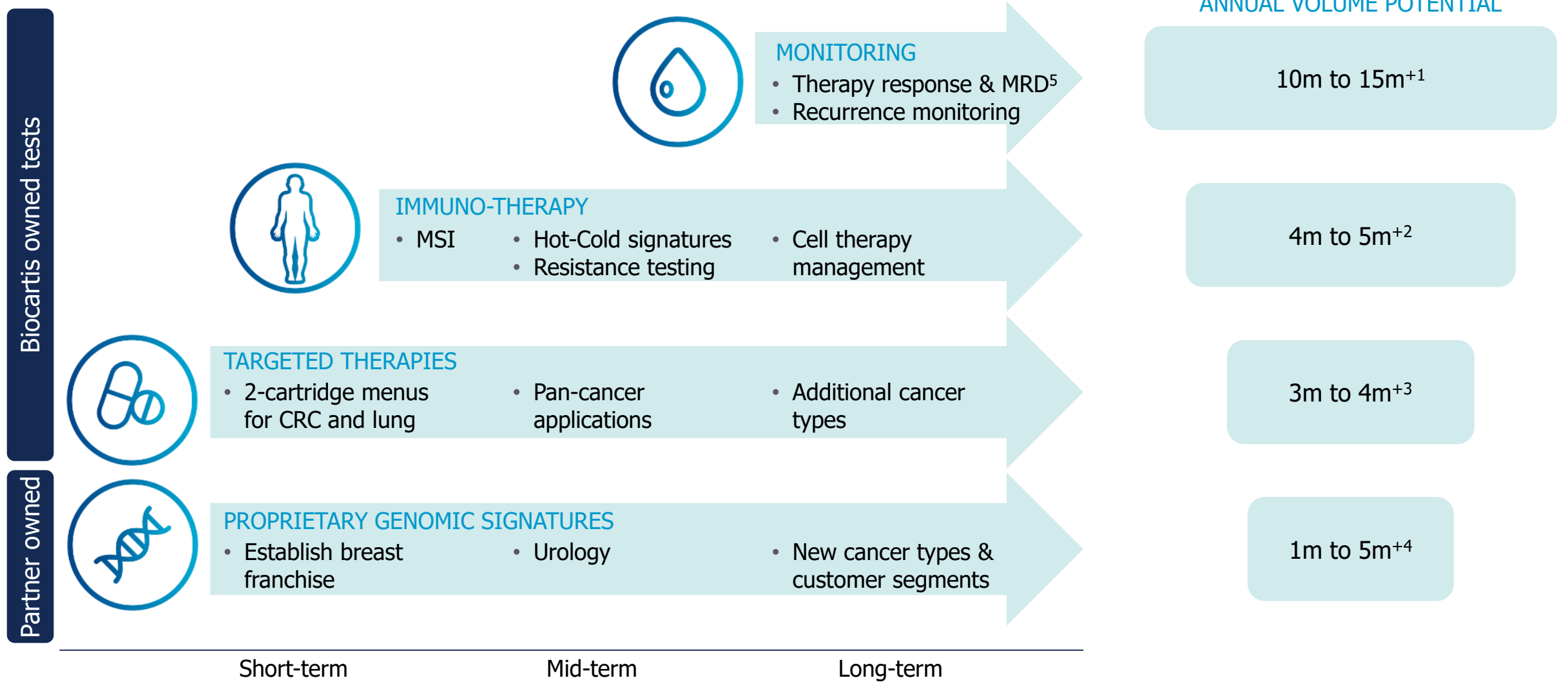
- MDx tests supporting immuno-oncology cancer treatments
- Consists of many different therapies, e.g.:
  - Immune checkpoint inhibitors
  - Cell and viral therapies
  - Vaccines
- High unmet need for underlying MDx testing



## Liquid biopsy

- MDx tests via liquid samples
- Use in diagnosis, prognosis and Molecular Surveillance (i.e. therapy selection, response and recurrence monitoring)
- Can be done through off-the-shelf catalogue panels as well as tumor-informed, personalized panels

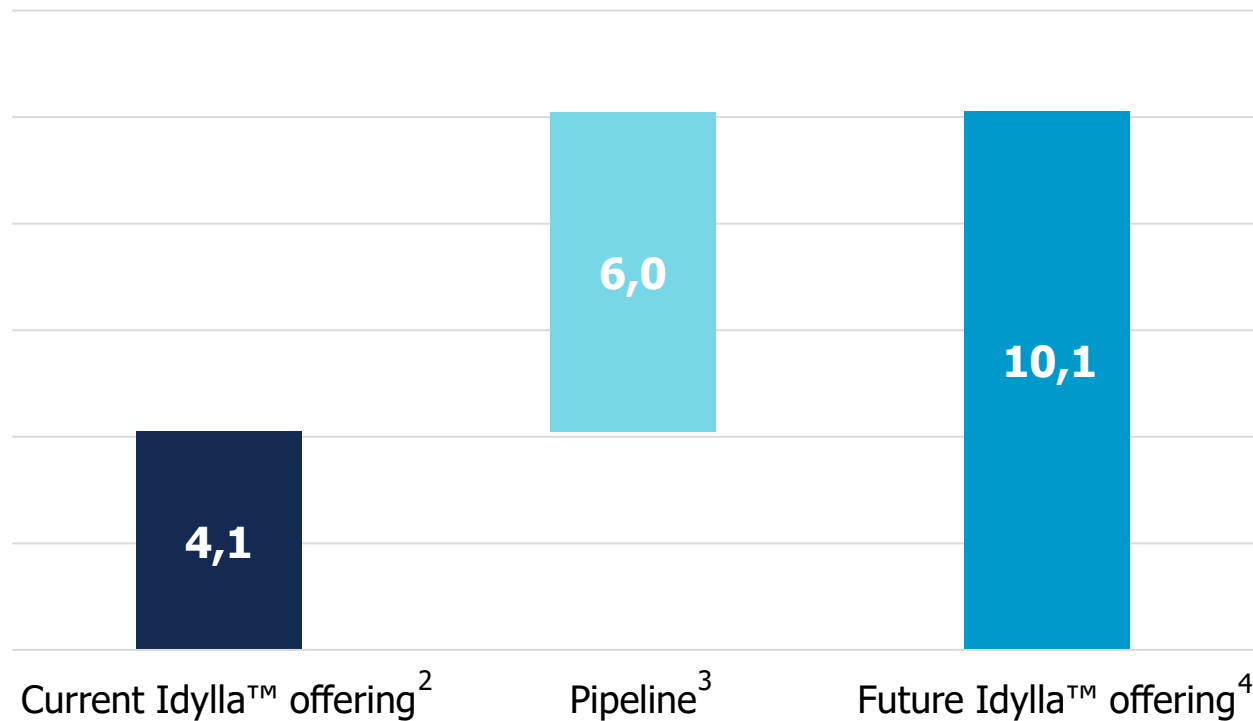
# IDYLLA™ ADDRESSABLE MARKET POTENTIAL IN ONCOLOGY



+ Depicts annual long term addressable Idylla™ cartridge volume potential. Based on management estimates. Focused on Europe, US and Japan (excluding China and RoW). For indicative purposes only. 1. Based on incidence / prevalence, potential eligibility (e.g., according to tumor stage and treatment) and # tests / patient. 2. Based on incidence and current / potential guideline testing eligibility for cancer types where immune checkpoint inhibitors and cell therapies are most relevant. 3. Based on incidence and current / anticipated cancer guidelines for colorectal, lung, and skin cancer. 4. Based on current partner content collaborations and addition of new content that could benefit from Idylla™ dependent on partnerships. 5. MRD = Minimal Residual Disease

# TOWARDS THE LARGEST MENU IN RAPID ONCOLOGY MD<sub>x</sub> TESTING

Total addressable market volumes (in millions)<sup>1</sup>



Unique Idylla™ USPs for rapid oncology Dx

- The **current Idylla™ testing offering** addresses approx. **4m** annual testing volume
- The **new Idylla™ pipeline** allows to grow to a total addressable market of **over 10m** annual testing volume
- High growth areas thanks to the combination of **unique Idylla™ characteristics**:
  - Fast time-to-result
  - Ease-of-use
  - Highly accurate
  - Sample versatility
  - Cost-effectiveness versus existing methods
  - Suitable technology for monitoring

<sup>1</sup> Total addressable market includes Europe, the US and RoW (including Japan, excluding China)

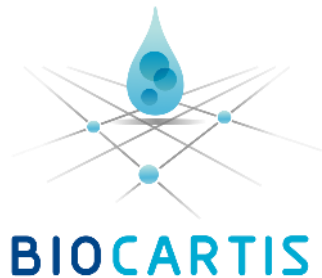
<sup>2</sup> Current Idylla™ offering includes Idylla™ assays in Melanoma (BRAF), Colorectal (KRAS, NRAS, BRAF and MSI) and Lung (EGFR)

<sup>3</sup> Pipeline includes assays in Lung (GeneFusion), Breast (Idylla™ ABC Panel), Pan cancer (MSI), Thyroid (ThyroidPrint® on Idylla™), Endometrium, Hematology and Brain

<sup>4</sup> Future Idylla™ offering excludes surveillance monitoring

# Infectious Disease strategy update

Herman Verrelst, CEO



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# THE IDYLLA™ INFECTIOUS DISEASE MENU STRATEGY BUILDING BLOCKS

## 1. COVID-19

- 🌐 **Pandemic-related testing:** temporary high need for decentralized MDx testing, faster installed base building in acute settings
- 🌐 Support **Intensive Care Unit (ICU)**<sup>2</sup> positioning, together with SeptiCyte® RAPID on Idylla™<sup>6</sup>
- 🌐 **Idylla™ tests:**
  - Launch **Idylla™ SARS-CoV-2 Test**<sup>2</sup> (CE-IVD, EUA pending) with good performance & positive early field feedback
  - Current development of **Idylla™ SARS-CoV-2/Flu/RSV Panel:** ability to support flu season testing
- 🌐 **Partnership Bristol-Myers Squibb COVID-19 Industry Consortium:** accelerate and improve COVID-19 testing across the globe<sup>1</sup>

## 2. SEPSIS

- 🌐 Responsible for **est. 8m deaths/year** globally<sup>3</sup>, est. annual hospital expense of **> USD 24b** in the US alone<sup>4</sup>
- 🌐 High **unmet need:** current markers are not rapid (blood cultures) or are non-specific (PCT, CRP)<sup>5</sup>; increased risk in pandemic times
- 🌐 Fast clinical decisions impact **patients outcome**
- 🌐 Relevant **Idylla™ tests:**
  - **SeptiCyte® RAPID on Idylla™**<sup>6</sup> (partnership Immunexpress)
  - **Idylla™ EndPoint test** (partnership EndPoint Health): aims at enabling biomarker-based therapeutic decisions in patients with critical illnesses<sup>7</sup>, such as sepsis

## 3. FUTURE POTENTIAL

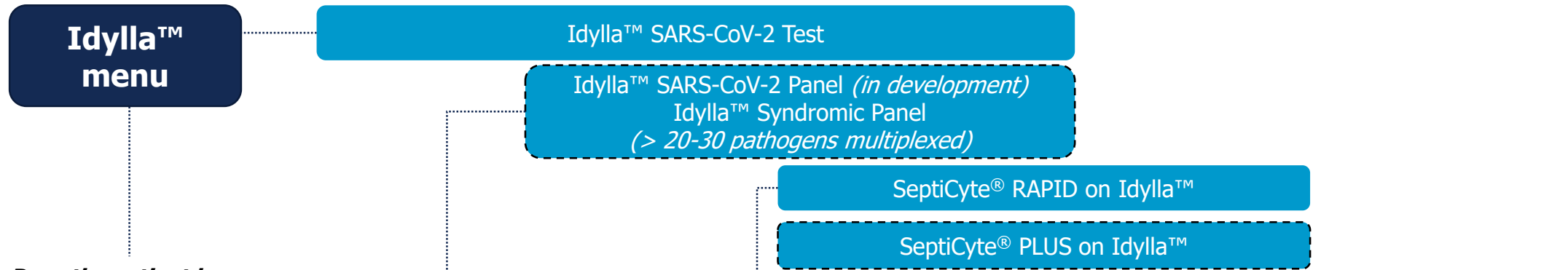
- 🌐 **Syndromic panel testing:**
  - One of fastest growing MDx segments
  - Idylla™'s **unique multiplexing platform capabilities** allow entry into this market



## LONG TERM STRATEGY:

Easy & rapid Idylla™ infectious disease testing to support the patient journey in the intensive care unit (ICU), including rapid triage and therapy selection of critically ill patients

# TOWARDS A PRECISION MEDICINE ICU WORKFLOW FOR PATIENTS WITH CRITICAL ILLNESS



🦠 **Does the patient have a SARS-CoV-2 infection?**  
Yes/No

🦠 **Which respiratory pathogen is causing the symptoms?**

🦠 **Does the patient have an infection?**  
Yes/No

🦠 **Does the patient have a viral/bacterial infection?**

🦠 **Which supportive therapy should the patient receive?**

- Corticosteroids
- Immuno-stimulants
- Anti-coagulants

To develop





## Background collaboration

- Endpoint Health (EPH) will lead the **development & registration** of the Idylla™ Endpoint test in interventional trials across a range of interventions incl. targeted immunotherapy & coagulation therapy indications
- Parties intend to **collaborate on the commercialization** of the test, building on growing worldwide commercial infrastructure of Idylla™ instruments
- Partnership highlights the **unique rapid, highly accurate and easy-to-use features** of Idylla™ in areas outside of oncology

## About critical illness

- Critical illnesses such as **sepsis** and Acute Respiratory Distress Syndrome (**ARDS**)<sup>1</sup> are life-threatening conditions often characterized by dysregulated immune response to infection
- Globally, sepsis alone is associated with **11m deaths annually**<sup>2</sup>, is one of the **most expensive health conditions** with annual healthcare costs est. at > USD 60bn in the US alone<sup>3</sup>
- Long recognized **need for more targeted approach to therapy development and patient care**<sup>4</sup>

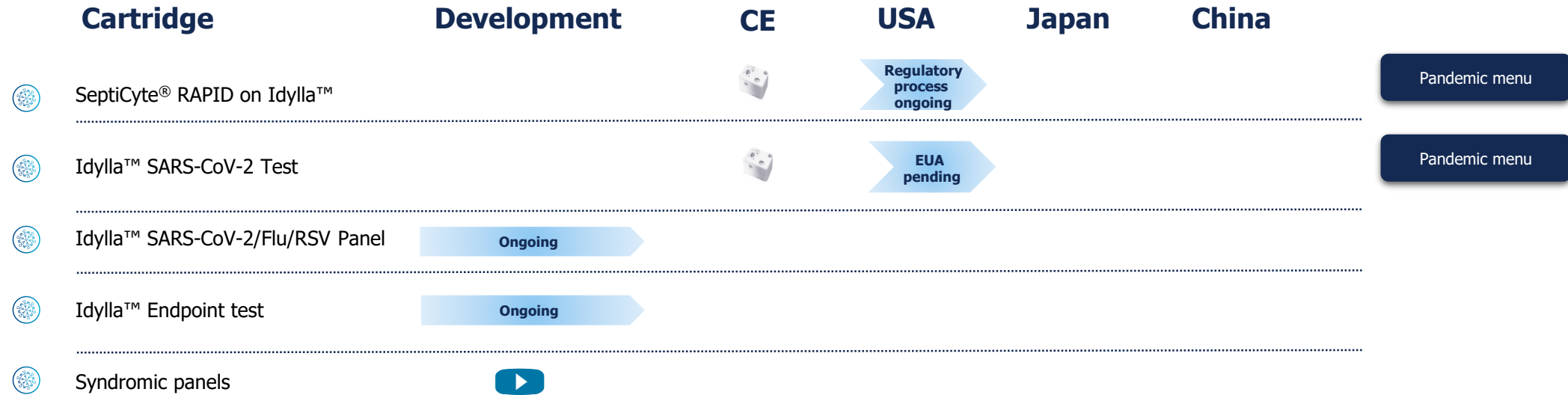
## Background Endpoint Health

- A **Palo Alto, CA (USA)** based company developing personalized care solutions and targeted therapies for critically ill patients
- On 28 September 2020, Endpoint Health announced a partnership to create **the world's first precision medicine clinical trial network** focused on critical illness
- Idylla™ Endpoint Test intended to be used in the network's first **interventional trial**




## About the Idylla™ Endpoint test

- **Rapid companion diagnostic** test aimed at enabling targeted therapies and personalized care approaches in critical illness
- In addition to Biocartis' current infectious disease tests, the Idylla™ SARS-CoV-2 Test<sup>5</sup> and the SeptiCyte® RAPID<sup>6</sup> on Idylla™, the Idylla™ Endpoint test is expected to **guide the safe and effective use of novel therapies and improve routine care choices in critically ill patients**

# IDYLLA™ INFECTIOUS DISEASE PIPELINE



### Legend

-  Ongoing
-  = planned start
-  = on market

RUO = Research Use Only, not for use in diagnostic procedures; CE = CE-marked IVD; EUA = Emergency Use Authorization. Source: US FDA website.

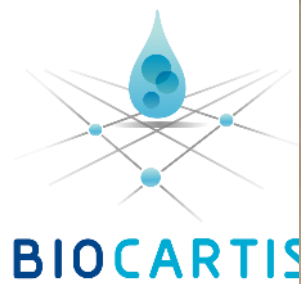
The Idylla™ development pipeline reflects the different cartridges and biomarkers in development, including cartridges that can be used for research applications. Please see [here](#) for more information about the respective studies, or to the specific product labeling for applicable intended use for each individual Biocartis product. Overview is subject to change in amongst others prioritization of test development by Biocartis and/or partners driven by commercial, partnering & operational considerations.

# LEADING WITH A UNIQUE TECHNOLOGY AND OFFERING IN A FAST GROWING MARKET

- Poised for growth in oncology – ready to scale
- Expansion plans to accelerate & deepen within oncology focus
- Confidence to broaden into infectious diseases, supported by maturing organizational strengths and strong partner network

**Leading with a unique  
technology,  
a strong organization  
and a unique diverse offering  
in a dynamic & fast growing  
market**

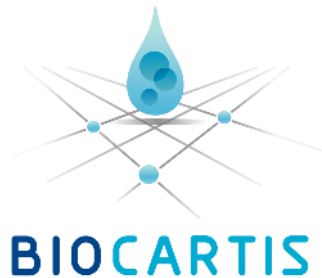
# Q&A



# Idylla™ partner and user testimonials

Herman Verrelst, CEO

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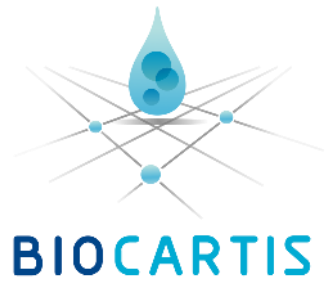


# Q&A



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