idylla
by BIOCARTIS

IDYLLA™ FIRST

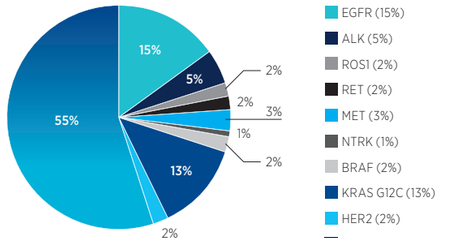
Guiding Fast and Accurate First-Line Therapy Decisions in NSCLC

Availability of biomarker results prior to first-line therapy is the key to enhancing patient outcomes

Although lung cancer remains the leading cause of cancer deaths worldwide, the survival rate has increased over the past few years due to the rapidly evolving treatment landscape for Non-Small Cell Lung Cancer (NSCLC).

Since **new therapies are becoming increasingly biomarker-driven**, an urgent and growing need for biomarker testing has emerged. **Molecular testing therefore plays a key role in the diagnostic work-up for early and late-stage NSCLC patients to guide therapy decisions in neoadjuvant, adjuvant and metastatic settings.**

The fast and accurate diagnosis of these actionable biomarkers is critical for selecting the appropriate targeted therapy. Consequently, international treatment guidelines (ESMO, NCCN) recommend molecular testing for *EGFR, BRAF, ALK, ROS1, RET, METex14 skipping, NTRK, HER2 and KRAS G12C* in every patient diagnosed with advanced/metastatic NSCLC.



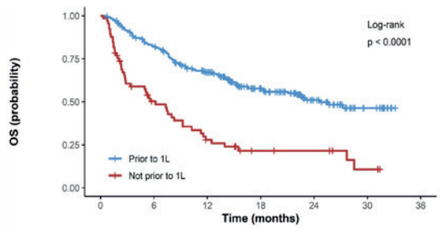
Actionable biomarkers in NSCLC according to international guidelines[1]

Time is of the essence in NSCLC

Today, the adoption rate of biomarker testing is far from ideal, resulting in suboptimal therapy decisions for many patients. One of the identified causes is the long turnaround time to receive biomarker results, in contrast with the critical need to start therapy immediately.

Studies have shown that when **biomarker results are available prior to first-line therapy, patients have a better overall survival** compared to patients for whom biomarker results were not available at first-line therapy selection.[2]

Overall Survival by Availability of Molecular Genotyping Results Prior to 1L Therapy[2]



Why IDYLLA™ FIRST?

- **Idylla™ helps save lives.** Patients die, rapidly deteriorate or receive sub-optimal treatment while waiting for their biomarker test results.[5-7]
- **Idylla™ alleviates patient anxiety** and allows them to focus on their well-being.[8, 9]
- **Idylla™ gets it right first time.** Idylla™ shows low failure rates combined with the ability to produce accurate results.[4, 10, 11]
- **Idylla™ only requires small sample sizes.** An NGS workflow needs nearly five times more tissue to meet NSCLC biomarker testing requirements.[5]

IDYLLA™ - A technology you can rely on

- **Strong scientific evidence** of Idylla™ in NSCLC in >50 publications
- Idylla™ is highly reliable, with a **low failure rate** of ≤1.5%[4, 10, 11]
- **Proven** Idylla™ performance[4, 11]

ALK	ROS1	RET	METex14	EGFR
sensitivity 97%	sensitivity 92%	sensitivity 100%	sensitivity 100%	sensitivity 94%
specificity 100%	specificity 100%	specificity 100%	specificity 100%	specificity 99%
142 samples 29 ALK +	142 samples 24 ROS1+	142 samples 31 RET+	142 samples 20 METex14+	1474 samples

Retrospective Study - Memorial Sloan Kettering Cancer Center, NY (US) - Standard of care: NGS[11]

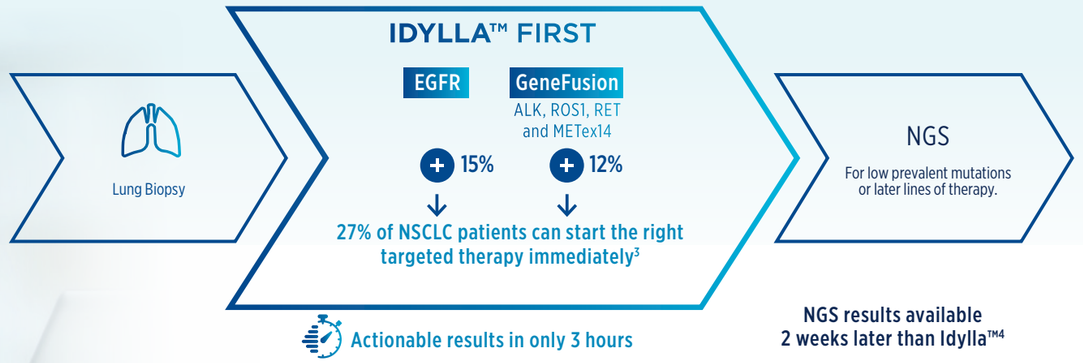
Prospective Study - 16 centers - Charité Berlin (DE) Standard of care: NGS - RT-PCR - Sanger[4]

IDYLLA™ - Actionable biomarker testing

Idylla™ solid biopsy assays focus on clinically relevant biomarkers according to **international clinical guidelines** of ASCO, ESMO, NCCN and IASLC.

EGFR (IVD)	exons 18 - 21
GeneFusion (IVD)	ALK, ROS1, RET, METex14

Fast detection of the most prevalent and high-impact biomarkers in only 3 hours



NGS results available 2 weeks later than Idylla™[4]

Idylla™ is a fully automated, easy to implement molecular testing platform suitable for any hospital lab setting and enabling **rapid in-house biomarker testing.**

Renowned institutions across Europe have already experienced the benefits of IDYLLA™ FIRST

Idylla™ meets the need for assessing EGFR on surgical specimens and enables better and rapid decision-making.

Prof. Dr. Nicolas Girard, Oncology Pneumology, Institut Curie, France

Our experience is fantastic. Idylla™ allows us to have an ultra-fast and reliable panel of biomarkers useful in therapeutic decision-making for the main molecular targets in lung cancer.

Dr. Antonio Calles, Medical Oncologist and KOL in lung cancer, Hospital Universitario Gregorio Marañon, Spain

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Biocartis NV
Generaal De Wittelaan 11B
2800 Mechelen - Belgium
+32 15 632 888

Follow us on
www.biocartis.com
customerservice@biocartis.com

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