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Biocartis Announces Multiple Abstracts Demonstrating the Impact of Idylla™ in Oncology Diagnostics to be Presented at USCAP 2025 Annual Meeting

Mechelen, Belgium, 18 March 2025 – Biocartis NV ("Biocartis"), an innovative molecular diagnostics company, is pleased to announce research on the Idylla™ Platform from several renowned institutions at the upcoming United States and Canadian Academy of Pathology (USCAP) 2025 Annual Meeting, taking place from 22-27 March in Boston, MA, US. Seven abstracts from leading research and academic institutions will be presented as posters, highlighting the rapid, fully automated molecular testing capabilities of the Idylla™ Platform across several different cancer types, including lung cancer[1], thyroid cancer[2], endometrial carcinoma[3] and colorectal cancer[4]. Biocartis also continues to focus on melanoma, blood, brain and breast cancer.

1. **From Discard to Discovery: Rapid KRAS and EGFR Mutation Detection in Lung Cancer Using Cytology Supernatants**
   Institution: MD Anderson Cancer Center
   To be presented: Monday 24 March, Stowell-Orbison – Cytopathology - Poster Board 20
   Researchers evaluated the use of the Idylla™ ctKRAS and ctEGFR Mutation Assays on cytology supernatants from lung cancer patients. The study demonstrated high concordance with next-generation sequencing (NGS) results, reinforcing the Idylla™ assays as valuable tools for rapid testing of cytology supernatants that would otherwise be discarded.

2. **Racing for Results: Ultra-Rapid BRAF Mutation Detection Through Fine Needle Aspiration (FNA) of Anaplastic Thyroid Carcinoma (ACT) and High-Grade Follicular Cell-Derived Thyroid Carcinoma (HGFCTC)**
   Institution: Memorial Sloan Kettering Cancer Center
   To be presented: Monday 24 March, Stowell-Orbison – Cytopathology - Poster Board 31
   This study compared the turnaround time and performance of the Idylla™ BRAF Mutation Assay with immunohistochemistry (IHC) and NGS in aggressive thyroid malignancies. The results demonstrated that Idylla™ can provide a significantly faster and reliable assessment of BRAF status in fine needle aspiration samples.

3. **Detailed Analysis of MSIsensor2 Signatures in Endometrial Endometrioid Carcinomas with Next Generation Sequencing**
   Institution: University of California, San Francisco
   To be presented: Monday 24 March, Stowell-Orbison – Informatics - Poster Board 306
   This study utilized MSIsensor2 within an NGS pipeline to assess MSI status across 100 cases of endometrial endometrioid carcinoma (EEC). The research analyzed tumor purity, the impact of mismatch repair (MMR) driver gene mutations, and the correlation of MSI scores

[1] Lung cancer remains one of the leading causes of cancer-related mortality, strongly linked to smoking and environmental exposures. Advances in biomarker testing have revolutionized treatment by enabling personalized approaches such as targeted therapies and immunotherapy. Depending on the stage of the disease, treatment may involve a combination of surgery, chemotherapy, radiation, or precision medicine.

[2] Thyroid Cancer develops in the thyroid gland, often detected as a painless lump in the neck. Prognosis is generally favorable, especially when caught early. Biomarker testing helps assess risk and guide treatment. Standard therapies include surgery, radioactive iodine, and thyroid hormone replacement.

[3] Endometrial Cancer is a malignancy of the uterine lining, that most commonly affects postmenopausal women. Biomarker testing plays a crucial role in assessing prognosis and guiding treatment decisions. Management typically involves surgery, with additional therapies such as radiation or hormone treatment considered based on individual risk factors and molecular profiling.

[4] Colorectal Cancer is affecting the colon or rectum, often linked to lifestyle and genetic factors. Biomarker testing helps guide treatment decisions, particularly in targeted therapy and immunotherapy. Testing for these markers can identify patients who may benefit from specific therapies, such as anti-EGFR or immune checkpoint inhibitors.

with molecular and clinicopathologic data. Orthogonal MSI testing was performed by fragment analysis or Idylla™.

4. **Comparison of Two Automated Real-Time PCR Systems for Cytological Smears in NSCLC: IDYLLA™ and AmoyDx® Pan Lung Cancer Panel**
   Institution: Clinica Universidad de Navarra
   To be presented: Monday 24 March, Poster II – Cytopathology - Poster Board 44
   This study compared the Idylla™ System with the AmoyDx® Pan Lung Cancer Panel for molecular testing on cytological smears in non-small cell lung cancer (NSCLC). Both systems showed high concordance with each other and with NGS results, when available. The Idylla™ System detected additional KRAS mutations not included in the AmoyDx® Panel, underscoring its broader detection capabilities. While NGS remained the gold standard, these automated systems offered faster turnaround times for targeted treatment decisions.

5. **Evaluation of Microsatellite Instability Testing by the Rapid Idylla™ MSI Assay in Endometrial and Other Cancers**
   Institution: Icahn School of Medicine at Mount Sinai
   To be presented: Tuesday 25 March, Poster IV - General Surgical Pathology
   This study evaluated the performance of the Idylla™ MSI Assay in endometrial and other cancers, revealing strong sensitivity and specificity in colorectal cancer and highlighting variability in endometrial carcinoma (EC). Adjustments in threshold settings demonstrated improved concordance metrics in EC.

6. **Assessment of (Rare) Endometrial Carcinoma with Double Molecular Classifiers Using Limited Panel Next Generation Sequencing (NGS): Evaluation of Surrogate Metrics for Tumor Mutation Burden (TMB) – A Proof of Concept Study**
   Institution: Mayo Clinic
   To be presented: Wednesday 26 March, Poster V - Gynecologic and Obstetric Pathology
   This study assessed a limited NGS panel and its ability to classify rare double-molecular-classifier cases in endometrial carcinoma. It incorporated Idylla™ as an orthogonal CLIA-validated MSI testing method, showcasing its role in resolving discrepancies in molecular classification.

7. **Routine Implementation of the Idylla™ Fusion Assay: An Assessment of Performance Based on Prospective Reflex Testing of Non-Small Cell Lung Carcinoma in a Large Laboratory Setting**
   Institution: Memorial Sloan Kettering Cancer Center
   To be presented: Wednesday 26 March, Poster V - Pulmonary, Mediastinal, Pleural, and Peritoneal Pathology
   This study evaluated the routine use of the Idylla™ GeneFusion Assay for detecting fusions in ALK, ROS1, RET, and NTRK1/2/3, as well as MET exon 14 skipping in NSCLC. The Assay demonstrated high sensitivity and specificity, with a fast turnaround time compared to traditional testing methods.

In addition, Biocartis will showcase the Idylla™ Platform and its innovations in molecular diagnostics at **booth #548**, where attendees can learn more about Idylla™'s ability to deliver actionable, molecular biomarker results in only 3 hours.

W. Michael Korn, M.D., Chief Medical and Scientific Officer of Biocartis, commented: "*The data presented at USCAP 2025 underscores the versatility and reliability of the Idylla™ Platform across a diverse range of oncology applications. These studies confirm the high concordance between Idylla™ and next-generation sequencing (NGS) in lung cancer, and Idylla™'s ability to detect microsatellite instability (MSI) reliably, demonstrating its clear value in delivering rapid, actionable molecular insights. The integration of Idylla™ into real-world laboratory settings, as highlighted in these independent*

investigator studies, reinforces its potential to streamline workflows and reduce turnaround times, ultimately improving patient management and outcomes."

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About Biocartis

With its revolutionary and proprietary Idylla™ Platform, Biocartis aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, easy, fast and suitable for any lab. The Idylla™ Platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house molecular biomarker testing in only 3 hours, allowing fast and optimal treatment selection. Idylla™'s continuously expanding menu of molecular diagnostic tests and research assays addresses key unmet clinical needs. Today, Biocartis offers tests supporting melanoma, colorectal, lung, breast, thyroid, brain and blood cancer. More information: www.biocartis.com. Follow us on LinkedIn, Facebook and X (Twitter).

Disclaimers

The data and conclusions provided in this external publication were derived externally by third parties and have not been validated in the development of the Idylla™ Assays or included in the products' current labelling by Biocartis NV. Biocartis NV products are designed to be used as described in the product-specific instructions.

Idylla™ ctKRAS, ctEGFR & BRAF Mutation Assays and Idylla™ GeneFusion & MSI Assays are for Research Use Only (RUO), not for use in diagnostic procedures. Idylla™ Platform is CE-marked in Europe in compliance with EU IVD Regulation 2017/746, listed as a class II device in the US under establishment registration 3009972873, and registered in many other countries. Biocartis and Idylla™ are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis NV.