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# **eyonis**™

New Horizons in Fighting Lung Cancer: eyonis™ LCS RELIVE study results & next steps towards marketing authorizations

Live Webcast - February 4, 2025

Speaker: Fredrik Brag, CEO and Founder of Median Technologies







## Lung Cancer Screening Challenges & Opportunities



Lack of diagnosis accuracy - a major hurdle to screening adherence & implementation, whilst I-ELCAP study showed 92% survival rate at 15y when diagnosed at stage 1 vs. 5% for stage 4<sup>(1)</sup>

#### **Facts & figures**

- 1st cancer killer worldwide: 1.8M deaths 2022 (19% of all cancer deaths),
   2.4M deaths projected in 2030<sup>(2)</sup>
- 18% 5-year survival rate: <25% stage 1 cases (68%-92% survival<sup>(3,4)</sup>)
   >40% stage 4 cases (<10% 5-year survival<sup>(4)</sup>)
- Rising frequency among never-smokers (20% US & UK) <sup>(4)</sup>
- Rising frequency among never-smokers <sup>(3)</sup>
- New CPT code \$650 for AI quantitative CT tissue characterization in the US

#### Screening programs

LCS program	ms implemented	Target population
US	USPSTF guidelines	15M (USPSTF 2021 recommendations) Near future 30M
Europe	UK Poland Croatia Germany Developing in IT/DE/FR	EU T5: 22M (Estimate)
Asia	South Korea & China regionally Japan in study phase	ASIA T3: 100M (Estimate)

#### Why is LDCT screening % so low in the high-risk populations?



#### Why eyonis<sup>™</sup> LCS? Seamlessly & effortlessly



Sources: [1] https://www.redjournal.org/article/S0360-3016(19)30110-5/fulltext [2] Cancer Tomorrow, IARC, Global Cancer Observatory 2020 - WHO [3] https://www.lungambitionalilance.com/our-initiatives/lung-cancer-screening-the-cost-of-inaction.htm [4] https://ndrsupport.acc.org/support/sclutolins/articles/1100003991-lcsr-state-reports Median eyonis<sup>™</sup> LCS is the Only SaMD-Candidate with Median CADe/CADx Features Designed for Lung Cancer Screening Indication



eyonis™ LCS Regulatory S	Has Achieve ubmissions	ed Continuous in Q2 2025	s Success,	Supportin	ng Median
De Al Model R Trai	esign Phase esearch, Definition, n/Tune/Test	Verification - Independent Verificat	Performance Validation - Standalone Validation	Clinical Validation - Multi Reader Multi Case	Regulatory Submission & Clearance - Review FDA / CE Mark
2022 - 2023	May 2024	June 2024	Aug 2024	Q1 2025	Q2 - Q3 2025
CADe CADe CADe CADe CADx CADx CaDe Cuspicious CaDe/x CADe/x CADe/x CADe/x CADe/x CADe/x CADe/x CADe CADx CADx Cuspicious	Manufacturer Values (MV) test Performed to determine eyonis™ LCS performance Sensitivity 93.3 % Specificity 92.4 % AUC=0.977 All cancer stages, at patient level	<ul> <li>Independent Verification (IV) Study</li> <li>Performed to verify eyonis™ LCS performance on an independent patient cohort</li> <li>Sensitivity 93.4 %</li> <li>Specificity 87.4 %</li> <li>AUC= 0.949</li> <li>All cancer stages, at patient level</li> <li>Based on an independent</li> </ul>	REALITY, 1 <sup>st</sup> pivotal study Performed to validate eyonis <sup>™</sup> LCS standalone performance to diagnose cancer compared to ground truth AUC= 0.903 All 10 primary & secondary endpoints met All cancer stages, at patient level	RELIVE, 2 <sup>nd</sup> pivotal study, MRMC Performed to demonstrate that eyonis™ LCS increases clinician performance in analyzing LDCT LCS images Primary endpoint met with statistical significance p value = 0.027	Submission Acknowledgment Completeness Review Substantive Review Interactive Review Decision Substantive Equivalence Letter EXPECTED IN Q3 2025
Based on a cohort of 8,709 patients (620 cancer) (LIDC: 1,010+ NLST: 7,699)	Based on a cohort of 2,163 patients (NLST +LIDC/IDRI data)	<b>ENRICHED</b> (COPD) cohort of 273 patients (91 Cancers / 182 Benign)	Based on an <b>ENRICHED</b> cohort of 1,147 patients (342 Cancers / 805 Benign)	Based on an <b>ENRICHED</b> cohort of 480 patients (160 Cancers / 320 Benign)	

## eyonis<sup>™</sup> LCS Pivotal RELIVE Trial (MRMC Trial)



MRMC study design plays a key role in the translation of novel imaging tools, such as AI algorithms, to clinical practice.

- 480 patients (160 cancers, 320 benign cases) and 16 readers
- Enriched cohort with a 1:2 distribution of cancer positive and cancer negative patients
- Paired-split-plot design
- Objective: Demonstrate that eyonis<sup>™</sup> LCS improves clinician performance in analyzing LDCT lung screening scans, reducing FPs and unneeded follow-up procedures



Statistical Analysis

Compared reading with LCS report vs without: **"How much better is the clinician with eyonis™ LCS"** 

### **Primary Endpoint**

Difference between with & without Median LCS in AUROC values that measures the modality performances on patient level data. Superiority with LCS report vs without to be achieved.

## **RELIVE Study at Glance**

### **Cohort & Data Sources**



**480** cases 160 cancerous & 320 non-cancerous **Ratio 1:2** 



Men: 244 (50.83%) Women: 236 (49.17%)



Baptist Memphis: 116 (24.17%)

modian

FJD: 70 (14.58%)

Gradient: 25 (5.21%)

MD Anderson: 73 (15.21%)

Navarra: 57 (11.88%)

UPENN: 103 (21.46%)

VEGA: 36 (7.50%)

**Cancer staging\*** 



### **Nodules characteristics**



Number of nodules/case 2.32 benign

USA: 353 (73.54%)

#### **173 cancerous** nodules

Non spiculated 60 (34.7%) Spiculated 113 (65.3%) Part-solid 19 (11%) Solid 154 (89%) Size 4-10 mm=60 (34.7%) Enriched population

## **RELIVE Study Results**



## Primary endpoint successfully passed (enriched population)



#### Graph 3.1 ROC analysis by arm

- Median is the first & only SaMD manufacturer who opted for Paired Split Plot design\* further to FDA pre-subs discussions.
- Average years of experience of readers very high: more than 15-years specialized chest radiologists
- RELIVE primary endpoint is a superiority test: Δ AUC (with LCS – reader alone) > 0.

## **△** AUC = 0.016, p value = 0.027

• Since it was successfully met, Median can file for Marketing Authorization.

\* PSP design as defined in: Chen W, Gong Q, Gallas BD. J Med Imaging (Bellingham). 2018 Jul;5(3):031410. doi: 10.1117/1.JMI.5.3.031410.

## Pivotal MRMC Clinical Trial RELIVE: Next Step

## Secondary endpoints analysis

#### **RELIVE SECONDARY ENDPOINTS**

Sensitivity<sub>with LCS</sub> – Sensitivity<sub>Reader alone</sub> > -0.1 (Non inferiority)

Specificity<sub>with LCS</sub> – Specificity<sub>Reader alone</sub> > -0.1 (Non inferiority)

AUC-LROC<sub>with LCS</sub> > AUC-LROC<sub>Reader alone</sub> ( $\Delta$  LROC>0)

Recall Specificity<sub>with LCS</sub> – Recall Specificity<sub>Reader alone</sub> > -0.1 (Non inferiority)

Recall Sensitivity<sub>with LCS</sub> – Recall Sensitivity<sub>Reader alone</sub> > -0.1 (Non inferiority)

Sensitivity with LCS > Sensitivity reader alone (Superiority)

Specificitywith LCS > SpecificityReader alone (Superiority)

Recall Specificity<sub>with LCS</sub> > Recall Specificity<sub>Reader alone</sub> (Superiority)

Recall Sensitivity<sub>with LCS</sub> > Recall Sensitivity<sub>Reader alone</sub> (Superiority)

Analysis Time<sub>with LCS</sub> < Analysis Time<sub>Reader alone</sub>

"When  $\Delta$  AUC is the primary endpoint, while sensitivity and specificity are secondary endpoints, a two-family gatekeeping approach should be used to control the study-wise type I error rate, where sensitivity and specificity are only tested if the primary endpoint is met."

> (Obuchowski NA. Published Online: February 15, 2022 https://doi.org/10.1148/radiol.211593)



## 2025 Key Milestones for eyonis<sup>™</sup> LCS



Now entering the last segment of clinic-regulatory pathway: Regulatory filings & Review



eyonis™ LCS filings (FDA 510(k) and CE marking)	Q2 2025
Expected FDA clearance assuming normal review time	Q3 2025
Expected CE marking assuming normal review time	Q1 2026

## 2025 Key Milestones for eyonis<sup>™</sup> LCS



Now entering the last segment of clinic-regulatory pathway: Regulatory filings & Review

## **FDA Review Process**



## Median Is Already Executing on its eyonis<sup>™</sup> LCS Launch Strategy Roadmap





Pursue engagement with US KOLs pulmonologists & radiologists, and initiate device trial use under research agreements



Engage payers with Health Economic Outcomes Model for reimbursement discussions and launch health economic studies



Reach-out to distribution partners



Prepare for setting up US commercial organization

## Median eyonis<sup>™</sup> LCS Partnerships & Opportunities



Seven segments for partnerships and potential opportunities



## 

# **Company Financing**

# Company cash runway extended from Q2 to at least Q4 2025



Operational improvements to enhance profitability of the iCRO Business Unit	Ongoing, higher prices, lower costs
Extension of the 2020 EIB loan maturity until October 2025	Agreement signed, shareholder approval pending
New EIB facility of €37.5 million, final due diligence process ongoing	Finalization of legal documentation expected in Q1 2025 Project description available on <u>EIB website</u>
€10 million financing agreement signed on January 23, 2024, with IRIS	First €4 million tranche drawn on January 23, 2025

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# **Next Steps and** Q & A Session

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- Major interest from U.S. financial markets
- Median to present at the TD Cowen Healthcare Conference in Boston early March
- Strategic partnerships expected to materialize in the coming months, prior to market launch

# median

ALMDT EURONEXT GROWTH

## **Our Core Values**

#### Leading innovation with purpose

Combine the spirit of innovation with our passion and conviction to help cure cancer and other debilitating diseases.

#### Committing to quality in all we do

Be dedicated to quality in everything we do. Quality begins with us and we are committed to it.

#### Supporting our customers in achieving their goals

Listen to the needs of our customers and help make their goals our goals through our innovation, imaging expertise, superior services, and quality solutions.

#### Putting the patient first

There is a person at the other end of the images we analyze who is counting on us to do everything we can to help make them healthier.

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