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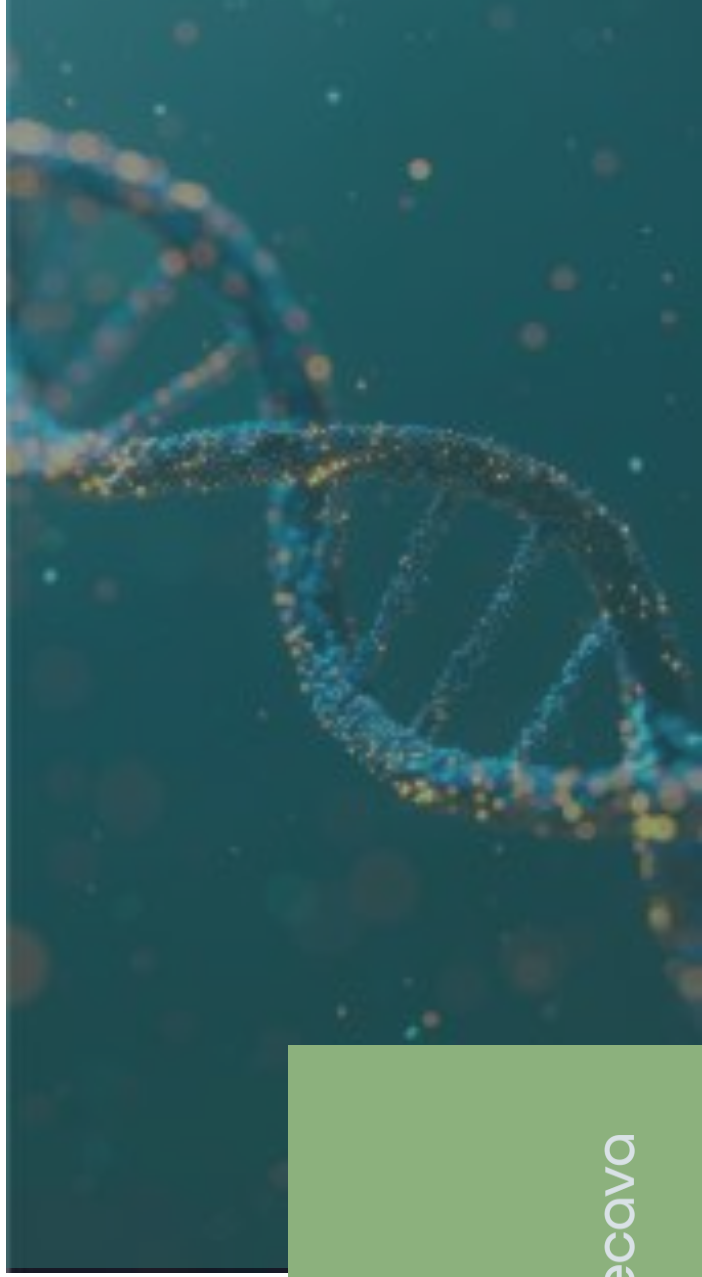
Transforming Cancer Care

A clinically-tested personalized peptide vaccine approach showing real patient impact

Mar 2025

Cecava: Launching a novel peptide-based approach to become a cancer vaccine leader

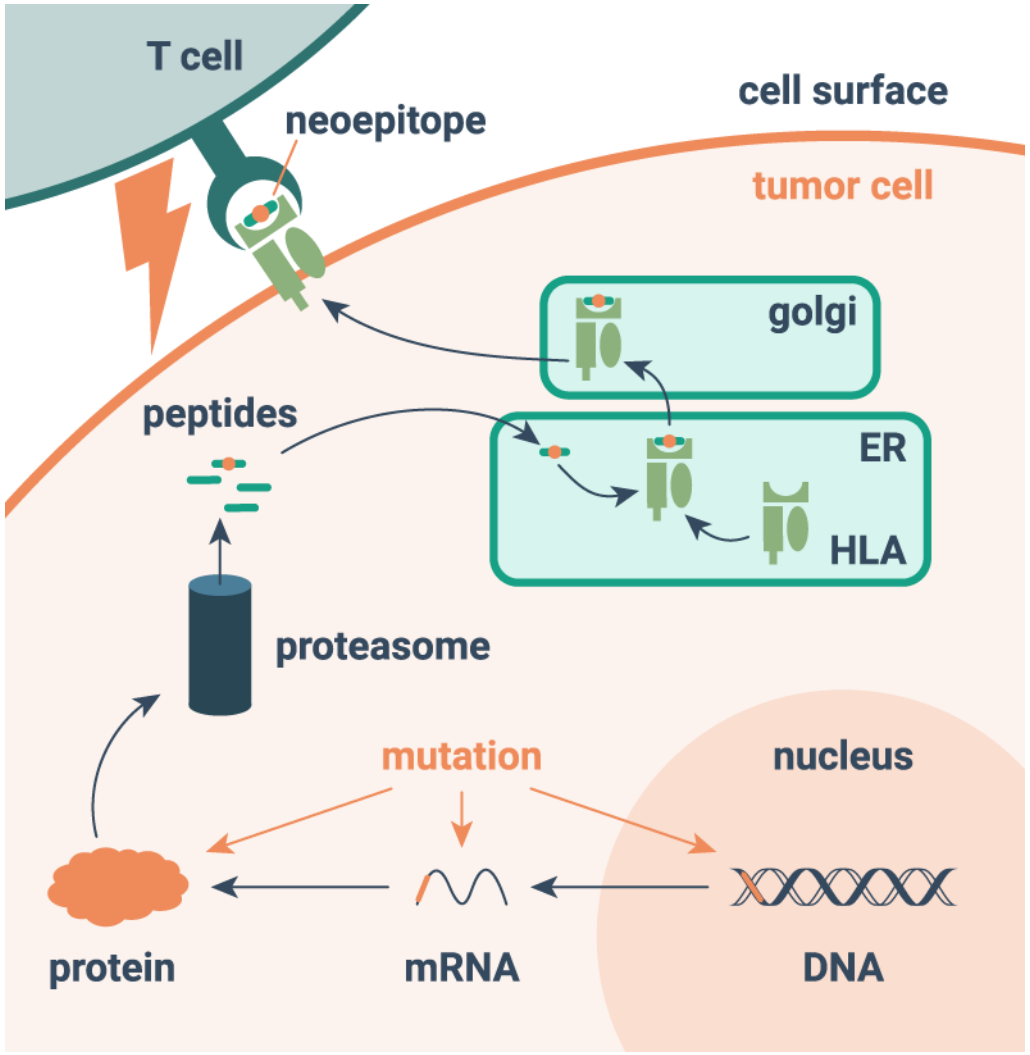
- Disruptive platform technology generating personalized cancer vaccines with significant potential in high-need, solid-tumor indications
- Clinical experience in nearly **700 cancer patients** has established safety, immunogenicity and therapeutic impact
- 2024 *Nature Comm* publication on vaccine use in **173 glioblastoma patients** demonstrated strong survival benefit and established lead indication
- Company will start glioblastoma pivotal Phase 1/2 study in 2025 aiming for accelerated approval based on positive FDA feedback
- Top-notch leadership team with 20+ years of experience and highly-recognized international clinical expert advisory board
- Raising capital to advance first program to regulatory application



Glioblastoma – An urgent unmet medical need

- GBM is the most aggressive and lethal form of brain cancer, no cure available
- Standard of care has remained unchanged since 2005 (Stupp protocol: Surgery + radiotherapy + temozolomide)
- Extremely poor prognosis:
  - Median overall survival: 12–18 months despite treatment
  - **75%** of patients die within the first year
  - **95%** mortality within five years
- Highly invasive tumors make complete surgical removal impossible, leading to inevitable recurrence
- Very limited treatment options
- Global incidence: ~300,000 new cases annually, with increasing numbers due to aging populations
- High socio-economic burden with significant impact on patients, caregivers, and healthcare systems

Mode of action – Personalized peptide vaccines



- Tumors acquire mutations that alter proteins, producing unique peptides (neoepitopes) displayed on the cell surface via HLA
- The immune system can recognize these neoepitopes as foreign, activating T cells to eliminate tumor cells
- By vaccinating with tumor-specific neoepitopes, Cecava's approach trains the immune system to target and destroy tumors
- Since mutations, neoepitopes and HLA profiles vary between patients, an effective vaccine must be personalized

Cecava's approach - Personalized peptide vaccines

1 **Biopsy**

Samples of patient's tumor & normal tissue are collected for sequence comparison

2 **Sequencing analysis**

DNA & RNA sequencing to identify tumor-specific mutations & patient's HLA type

3 **Neoepitope Prediction & selection**

Predict, prioritize & select the clinically most relevant neoepitopes for treatment with proprietary AI-based *in silico* pipeline

4 **Vaccine production**

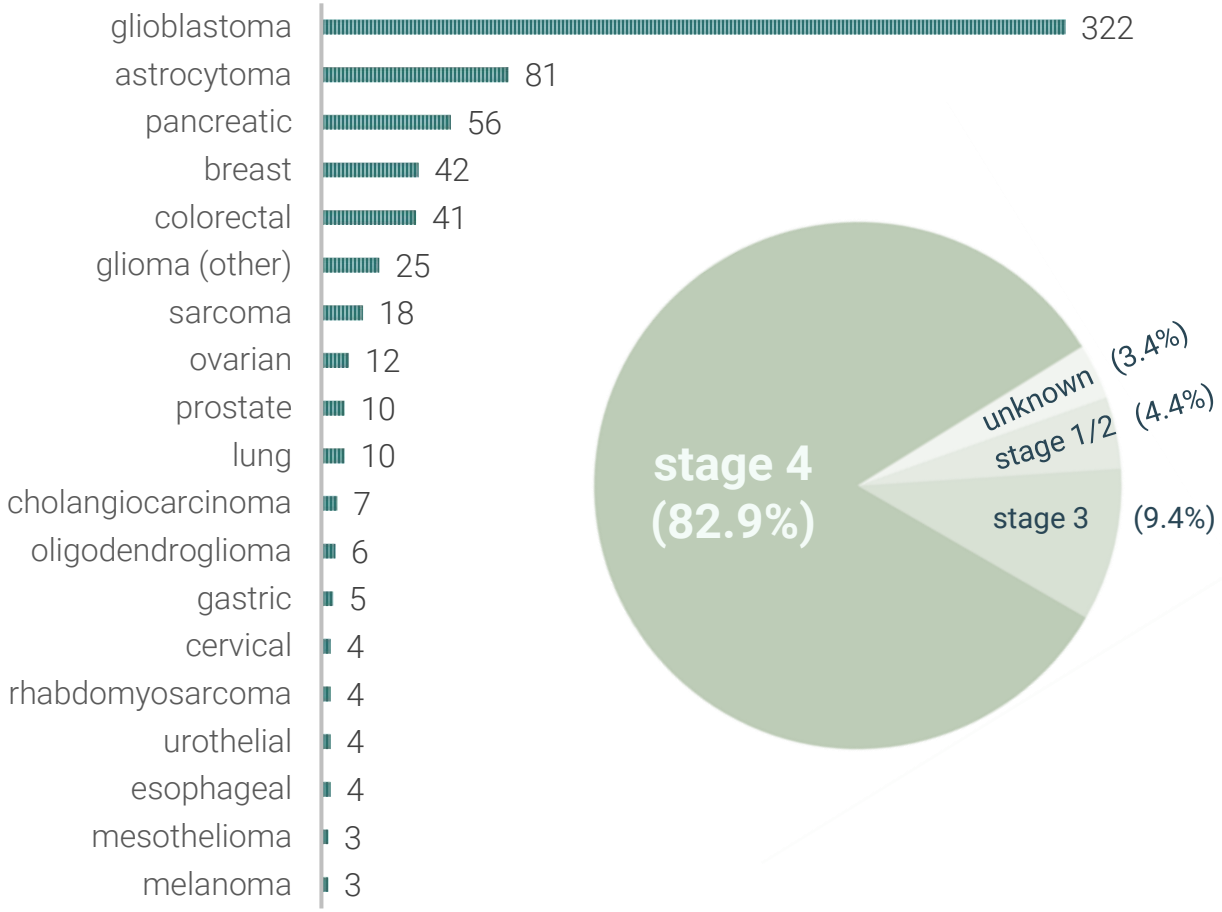
Manufacture 20 - 24 neoepitope peptides & 2 personalized vaccines with up to 10 peptides each

5 **Vaccination**

Repeatedly treat each patient with 2 personalized vaccines together with adjuvants

Cancer patients treated with Cecava's vaccines

Number of vaccinated patients per tumor type



Tumor types with ≥ 3 cases treated

Treated patients:
683

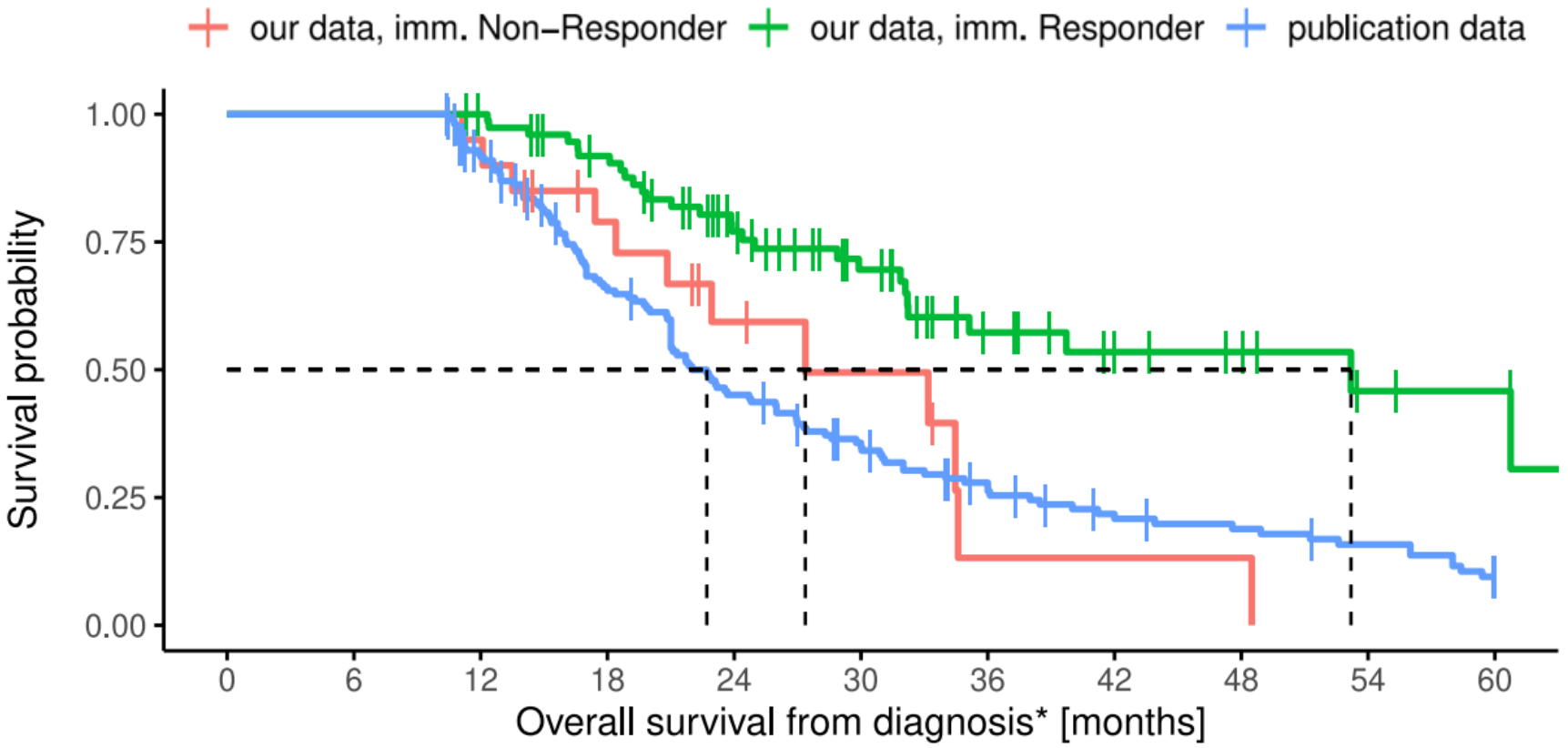
Cut-off date:
1 Jan 2025

Treated tumors:
Solid tumors of distinct origin; mainly late stage (> 92% stage 3-4)

Time on vaccine:
16 months mOS since 1st vaccination;
47.9% patients were still alive at data cut-off

Side effects:
Mostly mild and transient

Neoepitope vaccines show promising activity in GBM



Of the vaccinated GBM patients with T cell response data **(97/173)** the patients with multiple vaccine-induced immune responses showed significantly longer survival (**green; n= 77; mOS= 53.2 mo; p= 0.03**) than vaccinated patients with no/low immune response (**red; n= 20; mOS= 27.4 mo**) or 159 historical control patients (**blue; mOS= 22.7 mo; p < 0.0001**).

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Clinical experience to date benefits from collaboration and support of the approach from leading U.S. neuro-oncology experts

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A real-world observation of patients with glioblastoma treated with a personalized peptide vaccine

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Check for updates

A list of authors and their affiliations appears at the end of the paper

Current treatment outcome of patients with glioblastoma (GBM) remains poor. Following standard therapy, recurrence is universal with limited survival. Tumors from 173 GBM patients are analysed for somatic mutations to generate a personalized peptide vaccine targeting tumor-specific neoantigens. All patients were treated within the scope of an individual healing attempt. Among all vaccinated patients, including 70 treated prior to progression (primary) and 103 treated after progression (recurrent), the median overall survival from first diagnosis is 31.9 months (95% CI: 25.0–36.5). Adverse events are infrequent and are predominantly grade 1 or 2. A vaccine-induced immune response to at least one of the vaccinated peptides is detected in blood samples of 87 of 97 (90%) monitored patients. Vaccine-specific T-cell responses are durable in most patients. Significantly prolonged survival is observed for patients with multiple vaccine-induced T-cell responses (53 months) compared to those with no/low induced responses (27 months; $P = 0.03$). Altogether, our results highlight that the application of personalized neoantigen-targeting peptide vaccine is feasible and represents a promising potential treatment option for GBM patients.

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Clinical experience to date benefits from collaboration and support of the approach from leading U.S. neuro-oncology experts

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Clinical trial design to deliver on unique vaccine opportunity

Pivotal Phase 1/2

- Safety, immunogenicity, and overall survival benefit; clinical trial readiness 2H 2025, randomized placebo-controlled trial, 50 centers in US and EU

Patients

- 300 non-methylated MGMT-promotor GBM patients / 2:1 randomization
- Subgroup with worst prognosis, resistant to chemotherapy, Standard of Care has hardly any survival benefit

Study arm

- Surgery + radiation, Cecava vaccines (w/o TMZ)

Control arm

- Standard of Care: Surgery + radio-chemotherapy with TMZ / adjuvant TMZ for 6 cycles

Differentiating aspects of the technology platform

Universality:	Custom design for every cancer patient
Feasibility:	Peptide vaccines are production- and cost-efficient
Specificity:	Neoepitopes exclusively present on tumor cells
Safety:	Very mild side-effect spectrum
Immunogenicity:	Profound activation of the immune system ($CD4^+$ & $CD8^+$ T cells)
Tumor escape:	Avoid immune escape by targeting up to 20 neoepitopes in parallel
Survival benefit:	Individual treatment data of > 600 patients support prolonged survival results as compared to available data from clinical trials, cancer databases & retrospective analysis
Glioblastoma (GBM):	**Survival benefit of MGMT unmethylated GBM patients treated with Cecava's personalized peptide vaccines vs. SOC: 25 mo vs 15 mo.**

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The Cecava founder team

Saskia Biskup, MD, PhD

- Medical Doctor, specialized in human genetics, molecular oncology, and translational medicine
- Developed the Cecava neoepitope vaccine technology and conducted first-in-human patient treatment
- Multiple awards such as Peter Gruber International Award of the Society for Neuroscience, Atlanta; EU Innovation Award for Woman

Dirk Biskup, PhD

- PhD in economics and mathematics, specialized in M&A, finance, and management, became CFO of international company with young age (34y)
- Multiple publications in high ranked journals
- Serial entrepreneur, co-founder of CeGaT, Cecava, Cenata, and CAG

Saskia and Dirk fully own and run businesses with +500 employees and > EUR 100m in revenues

The Cecava team and scientific advisory board (SAB)

Dr. Dirk Hadaschik, CSO, Dr. Dieter Götte, CMO, Dr. Dirk Biskup, CEO,
Dr. Dr. Saskia Biskup, CEO, Rosanna Krebs & Eike Pertuch, Bioinformaticians

SAB

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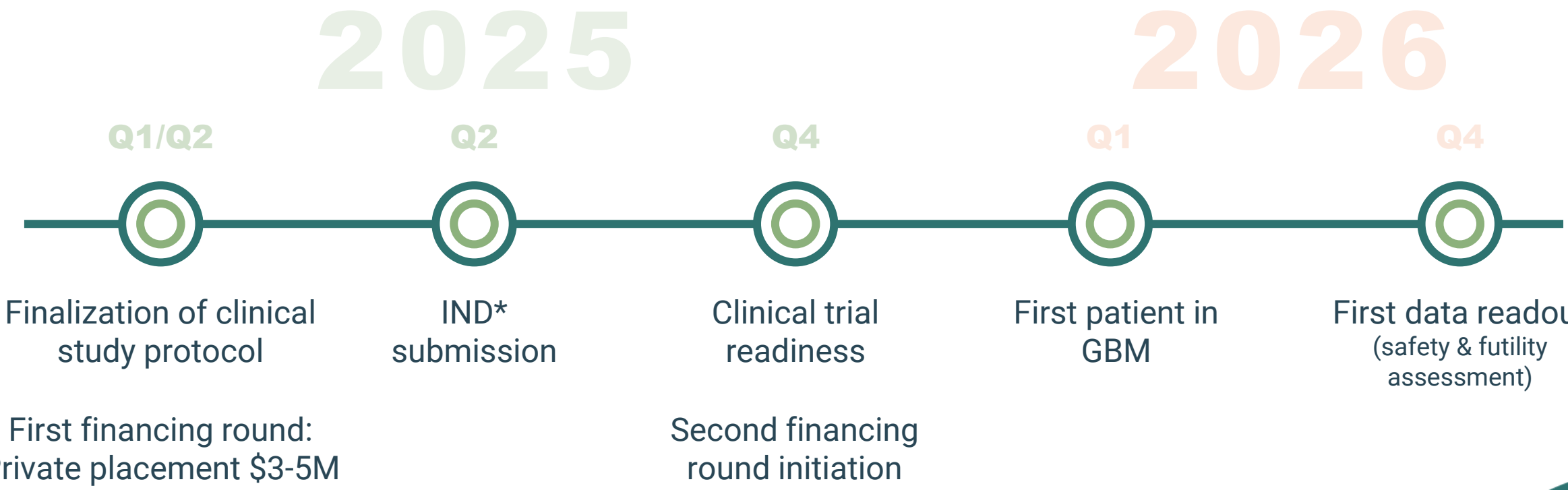
Cecava – History and incorporation

- Founded in 2018 by CeGaT and B. Braun Melsungen AG, Cecava is a German biotech company dedicated to pioneering advancements in neuro-oncology
- In 2024, Saskia and Dirk Biskup, the founders of CeGaT, became sole owners of Cecava, ensuring a clear strategic vision and financial independence
- Led by an expert team, company operates with a lean, highly skilled workforce, including a CSO, CMO, QM, and two bioinformaticians
- The company is guided by a scientific board of international neuro-oncology experts, reinforcing its commitment to cutting-edge research and innovation

Key milestones & strategic initiatives



*IND: Investigational New Drug Application at FDA

Cecava investment opportunity

Cecava is raising an initial round to achieve GBM trial readiness and clear regulatory path forward

Based on rapid positive clinical trial outcome, Cecava aims to complete development in GBM on accelerated timeline

Delivering on the approach's potential in GBM paves the way for further application of the technology platform in hard-to-treat solid tumors

Company aims to establish leadership position in effective cancer vaccines

Thank You!

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