

# FULL YEAR 2022 RESULTS WEBCAST AND CONFERENCE CALL

April 19, 2023

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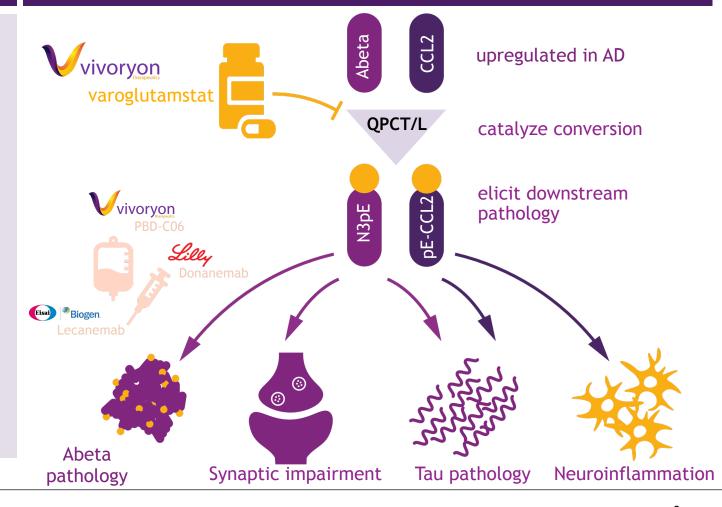


# Lead Product Candidate: Varoglutamstat Prevents Formation of Toxic N3pE in AD

#### DIFFERENTIATED APPROACH TO AD

- STATISTICALLY SIGNIFICANT changes in working memory
- ◆ **CONVENIENT ADMINISTRATION** with oral availability in outpatient setting
- ADDRESSES ALL KEY PATHOLOGICAL HALLMARKS OF AD
  - Designed as upstream intervention compared to e.g. mAbs
  - Prevents formation of neurotoxic Abeta variant N3pE
  - ◆ Captures all Abeta aggregation states
  - Second mode of action modulates neuroinflammation and tau pathology
- PROMISING SAFETY PROFILE with no ARIAs seen in the clinical setting

#### VAROGLUTAMSTAT TARGETS UPSTREAM PATHOGENESIS





### Varoglutamstat Clinical Development Strategy

Clear Path To Potential Regulatory Approval Based on Well-Informed, Extensive Phase 1 and Phase 2 Trials









#### **COMPLETED**

- QPCT inhibition improves cognitive parameters in AD mouse models
- ◆ QPCT is essential for N3pE amyloid and pE-CCL2 formation in vivo



#### Phase 1

Assessment of safety and tolerability in 205 healthy volunteers

#### COMPLETED

◆ Varoglutamstat is welltolerated - no DLT at 800 mg twice daily or up to 3.6 g once daily

#### Phase 1

Assessment of safety and tolerability in 60 healthy Chinese volunteers

IN PREPARATION



#### Phase 2a SAPHIR

Assessment of safety and tolerability in 120 patients with early AD

#### **COMPLETED**

- Statistically significant changes from baseline in working memory after only 3 months of treatment (as measured by CogState)
- High target occupancy detected at doses of 150 mg BID and above

#### Phase 2b VIVIAD

Assessment of safety, tolerability and efficacy in 250 patients with MCI or mild AD

#### Fully recruited Final readout Q1/2024

- ◆ Endpoints: safety, attention/ working memory, NTB, biomarkers
- ◆ Parallel group, dose-finding part completed, study continues with DSMB recommended maximum dose of 600 mg BID or placebo
- ◆ Fully enrolled (259 pts); planned to allow for mean treatment duration of ~82 weeks

#### Phase 2a/b VIVA-MIND

Assessment of efficacy and safety in 180 patients with early AD

Expanded treatment duration in Phase 2a portion (72 weeks) Study status update in H2/2023

Endpoints: safety, attention/working memory, CDR-SB, biomarkers

#### Pivotal study or accelerated approval

- ◆ FDA Fast Track designation granted in 2021
- Two possible scenarios for late-stage development
  - Application for accelerated approval (based on consistent / positive data of Phase 2b studies)
  - Phase 3 clinical development



### Clinical Portfolio Highlights

2022 and Post-Period

- VIVIAD European Phase 2b study of varoglutamstat: on track for final data readout Q1/2024
  - Parallel group, dose-finding part of study completed; independent DSMB selected highest dose investigated, 600 mg BID, as final dose in second part of study
  - Detailed safety data presented at AAIC 2022 in San Diego, showed varoglutamstat was well-tolerated at 600 mg BID
  - Enrollment completed as planned and study adapted to enable longer average treatment duration of participants (anticipated average treatment duration ~82 weeks)
  - Data¹ presented at AD/PD 2023 from >100 of 259 participants treated for ≥48 weeks showed that varoglutamstat was well-tolerated in the study to date, no on-target toxicity and no clinical signs of ARIA; both total number of SAEs and discontinuation rate were considerably lower than seen at 800 mg BID dose in prior Phase 2a study
- VIVA-MIND U.S. Phase 2a/b study of varoglutamstat: update in H2/2023
  - Study design adapted to enable all 180 patients to be treated for at least 72 weeks, allowing for opportunity to progress seamlessly to potential Phase 3 study
  - Study actively enrolling patients at 18 sites across the U.S., with DSMB having unanimously recommended to continue study without modification



### Corporate Development Highlights

2022 and Post-Period

- ◆ Financing events to support ongoing clinical development of varoglutamstat
  - ◆ April 2022: EUR 21 million raised in private placement; capital raise supported by a number of high-quality institutional investors from Europe and U.S. / members of Vivoryon's Executive and Non-Executive Boards
  - September 2022: EUR 15 million raised in private placement with option to place an additional EUR 15 million;
     supported by longstanding investor Claus Christiansen and new investor KKR Dawn Aggregator
- ◆ Clinical Trial Application submitted by partner, Simcere, for the development of varoglutamstat in Greater China approved by China's Center for Drug Evaluation (CDE); preparations ongoing for Phase 1 study and subsequent Phase 2 study
- Non-Executive Board expanded and diversified by appointment of Claudia Riedl, PhD and Samir Shah,
   MD; all existing members re-appointed by AGM

### Condensed Statement Of Profit And Loss

In €k	2022	2021	%
Gross profit	-	9,196	
Research and development expenses	(20,224)	(17,452)	16 %
General and administrative expenses	(8,908)	(4,549)	96 %
Operating loss	(29,113)	(12,798)	127 %
Finance result	758	575	32 %
Income taxes	199	(432)	
Net loss for period	(28,156)	(12,655)	122%
Loss per share (basic and diluted) (in EUR)	(1.28)	(0.63)	



## Key Financial Figures

In €k	December 31, 2022	December 31, 2021
Cash and cash equivalents	26,555	14,661
Total assets	31,378	24,520
Total equity	26,506	16,557
Shares (number)	24,105,278	20,050,482

In €k	December 31, 2022	December 31, 2021
Cash flows used in operating activities	(21,794)	(11,257)
Cash flows used in investing activities	(13)	(28)
Cash flows from financing activities	33,381	(827)
Cash and cash equivalents at the end of period	26,555	14,661



### Positioned for Continued Value Generation



## Varoglutamstat: Differentiated Phase 2 Asset with Unique Potential in AD

- STATISTICALLY SIGNIFICANT changes in working memory
- CONVENIENT ADMINISTRATION with oral availability in outpatient setting
- ADDRESSES ALL KEY PATHOLOGICAL HALLMARKS OF AD
  - Designed as upstream intervention compared to e.g. mAbs
  - Prevents formation of neurotoxic Abeta variant N3pE
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#### Catalysts and Future Opportunities

- UPCOMING CATALYSTS:
  - VIVIAD European Phase 2b: Final readout Q1/2024
  - VIVA-MIND U.S. Phase 2a/b: Study status update in H2/2023
- FUTURE OPPORTUNITIES:
  - Potential to develop varoglutamstat in combination with mAbs in AD (own and external assets)
  - Follow-up programs into the clinic beyond AD
  - Through regional partnership with Simcere:
     Development opportunities for varoglutamstat and
     PBD-C06 in AD in Greater China



