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# SAPHIR trial data published in Alzheimer's Research & Therapy

**HALLE (SAALE), Germany, 16 October 2018** - Probiodrug AG (Euronext Amsterdam: PBD), a clinical stage biopharmaceutical company developing novel therapeutic solutions to treat Alzheimer's disease (AD), announced today that results from its SAPHIR trial were published in one of the leading peer-reviewed medical journals, *Alzheimer's Research & Therapy.* 

The publication entitled: "Safety, tolerability and efficacy of the glutaminyl-cyclase inhibitor PQ912 in Alzheimer's disease: results of a randomized, double-blind, placebo-controlled Phase 2a Study," can be <u>found here</u>.

The publication summarizes and highlights the results of the SAPHIR trial (<u>Clinicaltrials.gov, NCT</u> <u>02389413</u>) which is the first clinical trial to investigate the Glutaminylcyclase (QC) inhibitor PQ912 in patients with early AD. The aim of the Study was to determine the maximal tolerated dose, target occupancy and treatment related pharmacodynamic effects. PQ912 is Probiodrug's lead product candidate and a first-in-class QC inhibitor. The results further confirm Probiodrug's treatment approach and strongly encourage the advancement into the next development phase.

**Prof. Dr. Philip Scheltens, Principal Investigator of the SAPHIR study commented:** "The results of the SAPHIR trial are highly encouraging, and endorse the potential of PQ912 as a novel disease modifying therapy. Results need to be confirmed in a larger trial for which preparation are on going. Alzheimer's impacts a huge population which is in dire need of treatment options."

The article is authored by researchers from VU University Medical Center, Amsterdam, The Netherlands; University of Eastern Finland, Kuopio, Finland; Technische Universität München, Munich, Germany; University of Münster, Münster, Germany; Cogstate Ltd., Melbourne, Australia; King's College London, UK; UMC Utrecht, The Netherlands; Brain Research Center, Amsterdam, The Netherlands; Probiodrug AG, Halle, Germany.

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#### Notes to Editors: About Probiodrug AG

Headquartered in Halle (Saale), Germany, Probiodrug AG (Euronext Amsterdam: PBD) is a clinical stage biopharmaceutical company focused on the development of new therapeutic products for the treatment of Alzheimer's disease (AD). Probiodrug has identified a new therapeutic concept linked to disease initiation and progression. The development approaches are targeting a key neuro-/synaptotoxic component of the pathology, pyroglutamate-Abeta (pGlu-Abeta) as a therapeutic strategy. Its lead product, PQ912, has successfully completed a Phase 2a (SAPHIR) study. The company's pipeline also includes PBD-C06, an anti-pGlu-Abeta-specific monoclonal antibody, in preclinical development. Probiodrug has medical use and composition of matter patents related to the inhibition of QC and anti-pGlu-Abeta-specific monoclonal antibodies, and has, in the Company's view, a leading position in this field of research.

## About PQ912

PQ912, is a first in class, highly specific and potent inhibitor of Glutaminyl Cyclase (QC), the enzyme catalyzing the formation of synaptotoxic pGlu-Abeta. PQ912 has shown therapeutic effects in AD animal models. A Phase-1 study in healthy young and elderly volunteers revealed a dose dependent exposure and showed good safety and tolerability up to the highest dose resulting in >90% target occupancy in the spinal fluid. In June 2017, Probiodrug announced top-line data of the Phase-2a SAPHIR trial of PQ912 and presented the study results at CTAD 2017. Results strongly support (a) the hypothesis of pGlu-Abeta being synaptotoxic and (b) the therapeutic concept pursued by Probiodrug. The study provides important guidance how to move forward with the development of PQ912 as a disease-modifying drug for AD. Altogether, the results make the program highly attractive for further development; the company has initiated the preparation of a Phase 2b core program.

#### www.probiodrug.de

### About Alzheimer's disease

Alzheimer's disease is a neurological disorder, which is the most common form of dementia, and ultimately leads to death. Today, 50 million people live with dementia worldwide, and this number is projected to treble to more than 152 million by 2050, as the global population ages. Dementia also has a huge economic impact. Alzheimer's has an estimated, global societal cost of US\$ 1 trillion, and it will become 2 trillion dollar disease by 2030. (World Alzheimer Report 2018).

### Forward Looking Statements

Information set forth in this press release contains forward-looking statements, which involve a number of risks and uncertainties. The forward-looking statements contained herein represent the judgment of Probiodrug AG as of the date of this press release. Such forward-looking statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any such statements to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statement is based.