I. **Background & Purpose**

Alzheimer’s disease has been called the greatest health challenge of the 21st century—the disease is notoriously difficult to diagnose, exacts monumental costs on individuals, families, communities, and healthcare societies, and has frustrated researchers looking for a disease modifying therapy (DMT) for the past 100 years. Adding urgency to an already critical situation, the incidence of Alzheimer’s disease is projected to quadruple by midcentury as populations age. With limited success in drug development over the past few decades, serious challenges remain that will need to be addressed if future innovations are to result in real-world patient access and outcomes.

Specifically, early Alzheimer’s detection remains difficult and out-of-reach for most—this presents a challenge, as the next generation of innovative DMTs and symptomatic treatments for Alzheimer’s disease are likely to be most effective for patients in the early, and potentially pre-symptomatic, stages of the disease. Further, new innovative treatments and diagnostics for Alzheimer’s disease will challenge today’s models for health technology value assessment and funding approaches. Providing access to and funding for future innovations in Alzheimer’s diagnosis and treatment will require new models for measuring and assessing value that include the holistic and societal benefits of Alzheimer’s disease treatments and diagnostics.

**Project Alzheimer’s Value Europe (PAVE)** has been established as a collaborative, multi-stakeholder forum focused on the value assessment of and funding for emerging therapeutic and diagnostic innovations in Alzheimer’s disease in Europe.

II. **Objectives and Scope**

PAVE’s goals are twofold: to educate policymakers, payers, and other Alzheimer’s disease stakeholders in European countries on the current challenges related to assessing value in Alzheimer’s disease; and, to work together with European payers and policymakers to develop solutions related to the value assessment of, and funding/financing for future Alzheimer’s disease therapies and diagnostics.
Along with the overarching goals, PAVE aims at achieving four primary outcomes:

1. **Improve Understanding of Epidemiology and Impact** by generating an updated, high-level review of epidemiological literature to clarify what currently defines and quantifies dementia and Alzheimer’s disease with the end goal of pinpointing eligible populations for treatment. Based on the outcomes of the epidemiological review of specified regions, the report would aim to help outline industry-wide budget and resource impacts of diagnosing and treating Alzheimer’s disease while providing common reference points for stakeholders beyond the general epidemiology of Alzheimer’s disease.

2. **Delineate how Alzheimer’s Registries** can be used to support a holistic value assessment using three guiding questions: how registry data can be used to inform value assessments that discern the full health and societal benefits of emerging therapies and treatments; how this information can be leveraged to secure payer support that will result in patient access; and what are the current barriers to using registry data, including any “data gaps,” in the creation of new drug value assessments.

3. **Identify and Catalogue Countries with Core Elements for Measurement** for approaches to health technology assessment (HTA) that take a broad view of the direct and indirect impact when evaluating innovative treatments and diagnostics for Alzheimer’s disease. Currently, HTA/cost effectiveness plans are assessing cost-benefits within healthcare systems and not fully addressing Alzheimer’s significant impacts on delayed institutionalization, caregiving homes, caregiver costs, etc. Therefore, there is a need to demonstrate the larger societal influence that innovative diagnostic tools and treatments will have.

4. **Address Payment and Access issues** by outlining potential new, innovative industry-wide mechanisms for funding, financing, and payment to support access and effective use of new diagnostic tools and treatments for Alzheimer’s disease.

III. **PAVE Funders**

PAVE is currently funded by Hoffmann–La Roche and Biogen (PAVE Funders) with the ability for other private sector organizations to join, fund and participate in PAVE moving forward. Potential new Funders should have separate agreements with High Lantern Group in place and the funding and sharing of project costs to be agreed with the existing PAVE Funders. PAVE Funders are responsible and accountable for all PAVE communication, outcome and created content. PAVE Funders must review and approve any dissemination of information and content (e.g. agendas and invitations, presentations, publications, social media communication etc.). PAVE Funders may use and share PAVE developed content and material, as aligned and agreed to by the Funders in advance of use. Any and all PAVE content or material shared must be branded as PAVE, and contain the PAVE logo.
PAVE Members and Funders will strive to reach agreement by consensus at a level that indicates that all are willing to accept the proposed action.

IV. **PAVE Members**

To accomplish these goals, PAVE enlists an informal, voluntary, network of expert advisors (PAVE Members) that understand clinical perspectives, value and access processes and decisions for Alzheimer’s disease innovations as well as leaders that have developed evidence that address the concerns of policymakers and relevant stakeholders. PAVE Members work collaboratively with the PAVE Funders to define objectives for the work of PAVE, provide a community perspective on key considerations, and are a sounding board for PAVE’s workplan and deliverables. PAVE requires collaboration to address barriers that may arise from project work. Members will also work towards consensus on the desired project goals, recruitment, and dissemination of PAVE deliverables. PAVE meetings occur virtually.

PAVE Members’ participation is based on interest, and they are not compensated for participating and contributing. Any proposal for enrollment of new PAVE Members and/or direct application for membership by third parties should be assessed by and approved by the PAVE Funders. The PAVE Secretariat should have confirmation from the new PAVE Members of their acceptance of membership and acknowledgement of the charter. PAVE Members are responsible for their engagement and transparency with their employer in their participation in this group.

Additional defining criteria for PAVE Membership includes (but is not limited to) those persons, groups or entities with:

- Relevant knowledge and experience in the Alzheimer’s community and/or expertise in relevant fields such as communications, policy, and healthcare systems;
- Leadership and vision willing to challenge assumptions and think strategically in pursuit of those Objectives and Scope outlined above;
- Additional and diverse points of view and the willingness and means to enable the dissemination of PAVE’s messages in pursuit of those Objectives and Scope outlined above; and
- Time and access to staff support, where appropriate, to liaise with other PAVE Members and with PAVE’s Secretariat (High Lantern Group).

PAVE Members agree to voluntarily:

- Provide expertise, including identifying emerging issues and trends;
- Review project reports and comment promptly;
- Attend quarterly virtual meetings to the extent possible and prepare appropriately;
• When presenting on behalf of PAVE, articulate and reflect the interests of PAVE at external forums;
• Maintain a focus on solutions that benefit the entire study area and broader Alzheimer’s disease community; and
• Comply with the antitrust applicable laws.
PAVE Members may decline their membership at any time with a written request to the PAVE Secretariat.

PAVE Project Teams
PAVE may put together Project Teams for specific projects. The Projects and corresponding Teams should be well defined, agreed and documented in the regular PAVE meetings. The Project Team participants/contributors may consist of Funders, Members, external consultants with particular competence and other ad hoc Subject Matter Experts.

V. Operating Guidelines
Meetings and communication guidelines consist of:
• Quarterly check-in calls to advance PAVE’s work and at an ad-hoc basis for specific projects;
• Bi-annual strategy meetings will be held at the time and date agreed upon by the PAVE Members and Funders in the course of their meetings;
• PAVE Members will be informed of, and invited to, meetings through email;
• Meeting and communications are facilitated by the PAVE Secretariat (High Lantern Group) and attended by outside counsel as deemed necessary to ensure respect of the antitrust regulations;
• Final project documents and notices will be posted on the PAVE website and distributed via email to PAVE Members;

The PAVE Secretariat will:
• Provide an agenda in advance of each meeting, keep a record of meeting attendees, key issues raised, and actions required with meeting summaries distributed alongside a clear understanding of expectations and assignments for next steps.
• Effectively manage the scope, schedule, and budget;
• Keep PAVE Members and Funders informed of progress;
• Provide documentation to support recommendations;
• Provide technical expertise and manage logistics for meetings; and
• Provide notification of PAVE meetings and time for comment on technical reports and other documents.