**ABLi Therapeutics Announces Details of the End of Phase 2 Meeting with FDA for Evaluation of Risvodetinib as a Treatment for Parkinson's disease**

*Agency supports primary and novel secondary and exploratory endpoints proposed for Phase 3 Trial(s)*

*Opportunity to utilize time-to-delay of levodopa/carbidopa initiation as an endpoint to measure trial success, which Company believes is a direct measure of disease-modification*

*Atlanta, GA and Boston, MA; May 21, 2025* - ABLi Therapeutics ("ABLi"), a biotechnology company developing therapeutics to address diseases that arise from activation of Abelson Tyrosine Kinases (c-Abl kinases), completed an End of Phase 2 (EOP2) meeting with the Food and Drug Administration (FDA) to discuss outcomes of the 201 Trial in untreated Parkinson's disease and to review plans for the Phase 3 program.

The meeting's primary purpose was to discuss endpoints to be used in a Phase 3 program and to define what tangential clinical and pre-clinical experiments may be necessary for a potential filing of a New Drug Application (NDA.) The Company presented data showing that the 201 Trial reached nominal significance for the Movement Disorder Society revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) and for the Schwab & England Activities of Daily Life (SEADL) scale in a 12 week treatment, which were consistent with the FDA's preference for evaluating patient quality of life as a primary assessment of clinical benefit. The Company proposed to use the change in the MDS-UPDRS Part 2 as the primary outcome measure for its planned Phase 3 trial, consistent with the Agency's view of the most clinically meaningful outcome for patients. The Agency encouraged continued use of Patient and Clinical Severity scales as was done in the Phase 2 trial to complement MDS-UPDRS and SEADL measures.

The Company further proposed a novel endpoint to determine if risvodetinib lengthens the time before levodopa/carbidopa treatment is initiated. In the Company's view, lengthening this time from the beginning of the Phase 3 trial relative to the placebo-treated controls represents a direct measure of modifying the course of Parkinson's disease. The FDA agreed with the use of this approach and encouraged a follow-up meeting to align on the clinical standard to be used to determine when a participant should go onto levodopa/carbidopa treatment.

The meeting simplified the requirement included in the Phase 2 trial for thorough monitoring of vision, and reduced the frequency of thorough monitoring to a six-month interval until one year dosing data is reviewed by the Agency. To date, no risvodetinib-related impact on vision has been observed for any participant administered any dose of risvodetinib once daily for up to 12 weeks.

The Agency encouraged the Company to continue its evaluation of skin biopsy and measures in other biological fluids before determining if the Company's approach using skin biopsy could become a prognostic marker of treatment success. The Company views the quantitative measure of alpha-synuclein clearance as a supportive measure alongside clinical outcome assessments because it is now well-established that all forms of

Parkinsonism arise from neuronal alpha-synuclein deposition in a variety of aggregated and fibrillar forms that may be characteristic of different types of Parkinson's disease. Risvodetinib is the first Parkinson's treatment that reduced pathological alpha-synuclein in the context of a clinical benefit.

**About Risvodetinib (ABLi-148009)**
Risvodetinib is a potent, selective small-molecule inhibitor of the non-receptor c-Abl kinases, designed for once-daily oral use that targets the underlying biological mechanisms driving Parkinson's disease initiation and progression. Risvodetinib is believed to be a disease-modifying therapy that halts disease progression and reverses the functional loss arising from Parkinson's disease inside and outside of the brain. All marketed therapeutic approaches to treat Parkinson's help manage the symptoms of the disease, but there are currently no available treatments to slow or stop the disease's relentless progression. Recently, risvodetinib was the first monotherapy to improve patient quality of life in a randomized, placebo-controlled clinical trial (NCT NCT05424276) and simultaneously reduced the underlying disease pathology in untreated Parkinson's disease. Risvodetinib currently has intellectual property protection beyond 2036.

**About ABLi Therapeutics**
ABLi Therapeutics ("ABLi") applies innovative medicinal chemistry and a deep understanding of disease biology to develop small molecule therapeutics that target the cause of diseases that arise from activation or dysfunction of the Abelson Tyrosine Kinases (c-Abl). Leveraging its expertise in drug design, ABLi utilizes clinically validated data of kinase inhibitors to design and develop novel product candidates with enhanced penetration into the brain, greater potency and target selectivity, and improved safety to treat diseases in which Abl kinase activation or dysfunction is implicated. The Company's primary focus is on developing therapeutics for the treatment of neurodegenerative diseases like Parkinson's disease and the Parkinson's-related neurodegenerative diseases Multiple System Atrophy and Dementia with Lewy Body that are all associated with Abl kinase activation or dysfunction. For more information visit www.ablitherapeutics.com or follow us on LinkedIn.

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