Statement: Biogen Provides Update on Parkinson's Disease Clinical Development Program

June 5, 2023

As part of its ongoing Research & Development (R&D) prioritization initiative and resource allocation, Biogen announced plans to revise the clinical development program for BIIB122, a small molecule inhibitor of leucine-rich repeat kinase 2 (LRRK2), which is being developed in collaboration with Denali Therapeutics Inc.

Prior to the planned revisions, the BIIB122 clinical development program encompassed two global late-stage clinical trials: the Phase 2b LUMA study in participants with early-stage Parkinson's disease, which commenced in May 2022; and the Phase 3 LIGHTHOUSE study in participants with Parkinson's disease related to LRRK2 mutations, which commenced in September 2022.

In consideration of the LIGHTHOUSE study's complexity including the long timeline with anticipated study completion in 2031, Biogen and Denali have agreed that efforts will be refocused to enable a timely readout on efficacy in early-stage idiopathic Parkinson's disease while gaining further clinical data in Parkinson's disease with and without a LRRK2 mutation.

The protocol for the LUMA study in patients with early-stage Parkinson's disease will be amended to now include eligible patients with a LRRK2 genetic mutation in addition to continuing to enroll eligible patients with early-stage idiopathic Parkinson's disease. The LIGHTHOUSE study of BIIB122 in patients with Parkinson's disease associated with LRRK2 mutations will be discontinued. Patients currently enrolled and randomized in LIGHTHOUSE will be offered the opportunity to join the LUMA study.

These modifications are not based on any safety or efficacy data from studies of BIIB122. Denali and Biogen have a strategic collaboration to jointly develop and commercialize small molecule inhibitors of LRRK2 and remain committed to advancing the development of BIIB122.

Further information about LUMA (NCT05348785) can be accessed at clinicaltrials.gov. Participants currently enrolled and randomized in the LIGHTHOUSE study should speak to their physician regarding participation in LUMA or other treatment options.

Biogen Safe Harbor
This press release contains forward-looking statements, relating to the potential benefits and results that may be achieved through Biogen's collaboration with Denali; the potential benefits, safety and efficacy of BIIB122 (DNL151) and other LRRK2 inhibitor molecules; the clinical development program for BIIB122 (DNL151) and other LRRK2 inhibitor molecules; the potential benefits of Denali's TV technology platform and TV programs including its ATV: anti-amyloid beta program; the treatment of Parkinson's disease; the potential of Biogen's commercial business and pipeline programs; Biogen's strategy and plans; the potential treatment of neurological and neurodegenerative diseases; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation: risks that the proposed transaction will be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed collaboration can be achieved; risks of unexpected hurdles, costs or delays; uncertainty of success in the development and potential commercialization of BIIB122 (DNL151) and other undisclosed neurological targets, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risks factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements.