

## Joint Statement by Six Parkinson's Disease Organizations Regarding Proposed Label Change for Azilect FDA Advisory Committee Meeting October 17, 2011

This statement is prepared on behalf of the American Parkinson Disease Association, The Michael J. Fox Foundation for Parkinson's Research, the National Parkinson Foundation, the Parkinson's Action Network, the Parkinson Alliance, and the Parkinson's Disease Foundation. Together we represent a large segment of the Parkinson's disease community and, on behalf of that community, we thank the Food and Drug Administration for holding today's meeting of the Advisory Committee to address the Teva Pharmaceutical application for a labeling of Azilect as a therapy that slows the clinical progression of Parkinson's disease.

As a community, when it comes to finding new ways of confronting Parkinson's disease, we are fiercely pro-investment, pro-progress and pro-development.

- We are all dedicated to the development of critically needed new and transformative treatments for people with this devastating disease.
- Each one of us has welcomed the achievement of each milestone in the development of new therapies, from Levodopa in the 1960s, to dopamine agonists and improved surgical approaches in the 1990s, and to MAOB inhibitors, such as Azilect, in the 2000s.
- All of us support the concept of partnering with industry to invest directly in the process of drug development.

As you know, despite the best efforts of our community, for those people who live with Parkinson's disease (PD) today, there is as yet no disease modifying therapy available – nothing that slows, reverses, or prevents the progression of the disease. And the treatments that we do have merely ease or mask the motor symptoms of PD for a limited period of time.

Parkinson's disease varies greatly from person to person, and there are vast unmet needs in our community. For these reasons, it is generally our position that any new treatment that offers benefit to some people in some circumstances – even in cases where that benefit is limited -- should be approved and made available as an option for the doctor and the person with Parkinson's to evaluate. However, given that today's meeting is about what would be the very first Parkinson's disease therapy to be approved and labeled for a slowing of progression, we believe a rigorous and dispassionate evaluation is warranted.

While we are encouraged by the evidence presented to date, it appears to our community that the data surrounding Azilect as a therapy that slows clinical progression of Parkinson's are not yet definitive, and that additional information is required to completely determine the impact of Azilect on clinical disease progression.

Nothing speaks more clearly to this point than the published report of the results of the ADAGIO study, in which the authors state that “the study results must be interpreted with caution.” (*Olanow et al, 2009*)

It is our understanding that Teva Pharmaceuticals is conducting an open-label follow-up study to examine the ADAGIO cohort further. We are pleased to hear this, and will welcome any additional insight that the study may provide upon its conclusion in 2013.



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Furthermore, we believe that the distinction between a treatment that slows the clinical progression of the disease and a true disease-modifying treatment requires elucidation, as the subtle yet significant difference between the two is likely to cause confusion and artificially raise expectations of general practitioners and people with Parkinson's disease. This is especially true given that Azilect is a therapy that has already been approved by the FDA as a symptomatic treatment for Parkinson's disease.

Finally, we wish to express our community's hope that the FDA, in evaluating this application, will use the opportunity to provide needed clarity to the pharmaceutical industry by detailing the requirements that will need to be met to demonstrate success for a disease-modifying therapy in Parkinson's disease. Such action will remove one aspect of uncertainty in the business decisions that must be made in developing the new treatments that will benefit those people who live with this disease and are most affected by its unrelenting progression.

Thank you for your attention.



Joel Gerstel, President & CEO  
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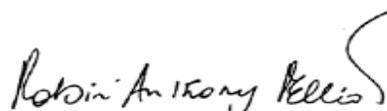
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