CRITICAL PATH INSTITUTE

C-Path Cosponsors Workshop on Combination Drug Development for Alzheimer's Disease

- Combination therapy development has been successful in other life-threatening diseases in part because collaborative approaches were established to identify necessary pathways and tools that enabled more efficient trials. The primary goal of this meeting held in Baltimore, MD November 29th 2012 was to explore how similar partnerships could foster more robust collaboration in Alzheimer's disease (AD) in order to encourage the development of combination therapies.

- AD drug development has focused on a single therapeutic mechanism (amyloid therapies) for > 20yrs. Yet emerging data suggests that like other complex diseases, multiple targets are likely required for effective delay of disease progression. The barriers to developing combination therapies were discussed and examples of success in other disease areas were highlighted. Notably, C-Path's CPTR consortium was featured as a prominent example where combination drug development is core to the mission and goals.

- FDA has published draft guidance on the co-development of multiple treatments for use in combination. Dr. Robert Temple, CDER, presented an overview of FDA's requirements for the development of multiple therapies in combination (per the FDA draft guidance) and discussed the practicalities of such development programs.

- Consensus was achieved that precompetitive collaborations will be critical to success and new opportunities for the future will be pursued.