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Physician Views: Gauging Doctors' Enthusiasm for Newest Wave of Alzheimer's Candidates

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Abstracts

There are an estimated 5.3 million Americans with Alzheimer's disease (AD), a number that is expected to grow as the Baby Boomers continue to age, which explains why drugmakers have not shied away from the space despite what an academic group recently estimated is a staggering 99.6-percent failure rate for compounds that have entered human testing.

The annual Alzheimer's Association International Conference is being held this week in Washington D.C., and will host the unveiling of new data for several high-profile members of the newest wave of Alzheimer's disease therapies, including Biogen's aducanumab and Axovant's RVT-101.

The two products are very different in both form and function, as aducanumab is a mAb that targets beta-amyloid and is believed to have disease-modifying potential, whereas RVT-101 is a small molecule that antagonises the 5-HT6 serotonin receptor antagonist and is thought capable of offering a modest benefit by delaying the cognitive decline associated with AD.

What's more, the two have captured the attention of investors for different reasons as well, as Biogen's programme is the latest would-be contender seeking to prove the often maligned "amyloid hypothesis" for explaining the pathogenesis of AD, while Axovant raised eyebrows by completing a massive $315-million IPO based solely on the prospects for RVT-101, a compound that the company bought only months prior for $5 million after it had been shelved by GlaxoSmithKline.

Data expected to be unveiled by Biogen on July 22 have generated the most discussion going into this week's meeting, as observers are anxious to see how effective a 6

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mg/kg dose of aducanumab will be and – importantly – whether it will prove safer than a 10 mg/kg dose, which proved remarkably effective but may be hamstrung by a high rate (41 percent) of amyloid related imaging abnormality (ARIA) events. (See ViewPoints: Ballyhooed safety data for Biogen's aducanumab coming next week – important or nah?)

As for Axovant, this week's readouts should likely prove less of an inflection point as the two scheduled presentations will involve discussions of completer and responder analyses from previously reported studies of RVT-101.

To gain better understanding about the views of doctors on the how recent events are shaping their perspective on AD as well as how these new agents may ultimately fit into the treatment algorithm, FirstWord PLUS is polling US- and/or EU5-based neurologists and asking them…

> According to results from a Phase Ib study, Alzheimer's patients receiving monthly 10 mg/kg doses of aducanumab (mAb against beta-amyloid) achieved a 71-percent reduction in cognitive decline on the CDR-SB test. However, 41 percent of patients had amyloid related imaging abnormality (ARIA) events, including 55 percent of ApoE4 carriers and 35 percent of ApoE4 non-carriers. Assuming this risk/benefit is similar in Phase III testing, to whom would you typically prescribe aducanumab?
>
> Assuming safety and efficacy data for a 6 mg/kg dose of aducanumab (to be presented on July 22) line up in between the 3 mg/kg and 10 mg/kg doses, how would that influence your belief in the "amyloid hypothesis" for Alzheimer's pathogenesis?
>
> Assuming safety and efficacy data for a 6 mg/kg dose of aducanumab line up in between the 3 mg/kg and 10 mg/kg doses, with its efficacy on measures like the CDR-SB test barely achieving significance while causing less ARIA events than 10 mg/kg, would you be more likely to prescribe 6 mg/kg or 10 mg/kg dose of aducanumab?
>
> Assuming one or more small molecule 5-HT6 serotonin receptor antagonists are approved over the next few years, describe your level of enthusiasm for prescribing an agent that offers a modest delay in cognitive decline when used as adjunct to donepezil but an expensive (branded) price tag?

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There are two small molecule 5-HT6 serotonin receptor antagonists in late-stage development, including idalopirdine (from Lundbeck/Otsuka) and Axovant's RVT-101. Assuming they both are approved as adjunct to donepezil based on similar efficacy profiles, what will be the most important criteria for deciding which to prescribe?

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