Alzheimer’s Disease (Mild to Moderate) | DecisionBase | US/EU | 2014

With aging populations, the seven major pharmaceutical markets face an ever-expanding Alzheimer's disease (AD) patient population that will surpass 10 million by 2022. Currently available symptomatic therapies offer only modest, short-term benefits, and none can prevent, stop, or modify the progression of AD. The rapidly growing AD patient population and the high unmet need for bona fide disease-modifying therapies (DMTs) support a considerable and largely untapped commercial opportunity. Despite repeated failures among investigational DMTs, the race to unlock this opportunity continues to attract pharmaceutical companies, and several late-stage trials of putative DMTs are ongoing. However, trial results thus far indicate that substantial effects on markers of disease pathology do not necessarily correlate with improved clinical outcomes for patients. As a result, surveyed neurologists and interviewed thought leaders remain eager for superior clinical benefits from emerging symptomatic alternatives as the wait for DMTs continues.

Questions Answered in This Report:

- Effect on cognition, as measured by mean change from baseline in the Alzheimer’s Disease Assessment Scale-cognitive subscale (ADAS-cog), is a key goal in the treatment of mild to moderate AD. What are the other key primary and secondary clinical trial end points with which new therapies are evaluated? How do U.S. and European neurologists weight specific efficacy end points and other drug attributes in their prescribing decisions for mild to moderate AD?

- Donepezil (Eisai/Pfizer’s Aricept, other brands, generics) is the patient-share leader for mild to moderate AD. What weaknesses exist in its profile that would allow emerging therapies to gain traction in the market? Have emerging therapies demonstrated potential on the attributes that surveyed neurologists indicate are the most important in their prescribing decisions? Which emerging therapies will offer clinical improvements over currently available therapies that surveyed MCO PDs seek from new therapies?

- An agent’s effects on cognition and function are key drivers of physicians’ prescribing decisions and/or are the focus of drug development for new mild to moderate AD therapies. What trade-offs across these and other clinical attributes are U.S. neurologists willing to make when considering the use of emerging therapies for mild to moderate AD? Based on the trade-offs in price and performance across key drug attributes that U.S. neurologists are willing to make, how do physician preference and prescribing likelihood vary across different target...
product profiles for mild to moderate AD?

- By 2017, Lu-AE58054 (Lundbeck/Otsuka) will emerge as the gold-standard therapy in our Drug Comparator Model, assuming a launch by that time, due to its potentially superior clinical profile over the key current therapies we evaluated; MK-8931 (Merck), an emerging disease-modifying therapy, achieves gold-standard status by 2022. On what clinical attributes are Lu-AE58054 and MK-8931 most differentiated from their competitors? Which current therapies are most likely to be used with Lu-AE58054 and MK-8931 in combination?

Scope:

Attributes included in conjoint analysis based assessment of target product profiles for mild to moderate AD:

- Effect on cognition.
- Effect on function.
- Effect on behavior.
- Effect on biomarkers.
- Rate of minor side effects.
- Delivery burden.
- Price.

Attributes included in assessment of U.S. payers’ receptivity to new therapies for mild to moderate AD:

- Effect on cognitive decline—symptomatic therapies.
- Effect on cognitive decline—disease-modifying therapies.
- Effect on functional decline—symptomatic therapies.
- Effect on functional decline—disease-modifying therapies.

Physicians surveyed: 60 U.S. and 32 European neurologists.
Payers surveyed: 20 U.S. MCO PDs.

Comprehensive List of Therapies Included in Our Research and Modeling:

Current Therapies

- Donepezil (Eisai/Pfizer’s Aricept, other brands, generics)
- Galantamine extended-release (ER; Shire Pharmaceuticals/Janssen/Takeda’s Reminyl/Reminyl LP/Razadyne/Razadyne ER, generics)
- Rivastigmine patch (Novartis’s Exelon Patch, generics; Ono Pharmaceutical/Novartis Pharma KK’s Rivastach Patch)
- Memantine (Merz Pharmaceuticals/Grünenthal’s Axura, Lundbeck’s Ebixa, generics; Forest Laboratories’ Namenda/Namenda XR, Daiichi Sankyo’s Memary)

**Emerging Therapies**

- Solanezumab (Eli Lilly)
- Gantenerumab (Roche/Chugai/MorphoSys)
- MK-8931 (Merck)
- Encenicline (EVP-6124; Forum Pharmaceuticals [formerly EnVivo Pharmaceuticals]/Mitsubishi Tanabe Pharma)
- Lu-AE58054 (Lundbeck/Otsuka)

**Report Details**

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