Specialty biotech in late stage development of an Alzheimer’s disease (AD) drug with a differentiated MoA

- First drug to address the inability of the Alzheimer’s brain to metabolize its main fuel, glucose.
- A risk-mitigated strategy with blockbuster potential to address one of the largest unmet needs.
- Excellent Phase 2 data showing an unprecedented change in cognition (3.4-4.8 in ADAS-cog).
- Phase 3 trial in final stage and due to readout in early 2017.
- Potential to be 1st positive Phase 3 data for a new drug substance in 13 yrs.
- Oral, adjunctive drug with good tolerability that fits within existing and future treatment paradigms.
- World-class team backed by committed investors (Nestlé Health Sciences, Inventages, POSCO).

World-class management team and committed investor base

Accera is focused on pioneering novel therapeutic approaches to treat neuro-degenerative diseases caused by metabolic deficiencies. The lead product, AC-1204, is a first-in-class drug to address the well-characterized regional decreases in cerebral glucose metabolism that are observed in Alzheimer’s patients. AC-1204 represents a new adjunctive therapy with a mechanism of action distinct, but complementary, to approved drugs and those currently in late-stage development.

Accera has assembled a world-class management team with specific experience in CNS drug development. Supported by one of the world’s largest companies, Nestlé, Accera has advanced AC-1204 to Phase 3 and is well positioned to take it to global approval.

Targets the metabolic deficit that starts >30 years before clinical symptoms

The brain is one of the most metabolically active organs in the body using 20% of the body’s energy and 120g of glucose/day. Studies performed in the early 1980s established that the AD does not uptake glucose as effectively as aged matched controls. Subsequent studies have demonstrated reduced glucose metabolism occurs early in the disease, worsens as the disease progresses and correlates with cognitive decline.

To tackle this metabolic defect, AC-1204, provides the brain with the body’s natural back-up fuel, ketone bodies. These ketone bodies have the potential to restore metabolism, prevent the death of neurons (brain cells) and the symptoms and progression of Alzheimer’s disease.
An unprecedented improvement in cognition has been consistently shown across pre-clinical and clinical studies, with potential to modify the disease

AC-1204 was evaluated in a randomized, double-blind, placebo-controlled, 90-day Phase 2b multicenter trial in mild to moderate AD patients. Improvement in ADAS-Cog scores of 4.77 (day 45, p value = 0.0005) to 3.36 (day 90, p value = 0.015) were observed in patients who do not carry the APOE4 gene compared to placebo. An improvement in ADAS-Cog scores of >2 is deemed to be clinically meaningful. Persistence of improved cognitive effect after washout of AC-1204 is suggestive of potential disease modification with longer therapy.

Increased levels of ketone bodies were observed and correlated with improvement in cognition. Adverse events were primarily restricted to mild and transient GI symptoms. AC-1204 is currently being evaluated in a US Phase 3 trial (NOURISH AD) with data read out expected in early 2017. Preparation is underway to initiate a second Phase 3 trial in H2 2016 to support global approval. After completion of this final study, approval is due in mid-2020.

Currently have a Phase 3 Study, NOURISH AD, ongoing throughout the US

The NOURISH AD study is a multi-center, double-blind placebo-controlled study in subjects with mild-to-moderate Alzheimer’s disease. The sample size is n = 413 (285 APOE4 non-carriers, 128 APOE4 carriers). The double blind treatment period is 6 months. The primary endpoints ADAS-Cog and ADCS-CGIC among APOE4 non-carriers in modified Intent to Treat (mITT) population

[1] Phase 2b study was conducted with AC-1202, an earlier formulation of AC-1204

All statements other than statements of historical fact included in this overview and that address activities, events or developments that we expect or anticipate may or will occur in the future are forward-looking statements. While any forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results may vary, sometimes materially, from any estimates, predictions, projections, assumptions or other suggestions of future performance herein. Undue reliance should not be placed on these forward-looking statements, which are based upon our assumptions and are subject to known and unknown risks and uncertainties and other factors, including, but not limited to, changing market conditions, the successful and timely completion of clinical studies, the establishment of corporate alliances, the impact of competitive products and pricing, new product development, uncertainties related to the regulatory approval process and other risks detailed from time to time in our ongoing quarterly and annual reporting. We undertake no obligation to publicly update or revise forward-looking statements; whether as a result of new information, future events or otherwise and such statements are expressly qualified by this cautionary statement.

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