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2024 Neuroscience Recap:

Key Breakthroughs and Developments

In recent years, significant advances in neuroscience have fueled growth in the pipeline and increased pharmaceutical investment. While these advancements reduce scientific and regulatory risks, commercial challenges remain, making strategic decisions crucial for demonstrating value to stakeholders. In this 2024 recap, Lumanity's Neuroscience strategy consulting team members highlight some of the most impactful breakthroughs and innovations, from new Alzheimer's and schizophrenia treatments to non-opiate pain therapies and diagnostic advancements, reflecting the evolving landscape of neurological care. Here are their insights:

Jumaah Goldberg, DPT, MBA

An emerging targeted solution for treating developmental and epileptic encephalopathies

Current antiepileptic drugs face significant challenges in treating developmental and epileptic encephalopathies (DEEs), as they often provide limited seizure control and do not address the underlying developmental and cognitive impairments. Additionally, many antiepileptic drugs are associated with side effects that can further impair quality of life for patients and caregivers. Bexicaserin, a selective 5-HT2C receptor agonist recently acquired by Lundbeck through their acquisition of Longboard Pharmaceuticals, offers a promising alternative by targeting serotonin pathways involved in seizure modulation and neurodevelopment. Although Phase 3 clinical trials are currently underway, prior studies suggest bexicaserin may reduce seizure frequency and severity while potentially improving developmental outcomes. By addressing these unmet needs, bexicaserin potentially represents a significant step forward in targeted DEE therapies.

Bobby Moy

New non-Opiate approaches to moderate to severe acute pain, with the promise of safe, long-term use

The ability to control pain is central to improving patient quality of life across a range of disorders and procedures. While opiates are effective and inexpensive, they carry significant social costs associated with risk of dependency. With a pair of successful Phase 3 trials with its NaV1.8 sodium channel blocker, Vertex's VX-548 appears to have demonstrated efficacy with manageable side effects and limited risk of dependency in acute settings opening up a potential new avenue for pain control and the potential to displace some opiate use, with the promise (trials ongoing) of longer-term use. We'll be watching closely to see how this new agent is used as patients, healthcare providers, payers, and policy experts work to balance efficacy, dependency risk to patients, costs to society and cost to the healthcare system.

Ginger Johnson, PhD

Disease-modifying therapies for Alzheimer's disease mark the beginning of a new era in care

The recent FDA and EMA approvals of Leqembi (lecanemab, Biogen/Eisai) and Kisunla (donanemab, Lilly) signify a revolutionary shift in Alzheimer's treatment from symptom management to disease modification. Despite modest clinical impact and notable safety concerns (e.g., ARIA), these therapies herald a new era in Alzheimer's care, with potential for next-generation treatments like tau-targeting therapies. These advancements also underscore the need for equitable access, cost-effectiveness, and early, accurate diagnosis. Effective integration into clinical practice will require significant infrastructure, clinician training, policy support, and a robust and quantifiable value proposition to maximize their impact.

The FDA approved the first schizophrenia drug with a new mechanism of action since the 1950s!

BMS/Karuna's Cobenfy (xanomeline, trospium chloride) leads a competitive wave of muscarinic activators modulating dopamine activity in specific neural circuits. This novel approach reduces psychotic and negative symptoms while avoiding side effects like weight gain and metabolic dysfunction. Agents in this class differentiate on subtype selectivity and activation mechanisms. Orthosteric agonists like BMS/Karuna's Cobenfy and Neurocrine's NBI-1117568 have demonstrated consistent clinical efficacy, but recent results from AbbVie/Cerevel's emraclidine were disappointing, with no significant separation from placebo in two Phase 2 trials. As more muscarinic agonists enter the market, differentiation in clinical and real-world outcomes will be essential to deliver value beyond the first mover.

Carolina Lahmann, PhD

Alzheimer's disease blood-based biomarker tests paving the way for a diagnostic revolution for neurodegenerative disorders

The FDA's recent granting of Breakthrough Device Designations to blood-based biomarker tests for Alzheimer's disease, such as the p-Tau 217 test, marks a significant advancement in the field of neuroscience. Traditional diagnostic methods like positron emission tomography (PET) scans and lumbar punctures for cerebrospinal fluid (CSF) testing are invasive, expensive, and often inaccessible, making blood-based tests a much needed alternative. Fujirebio has filed its Lumipulse® G pTau 217/β-Amyloid 1-42 Plasma Ratio in-vitro diagnostic test with the FDA, which is expected to be the first commercially available blood-based test in the U.S. for confirmatory diagnosis of Alzheimer's disease. This breakthrough not only enhances patient care for Alzheimer's but also sets a precedent for the broader field of neuroscience. The availability of accurate, affordable, and accessible blood-based diagnostic tests will present a paradigm shift for the early diagnosis (ideally preclinical) and development of more effective interventions for neurodegenerative conditions, ultimately transforming patient outcomes on a global scale.

Contact Us

Contact us to learn more about how Lumanity can support your unique challenge today.

Lumanity offers extensive experience-based strategic guidance and insights in the field of neuroscience. Our goal is to provide our clients with actionable solutions that de-risk and optimize the development and commercialization of therapies, ultimately improving the lives of patients who are impacted across a range of conditions.

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