Drug news 15 to 21 April 2024

Many readouts of phase 2 and phase 3 studies, pipelines are moving ahead.

HE Advisory team
info@HE-Advisory.com
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European Medicines Agency (EMA)

The EMA's Committee for Medicinal Products for Human Use (CHMP) is scheduled to hold its monthly meeting from April 22 to 25.

US Food and Drug Administration (FDA)

The FDA made the following decisions:

1. Alecensa (alectinib, Genentech) approved as an adjuvant treatment for patients with early-stage, ALK-positive non-small cell lung cancer (NSCLC) after tumor resection. Genentech press release.
2. Entyvio (vedolizumab, Takeda) has received an extended indication for its subcutaneous formulation. This approval allows it to be used as a maintenance therapy for patients with moderately to severely active Crohn's disease following prior intravenous treatment with Entyvio. Takeda press release.
3. Selarsdi (ustekinumab-aekn, Alvotech & Teva), a biosimilar of J&J's Stelara, is approved and scheduled for launch in February 2025. Alvotech press release.

New data from clinical trials (Phase 2, Phase 3)

Here are the recent updates on Phase 2 and Phase 3 clinical trials with published data between April 15 and April 21, 2024:

1. Cerevel Therapeutics announced positive results for tavapadon in a Phase 3 trial in patients with Parkinson's Disease. Cerevel press release.
2. Sage Therapeutics reported that Dalzanemdor (SAGE-718) failed to meet its primary endpoint in a Phase 2 study in patients with Parkinson's Disease, marking the end of its development for this indication. Sage press release.
3. Ultragenyx shared positive interim Phase 1/2 data for GTX-102 in patients with Angelman Syndrome, noting that despite serious adverse events, all affected

participants continued their treatment. Ultragenyx press release.

4. Barinthus Biotherapeutics (formerly Vaccitech) released positive data from its Phase 1b/2 trial of VTP-200 for human papillomavirus (HPV) treatment. Barinthus press release.
5. ntra-Cellular Therapies shared positive Phase 3 results from the study evaluating Lumateperone as adjunctive therapy in patients with Major Depressive Disorder, meeting its primary and key secondary endpoints. Intra-Cellular press release.
6. Pulmocide announced positive Phase 2 results for inhaled opelconazole as a preventive treatment against pulmonary aspergillosis in patients with lung transplant. Pulmocide press release.
7. MaaT Pharma presented positive data from its Phase 3 trial of MaaT013 in treating acute graft versus host disease (aGvHD). MaaT press release.
8. Columvi (glofitamab, Genentech) met its primary endpoint in a Phase 3 study in relapsed or refractory diffuse large B-cell lymphoma (DLBCL), demonstrating improved overall survival when combined with gemcitabine and oxaliplatin (GemOx). Genentech press release.
9. Eli Lilly announced positive results from the Phase 3 trials of its GLP-1 agonist, Zepbound (tirzepatide), which has the potential to reduce the severity of sleep apnea in adults with obstructive sleep apnea (OSA) and obesity. Eli Lilly press release.
10. Novartis published interim analysis results from the Phase 3 trial of Fabhalta (iptacopan) in patients with Immunoglobulin A nephropathy (IgAN). Novartis press release.
11. GSK announced positive data from the Phase 3 trial of gepotidacin for the treatment of uncomplicated urogenital gonorrhoea in adolescent and adult patients. GSK press release.
12. Roche reported positive results from the Phase 3 study of a subcutaneous (SC) injection of Ocrevus (ocrelizumab) in individuals with relapsing or primary progressive multiple sclerosis (RMS or PPMS). Roche press release.

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