

# FINALISTS 2022

## Clinical Advance of the Year

This Scrip Award seeks to recognize success in a clinical trial of a new drug product expected to lead to an advance in healthcare.

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### **Boehringer Ingelheim and Eli Lilly's** Phase III EMPEROR-Preserved trial of Jardiance in heart failure

Based on EMPEROR-Preserved, Jardiance (empagliflozin) became the first and only FDA-approved heart failure therapy to demonstrate a significant risk reduction in cardiovascular death and hospitalization for heart failure, regardless of ejection fraction. It provided a new option for millions of adult heart failure patients with preserved ejection fraction, a patient population that accounts for about half of all heart failure cases and has been described as "the single largest unmet need in cardiovascular medicine."

### **Daiichi Sankyo and AstraZeneca's** Phase III DESTINY-Breast04 trial of Enhertu in breast cancer

Enhertu (trastuzumab deruxtecan) became the first HER2 directed therapy to show a survival benefit in patients with HER2 low metastatic breast cancer in the DESTINY-Breast04 trial. The results showed that the antibody-drug conjugate could provide benefit to patients across the HER2 spectrum, requiring reconsideration of the breast cancer classification system that has been guiding breast cancer diagnosis and treatment for more than two decades. The US FDA followed with a swift approval for the new indication in August.

### **Intellia Therapeutics'** Phase I trial of NTLA-2001 for transthyretin amyloidosis

In June 2021, Intellia Therapeutics opened a new era in medicine by showing it is possible to treat, and potentially cure, a disease through genome editing. The company's interim Phase I data, published in the New England Journal of Medicine, demonstrated substantial reduction of a disease-causing protein in transthyretin amyloidosis patients with a one-time, systemically delivered CRISPR-based therapy – the first time this revolutionary technology's potential had been harnessed as a systemically administered medicine since CRISPR's discovery.

### **Janssen Oncology's** Phase I/II MajesTEC-1 study of teclistamab in multiple myeloma

Janssen Oncology's Tecvayli (teclistamab) is a recently approved, off-the-shelf, T-cell redirecting bispecific antibody targeting B-cell maturation antigen, which showed promising results in heavily pretreated, relapsed/refractory patients in the MajesTEC-1 study with a high rate of deep and durable responses. Despite multiple therapeutic options, multiple myeloma most often recurs and remains incurable and there remains a significant and critical unmet need for new therapeutic options. Teclistamab is also being studied in earlier lines of therapy.

### **Lumosa Therapeutics'**

Phase IIa study of LT3001 for stroke  
In this Phase IIa study, LT3001, a first-in-class new chemical entity under development by Lumosa Therapeutics for ischemic stroke met its primary safety endpoint with no symptomatic intracranial hemorrhage observed and also demonstrated NIH Stroke Scale and Modified Rankin Score improvements. This landmark study paves the way for future studies where LT3001 can be delivered intravenously at an extended treatment window, either alone or in combination with mechanical stroke treatment.

# SCRIP AWARDS 2022

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### **Servier's** Phase III AGILE trial of Tibsovo in IDH1-mutated AML

The US FDA approved of the isocitrate dehydrogenase-1 inhibitor (IDH1) Tibsovo (ivosidenib) as the first therapy targeting cancer metabolism in combination with azacitidine for patients with newly diagnosed IDH1-mutated acute myeloid leukemia (AML) based on the Phase III AGILE study. This study marked the third global pivotal trial for Tibsovo to demonstrate a significant clinical benefit for AML patients with IDH1 mutations, and it is now approved across multiple IDH1-mutated cancer types.

Winners are announced at the Awards ceremony and dinner on Wednesday 30th November at the Royal Lancaster Hotel, London.