

Patients will benefit if Europe modernizes its policy framework to reflect the distinct promise of cell and gene therapy, the Alliance for Regenerative Medicine will highlight in 29 November EU Parliament event

Brussels – November 24, 2022

The event will feature first pediatric patient to receive a CAR-T therapy and focus on policy recommendations to reverse Europe's declining competitiveness.

The European Union can reverse its declining competitiveness and ensure patient access to transformative treatments if it modernizes its policy and regulatory framework to reflect the distinct promise of cell and gene therapies as the future of medicine, the Alliance for Regenerative Medicine (ARM) will say during an event at the EU Parliament on 29 November.

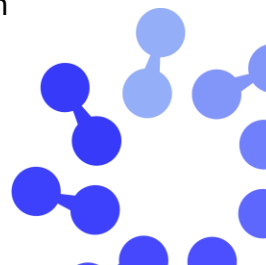
ARM and Member of the European Parliament Dr. Stelios Kypouropoulos of the European People's Party will highlight concerning trends for advanced therapy medicinal product (ATMP) developers, clinical trials, and investment in the EU. *"Cell and gene therapies represent tremendous hope for patients with serious diseases in the EU – but if we don't act to ensure patients have access, hope is all we will have,"* **said MEP Kypouropoulos**, who lives with spinal muscular atrophy, a rare genetic neuromuscular disease. MEP Kypouropoulos recently signed a letter with 25 MEPs asking the European Commission not to undermine the European pharmaceutical and biotechnology sectors with its upcoming proposal to revise the EU pharmaceuticals legislation.

The 29 November event – The Future of ATMPs in Europe – will focus on the first-in-a-generation revision of the EU pharmaceuticals legislation, the future implementation of the EU Regulation on Health Technology Assessment, and other key policy initiatives that will determine the role of cell and gene therapies in Europe's healthcare landscape for years to come.

"If Europe modernizes its policy and regulatory framework to truly embrace ATMPs as the future of medicine, European patients living with cancer, rare diseases, and other serious and often life-threatening disorders will benefit tremendously," **said Timothy D. Hunt, chief executive officer of ARM.** *"The same policies and approaches that brought us yesterday's biomedical innovation simply will not work for the cell and gene therapies of today and tomorrow. The EU has led before – and can lead once again – but the time to act is now."*

Seven of the 23 ATMPs that have been approved in the EU have been withdrawn from the market. ARM's data further illustrates the sector's struggles in Europe:

- As of the end of June 2022, the number of ongoing industry clinical trials in Europe increased by just 2% and the number of developers headquartered in Europe declined by 2% compared to five years ago, while the numbers in



North America increased by 41% and 42%, respectively, and the numbers in Asia-Pacific increased by 74% and 271%, respectively.

- Europe accounted for just 11% of new trials starting in the first half of 2022, with only two phase 1 trials.

More information can be found in ARM's H1 2022 Sector Report, "[Regenerative Medicine: The Pipeline Momentum Builds.](#)"

During the event, ARM will release policy recommendations that would modernize the EU's regulatory and access frameworks, and encourage cell and gene therapy companies to develop, test, and commercialize their therapies in the region.

Other speakers include Emily Whitehead, who was the first pediatric patient globally to receive a CAR-T therapy, an engineered cell therapy that attacks cancer cells. Ten years later, she is considered cured of leukemia.

*"Getting to travel and advocate for this treatment in Europe is an honor," said **Whitehead**, now 17. "It is my hope that every child in the world can someday have access to these treatments and get back to their normal lives and be happy and healthy."*

Emily's father, **Tom Whitehead, president and co-founder of the Emily Whitehead Foundation**, will also speak. *"We have heard from many families from Europe since Emily had her success with CAR-T cell therapy, and we are honored to share our story to hopefully get more access to these new amazing cancer treatments so more patients can not only survive their cancer but thrive in life after."*

Media inquiries

For more information or for media requests and registration, please contact Stephen Majors, Senior Director of Public Affairs for ARM, at smajors@alliancerm.org.

About the Alliance for Regenerative Medicine

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization dedicated to realizing the promise of advanced therapy medicinal products (ATMPs). ARM promotes legislative, regulatory, reimbursement and manufacturing initiatives in Europe and internationally to advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-engineered therapies. Early products to market have demonstrated profound, durable and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options.

Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing ATMPs. In its 13-year history, ARM has become the global voice of the sector, representing the interests of 400+ members worldwide and 80+ members across 15 European countries, including small and large companies,

academic research institutions, major medical centers and patient groups. To learn more about ARM or to become a member, visit <http://www.alliancerm.org>.