The EU Biotech Act is a potential turning point for advanced therapies in Europe

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The Alliance for Regenerative Medicine (ARM) welcomes the publication of the European Commission's EU Biotech Act as a potential turning point for Europe's advanced therapies agenda. The proposal recognises that the success of the Advanced Therapy Medicinal Product (ATMP) sector – and ultimately access for patients -- depends on how regulation, investment, and delivery work together, not on isolated regulatory changes.

ARM is pleased that the Commission's proposal adopted several of the policy recommendations that ARM shared with EU leaders in a policy blueprint earlier this year.

Clinical development is a key focus of the proposal and for ATMP developers. The proposal removes an extra 50-day assessment period for ATMP clinical trial applications, a recognition that this burden unnecessarily delays the start of trials for EU patients. The introduction of a more risk proportionate approach for certain investigational ATMPs containing or consisting of GMOs further reflects a shift toward a more modern regulatory framework.

More broadly, the revision of the Clinical Trials Regulation represents a critical – and second -- opportunity to streamline the process for conducting multi-country clinical trials. If the changes do not go far enough to deliver genuine harmonisation and predictability across Member States, the opportunity to increase the number of ATMP clinical trials in Europe risks being lost.

The Act also takes an important step on incentives by introducing a 12-month supplementary protection certificate extension for innovative therapies, including ATMPs. Targeting advanced therapies within the EU incentive framework sends an important signal for long-term investment decisions in a sector characterised by high risk, long development timelines, and significant capital intensity.

Access to capital remains a decisive factor for whether advanced therapies are developed and scaled in Europe. The commitment by the European Commission and the European Investment Bank Group to mobilise up to €10 billion in investment in 2026 and 2027 is particularly welcome.

2-4 Schuman Roundabout
B-1040 Brussels, Belgium

www.alliancerm.org
info@alliancerm.org

@alliancerm
@Alliance for Regenerative Medicine

The creation of ATMP Centres of Excellence is an important strategy to leverage regional hubs for the benefit of the entire EU. However, ARM encourages legislators to embed the centres of excellence within Europe's biotechnology cluster strategy, recognising them as a flagship industrial engine for translating science into commercially viable therapies.

As the Biotech Act advances, ARM stands ready to work with the Commission, Member States, and the European Parliament to ensure that the Biotech Act delivers tangible benefits for patients and strengthens Europe's position in advanced therapies.