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Event Report

The First JCA Reports: What To Look Out For

22 June 2026

On June 22, 2026, the *Alliance for Regenerative Medicine* (ARM), *Cancer Patients Europe* (CPE), *Fondazione Telethon,* and the *European Haematology Association (EHA)* co-hosted a fourth webinar in a continuing series of online discussions on the implementation of the EU Health Technology Assessment (HTA) Regulation and its new Joint Clinical Assessment (JCA) framework for Advanced Therapy Medicinal Products (ATMPs).

The session, titled ***'The First JCA Reports: What To Look Out For',*** gathered over 40 representatives from 35 organisations, including patient organisations, medical societies, and developers, to discuss the insights collected from the first JCA report and the first signals it sends for future ATMP JCAs.

This event builds on three earlier joint discussions in 2024 and 2025, which collectively shaped an informal advocacy platform focused on promoting flexibility in evidence requirements and ensuring meaningful patient and clinical involvement in the JCA process.

The discussion was a key opportunity for participants to:

- **Take stock of JCA implementation progress**, including ATMPs currently under assessment and expected timelines for the next reports.
- **Understand key insights from the first report,** and their implications for future ATMP assessments.
- **Learn about activities undertaken** by this stakeholder community in preparation of, and in response to, the publication of the first JCA report.
- **Explore potential areas for joint action** at EU and national level.

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Welcome & Introductory Remarks

Paolo Morgese, *Vice President of Public Affairs Europe, ARM*

Paolo Morgese opened by reflecting on the policy developments shaping Europe's life sciences agenda. While major initiatives, including the Biotech Act and the Life Sciences Strategy, are reshaping the European landscape for innovation and regulation, he stressed that the priority must now be to ensure these ambitions translate into meaningful implementation.

Following the adoption of the EU HTA Regulation, the establishment of the Joint Clinical Assessment (JCA) framework, and several years of coordinated stakeholder engagement, the publication of the first JCA report on 9 June marked an important milestone. For a community that has invested significant time and effort preparing for this moment, it also provided the first opportunity to reflect upon how the new framework is working in practice.

The JCA is intended to establish a common framework for assessing the relative clinical benefit of new medicines and interpreting clinical evidence. In doing so, it will help shape a shared European approach to clinical assessment across Member States. The implications extend well beyond the assessments themselves. JCA outcomes have the potential to influence developers' decisions about whether and when to launch products in Europe, while also shaping the pricing and reimbursement decisions that ultimately determine patient access.

"The JCA reports will have a broad impact across Europe, both on companies' willingness to launch, and on countries' willingness to reimburse new drugs. Therefore, the implications are very significant for our community in the cell and gene therapy space.

It's time to start proposing solutions and a vision for how things should work, rather than only react to the current context."

JCA Status update: current dossiers in the pipeline

Lydia Shotton, *Associate Director Government Affairs Europe, ARM*

Lydia Shotton provided an update on the pipeline of JCAs, outlining the ATMPs currently progressing, and highlighting some early observations from the first wave of assessments.

As of 22 June 2026, of 18 dossiers currently in process across all therapeutic areas, five are ATMP-specific:

- **Tacquell,** a hospital-developed tumour-infiltrating lymphocyte (TIL) therapy for melanoma, trialled via an open-label randomised trial.[1]
- Novartis's **Itvisma** for spinal muscular atrophy (SMA), which builds on the learnings from Zolgensma but covers a new population (patients aged two and older) and a new route of administration. It was approved by the FDA on the basis of a randomised, sham-controlled pivotal trial supported by a single-arm trial of around 27 patients previously on a different SMA therapy.
- **Papzimenos** by Precigen, an immunotherapy for adults with recurrent respiratory papillomatosis, approved by the FDA based on a single-arm, open-label trial. This is expected to be an important test case for how single-arm evidence is assessed.
- **Zamto-cel** by Miltenyi Biomedicine, a CAR-T cell therapy for large B-cell lymphoma, not yet approved by the FDA or another agency, and currently being trialled via RCTs run across 12 EU Member States.
- **Otarmeni** by Regeneron, a gene therapy reversing deafness caused by a specific mutation in the OTOF gene, approved by the FDA on the basis of a single-arm trial with a surrogate endpoint (another likely test case for single-arm evidence) and currently under accelerated assessment review by the EMA.

Looking across all 18 dossiers, **Lydia** stressed that while it remains too early to identify clear trends, nevertheless, several early observations are beginning to emerge:

- Germany is one of the most active assessing countries, involved in 8 of the 18 dossiers and lead assessor in 75% of those.
- Ireland's NCPE is an assessor on three of the ATMP dossiers.
- Austria, Sweden and the Netherlands also feature frequently as lead assessors.
- Poland, Hungary, Slovenia, Spain, Slovakia and Norway have so far only acted as co-assessors, and Italy has not yet participated.
- 15 of the 18 dossiers concern oncology indications, and none so far relate to label extensions, all covering new marketing authorisations.

[1] This JCA was withdrawn on the 24th of June.

For a full list of ongoing JCA dossiers as of June 24th, please see the Annex.

JCA Assessment Framework: ARM's response to the first report

Lydia Shotton, *Associate Director Government Affairs Europe, ARM*

Lydia Shotton also presented a draft assessment framework developed by ARM to evaluate JCA reports in a structured and consistent way. The objective is to build an evidence base that allows trends to be tracked over time and supports informed discussions with the European Commission, HTA bodies and the wider stakeholder community.

Reports are assessed against five criteria:

1. **Flexibility:** Does the assessment adapt proportionately to the realities of ATMP evidence generation in severe, paediatric, rare and ultra rare conditions?

2. **Uncertainty:** How does the assessment characterise and communicate uncertainty in the evidence?

3. **Feasibility:** Does the assessment expect comparator evidence that is clinically and practically realistic?

4. **Patient & Clinician relevance:** Does the assessment focus on outcomes and evidence that are meaningful to patients and clinicians?

5. **Usefulness to national HTAs:** Is the assessment methodology transparent, operationally interpretable, and likely to support decision making across Member States?

Each assessment will also receive an overall score, providing an 'at a glance indication' of how well the report accommodates the particular characteristics of ATMP.

Moderated discussion & Q&A

Joséphine Mosset, *Senior Policy Officer, Cancer Patients Europe (CPE)*
Robin Doeswijk, *Head of European Affairs, European Hematology Association (EHA)*
Carlotta Emili, *Market Access Specialist, Fondazione Telethon*
Stefano Benvenuti, *Head of Public Affairs and Market Access, Fondazione Telethon*

Tresja Bolt*, Executive Director, Harwood Levitt Consulting****,*** moderated a discussion on the early lessons emerging from the first published JCA report, on tovorafenib for paediatric low-grade glioma. The conversation explored what the report reveals about PICO scoping, methodological choices, assessor flexibility, and the implications for future evidence requirements, particularly for ATMPs.

Tresja Bolt (HLC): From a developer's perspective, having closely tracked the methodological questions, what stood out the most from the first report?

Carlotta Emili (Fondazione Telethon) stated that the first report confirmed long-standing concerns: the standard HTA framework struggles to accommodate rare disease therapies. Small populations, reliance on single-arm trials, difficulty constructing comparators, and inconsistent outcomes all contribute to a fundamental misalignment between what developers can realistically generate, what assessors expect, and what patients need. This ultimately results in unnecessary complexity, duplication, and delays.

"This first report confirms, predictably, what many of us working in rare diseases expected: that the standard assessment framework doesn't easily accommodate rare disease therapies."

She highlighted four points that stood out from the report:

1. **Mismatch between the assessment scope and the evidence available**. Eight PICOs were defined across three populations, yet only one PICO was selected by the assessors on the basis of the available comparator evidence. For many rare diseases, treatment is highly individualised, making stable comparators difficult or impossible to identify. As Carlotta noted, each PICO caries a real cost in time, money and analytical effort, much of which, in hindsight, went towards questions that were not answerable.
2. **Assessment of non-randomised evidence.** An unanchored comparison was used for the single non-comparative trial, and once the necessary adjustments were applied, the sample size shrank substantially, leaving barely any overlap between the populations being compared. As a result, the remaining evidence was considered highly uncertain. However, this is the reality of rare disease research, where small patient populations and non-randomised studies are often the only feasible source of evidence.

3. **How uncertainty was framed.** The report repeatedly notes that efficacy and safety estimates should not be interpreted as demonstrating a causal treatment effect. This is notable given that the same molecule, based on the same evidence base, was deemed to have a positive benefit–risk profile by the EMA and granted conditional marketing authorisation.
4. **The assessment appeared less flexible than many stakeholders had anticipated,** particularly given the discrepancy between the first applicants to the JCA process, who developed their trial protocol far in advance of the publication of the JCA methodological guidelines.

Gilles Vassal (SIOPE) built on this, questioning whether defining eight separate PICOs was truly useful for what is essentially one disease which has been recently molecularly defined by 2 biomarkers/targets. The fact that no useable data was identified for seven of the eight PICOs raises the question of the usefulness of seven PICOs and how this will impact decisions at the member state level. This raises the importance of:

i. more largely generating real word data from standard treatment practice for rare diseases, and
ii. early joint EMA and HTA advice/consultation during the implementation of a pediatric investigation plan on what data are needed for evaluation by both EMA and HTA regarding a new asset for a pediatric indication.

"We need experts who know the disease, but we also need a better way of providing information on how the disease is actually managed and treated across Europe."

He further illustrated this concern by relaying feedback from the clinical expert involved in the assessment. While the expert found the process constructive and the HTA Secretariat very supportive, she was uncomfortable being asked the same questions beyond her own clinical practice/country across EU member states. This is a genuinely difficult ask, as even the most experienced individual expert cannot reasonably speak to practice variation across every Member State. Establishing expert approved standard treatment guidelines would help evaluation by HTA in the rare disease field.

Tresja Bolt (HLC): From a patient organisation's perspective, what were you looking for when you went through the report, and is there limited recognition of the paediatric and rare disease context?

Joséphine Mosset (CPE) emphasised both progress and gaps in the report. While it was encouraging that a carer contributed to and commented on draft reports, only one individual was involved, raising concerns about representativeness.

Additionally, there remains very limited visibility into how that input shaped the choice of outcomes, the interpretation of the evidence, or the final conclusions reached. Greater transparency on this point would go a long way towards helping patients understand the real value of their contribution and sustaining their willingness to engage over the long term. Indeed, there is real enthusiasm and willingness among patients to get involved in shaping

the regulation: therefore, the JCA needs to show proper appreciation and recognition of this work.

"People need to feel they're genuinely being taken seriously, not just ticking a box, otherwise, engagement will decline over time. We need to get this right from the get-go.

It's not just about having a seat at the table; it's about being treated as a genuine equal partner."

Joséphine also flagged that patient input has not yet been harmonised across JCAs, and the gap in experience can be stark: one carer read and annotated the full 185 pages of a report and contributed extensively, while another patient received limited guidance and support, and therefore could only submit half a page of comments. The encouraging news is that a harmonised template for patient input is now under development, driven by work in consultation with patient groups in the stakeholder network. Additionally, patients have recently been starting to get dedicated support in their participation in JCAs through a dedicated staff member at the Brussels Centre of Collaboration in Health (BCCH).

Mimi Choon-Quinones (Partners for Patients NGO) added that the definition of "carers" should explicitly include nurse practitioners and nurses who form the wider care team.

***Tresja Bolt (HLC):* Does the first report give any insight into whether clinical expertise was meaningfully built and incorporated into the process?**

Robin Doeswijk (EHA) echoed many of the concerns raised about expert involvement. While the report acknowledges input from one clinician and one carer, Robin argued that it provides little insight into how those contributions influenced the final assessment.

"It's critical that when only one clinician is involved, that person's views are representative of the wider expert community, and we're still trying to establish whether that was the case for this report."

As an example, **Robin** described a separate, non-ATMP assessment in which EHA had nominated several experts, all of whom cleared the declaration of interest process. Despite ranking one expert as its preferred nominee, a different expert was selected without explanation. He argued that greater transparency around these decisions would help build confidence in the process.

EHA has also developed consensus-based PICO recommendations at European level, later adapted by national haematology societies to reflect local standards of care. In **Robin's** view,

European medical societies could play a much greater role in future assessments by helping to build expert consensus on clinically relevant PICOs, strengthening the quality and consistency of assessments across Member States.

Tresja Bolt (HLC): ***For the participants who have been involved in national HTA processes, what are your views on the usefulness of the reports? What is the importance of a fit-for-purpose methodology so that national assessors can use these reports in a meaningful way?***

Speaking from Cyprus, **Androulla Eleftheriou (TIF)**, stressed the importance of the JCA for smaller health systems that often lack extensive HTA capacity of their own. Drawing on past experiences, when the first gene therapy was authorised, she recalled the challenges faced when innovative treatments became available before national systems were fully prepared to assess and implement them. This was a very critical situation for patients who had been waiting years for a curative, scientifically validated treatment. Real-world data, she stressed, remains every bit as important alongside the formal evidence base in accurately assessing the value relative to the cost of genetic and hereditary disorders that require lifelong care.

Looking ahead, **Dr. Eleftheriou** expressed cautious optimism that the HTA Regulation could provide a stronger common assessment framework. At the same time, she stressed that its success will depend on meaningful engagement by Member States and appropriate consideration of real-world evidence is considered alongside clinical trial data.

"We don't want a repeat of what happened with the first gene therapy, where Europe, and countries like Cyprus, simply weren't ready."

Tobias Hagedorn (E.S.PKU) speaking for the European and German PKU communities, emphasised that rare disease patients want a system that supports both sustainable innovation and equitable access. While recognising the importance of affordability and commercial viability, he cautioned against JCAs becoming a vehicle for cost containment at the expense of patient access. He framed the discussion around a series of broader questions:

- To what degree does the JCA promote or inhibit access to OMPs and ATMPs?
- To what degree are patient, payer and regulatory perspectives reflected and assessed in their full complexity?
- To what degree are unmet needs equally assessed on criteria beyond mortality and morbidity, including quality of life and social and professional participation?
- To what degree will incremental but still beneficial innovation potentially be deprioritised in favour of breakthrough innovation?
- To what extent will the JCA help improve study design where possible, without inhibiting progress where it isn't?

- In a nutshell: **will JCA implementation fuel or slow R&D in metabolic medicine and other rare disease areas?**

"We are not willing to pave the way for cost-cutting that compromises legitimate access to innovation, nor do we want to be used as emotional leverage to justify higher profits."

Paolo Morgese (ARM) agreed, arguing that the community also needs to confront a broader strategic question: could the JCA inadvertently reward medicines that satisfy methodological requirements, while disadvantaging therapies that address significant unmet need but cannot generate the type of evidence the framework expects?

Florian Innig (ACHSE) offered a more cautious interpretation of the first report. He argued that many of the evidence gaps simply reflected the limitations of the available trial data rather than shortcomings in the assessment itself.

Given the rarity of the condition and the complexities of paediatric oncology, he was not particularly surprised by the findings of the report. While acknowledging its limitations, he cautioned against drawing broad conclusions from a single assessment and argued that a clearer picture will emerge only as more JCA reports become available. He also noted that the published report contained fewer redactions than had initially been requested by the developer, which he viewed as a positive sign for transparency.

On the issue of clinicians being asked to comment on comparators used across Europe, **Florian** viewed this as entirely consistent with the purpose of the JCA process, which is to establish what treatments are actually being used in clinical practice across Member States.

Tresja Bolt (HLC): From your reading of the report, how well do you think the JCA is integrating with the wider evidence generation and regulatory process around it?

Kacper Rucinski (EAMDA) shifted the discussion to the relationship between the regulatory and HTA processes. He noted that the evidence underpinning a JCA is typically generated through studies designed with EMA scientific advice, agreed endpoints and outcome measures. Once a medicine received regulatory approval, the JCA may revisit many of the same questions, including the relevance of endpoints, populations, and comparators. In his view, this means the same evidence base being judged against two different sets of expectations.

"If JCA is assessing the same evidence that EMA has already reviewed and approved, why are JCA and EMA arriving at different conclusions?"

While acknowledging the limitations of the data available in this report, **Kacper** argued that greater alignment between JCA and EMA remains a crucial issue for the future.

Susanne Goldbach (SMA Europe) echoed Kacper's concerns, stressing the need to harmonise and optimise the process going forward.

"We need to make better use of real-world evidence and registry data; for example, we have a great deal of registry data for SMA that should be used more systematically."

One particular area in need for harmonisation, she suggested, is information asymmetries: to her knowledge, experts contributing to JCAs do not currently appear to have access to the underlying EMA assessment reports available to assessors. She also emphasised the untapped potential of real-world evidence and patient registries, noting that the SMA community holds a wealth of registry data that should be put to better use in future assessments.

Stefano Benvenuti (Fondazione Telethon) picked up on a point the discussion had not yet fully explored: timing. The methodological guidance underpinning the JCA process was only published a few months before the regulation took effect, leaving developers with little opportunity to adapt ongoing evidence generation plans, meaning they must either delay submission for several years while generating additional data or proceed knowing that the dossier will not fully meet JCA expectations. In **Stefano's** view, this timing constraint was one reason why many stakeholders expected greater flexibility in the first assessments.

"If you're planning to submit your dossier in 2025 and discover midway 2024 that you're missing data the JCA methodology requires, it can take two to three years to generate that evidence."

Work done so far, and what's coming next

Josephine Mosset, *Senior Policy Officer, Cancer Patients Europe (CPE)*
Lydia Shotton, *Associate Director Government Affairs Europe, ARM*
Robin Doeswijk, *Head of European Affairs, European Hematology Association (EHA)*

Josephine Mosset (Cancer Patients Europe) updated participants on the work underway across the patient community, noting that this first JCA report would be a central topic at the upcoming stakeholder meeting the following day.

Patient organisations participating in the Stakeholder Network continue to coordinate, pooling resources and developing common positions. On the day of the webinar, they published a joint statement[2] welcoming the first report as an important first step while identifying areas for

[2] Patient Organisations' Joint Statement on the first Joint Clinical Assessment (JCA) Report

further improvement. The statement welcomed the report as a constructive first step, particularly the inclusion of a carer perspective, while also recognising its limitations.

Looking ahead, the patient community's priority is to strengthen involvement through earlier engagement and broader participation, ensuring that outcomes assessed through the JCA reflect what matters most to patients, including quality of life, symptom burden and day-to-day functioning.

She also emphasised the importance of making JCA reports more accessible to patients across Europe: using plain language instead of dense technical terminology and providing translations into all official EU languages, as English-only reporting remains a significant barrier for many communities, and limits the overall value of the reports.

Lydia Shotton (ARM) then outlined a number of ongoing industry-led initiatives aimed at supporting preparation for the JCAs. Together with EFPIA, EUCOPE and EuropaBio, ARM is developing a shared database to track publicly available information from JCA reports. Expected to launch in autumn, the platform will allow stakeholders to monitor emerging trends in the short term while building a more robust evidence base as additional reports become available.

She also highlighted a complementary analysis comparing how uncertainty is described in pre-JCA national HTA reports for ATMPs versus in JCA reports. The aim is to assess whether European-level assessments apply more conservative or inconsistent language than has historically been the case at national level.

Robin Doeswijk (EHA) described the growing coordination taking place across European medical societies through both the formal stakeholder network and through initiatives such as the BioMed Alliance HTA Working Group and the European Access Academy. A key priority for the medical societies is to make sure that clinicians are well prepared and able to provide coordinated, evidence-based input.

Robin highlighted two areas where medical societies have reached broad consensus:

1. **Joint Scientific Consultations should be an absolute prerequisite ahead of every JCA**, with clinicians involved early enough to help develop realistic PICOs rather than being asked later to explain why certain PICOs are unworkable.
2. **Clinical input should reflect the collective expertise of European and national medical societies rather than relying solely on individual experts**: clinical input should be grounded in the broader consensus-building processes within European and national medical societies, while still preserving some flexibility in how this is reflected in the legislative text.

On a more positive note, **Robin** highlighted progress on the issue of conflicts of interest. This is especially important in rare diseases, where excluding all experts with prior involvement in research or development activities can significantly reduce access to relevant clinical expertise. The more pragmatic approach long advocated by medical societies appears to be

gaining traction, with credit given to the European Commission's HTA Secretariat for its constructive engagement with clinicians and patient groups. He suggested the remaining challenge is ensuring that HTA bodies themselves fully recognise the value of earlier and broader involvement of clinical experts and professional societies throughout the assessment process.

Conclusions & next steps

Josephine Mosset, *Senior Policy Officer, Cancer Patients Europe (CPE)*
Lydia Shotton, *Associate Director Government Affairs Europe, ARM*

Josephine Mosset (Cancer Patients Europe) proposed that the Alliance develop a short, joint stakeholder response to the publication of this first JCA report. While acknowledging that several other letters and statements are already in motion, she argued there is real, distinct value in this broader coalition articulating a shared perspective on the issues facing ATMPs, particularly given that the HTA Regulation explicitly recognises that methodologies may need to be adapted where robust evidence cannot readily be generated.

She stressed that the proposed statement is not intended to draw definitive conclusions from a single assessment. Rather, it would offer a constructive reflection on the implementation challenges emerging from the first real world test of the JCA system, viewed through the lens of ATMPs.

The statement would focus on three key themes:

1. The gap between evidentiary expectations and what can realistically be generated in rare paediatric and advanced therapy settings;
2. How disease realities, patient experience and clinical expertise are reflected (or not) in the interpretation of evidence and uncertainty;
3. Whether implementation is evolving in a way that genuinely reduces duplication, improves consistency, and supports patient access.

The letter would subsequently be shared with the HTA Coordination Group, the European Commission and other relevant stakeholders.

Closing the webinar, **Lydia Shotton (ARM)** thanked the co-hosts and participants for their active engagement throughout the discussion. She reiterated the importance of staying connected as a network and continuing to advocate for a JCA process that works for patients, clinicians, developers, and all involved.

Annex

***Figure 1**: Table of published JCA reports as of 8th July 2026.*

Common name	Indication	Classification	Assessor	Co-assessor	Publication
Tovorafenib	Treatment of paediatric low-grade glioma (LGG)	Chemicals	Ireland	Germany	09/06/2026
Lurbinectedin	Maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	Chemicals	Germany	Portugal	08/07/2026
Tarlatamab	Treatment of extensive-stage small cell lung cancer	Biologicals	Germany	Hungary	08/07/2026

***Figure 2**: Table of current ongoing ATMP JCAs as of 8th July 2026.*

Common name	Indication	Classification	Assessor	Co-assessor	EMA validation
Onasemnogene abeparvovec	Treatment of 5q spinal muscular atrophy (SMA)	ATMP	Ireland	France	22/05/2025
Zopapogene imadenovec	Treatment of respiratory papillomatosis in adults	ATMP	Denmark	Austria	27/11/2025
Zamtocabtagene autoleucel	Treatment of adults with large B-cell lymphoma	ATMP	The Netherlands	Ireland	26/03/2026
Lunsotogene parvec	Treatment of biallelic OTOF variant-associated hearing loss in adults and children	ATMP	Germany	Norway	21/05/2026

***Figure 3**: Table of current ongoing Chemicals and Biologicals JCAs as of 8th July 2026.*

Common name	Indication	Classification	Assessor	Co-assessor	EMA validation
Camizestrant	Treatment of adults with locally advanced or metastatic breast cancer	Chemicals	Austria	Belgium	19/06/2025
Senaparib	Maintenance treatment of advanced epithelial high-grade ovarian, fallopian tube or primary peritoneal cancer	Chemicals	Germany	Slovenia	14/08/2025
Relacorilant	Treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	Chemicals	Portugal	Sweden	30/10/2025
Ensartinib	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).	Chemicals	Austria	Spain	27/11/2025
Sintilimab	Treatment of non-squamous non-small cell lung cancer in adults	Biologicals	Germany	Slovakia	25/12/2025

Sonrotoclax	Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL)	Chemicals	Belgium	Sweden	22/01/2026
Taletrectinib	Treatment of adults with ROS1 positive advanced non-small cell lung cancer	Chemicals	Sweden	Germany	26/03/2026
Cosibelimab	Treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma	Biologicals	Germany	France	21/05/2026

***Figure 4**: Table of discontinued or withdrawn JCAs as of 8th July 2026.*

Common name	Indication	Classification	Reason for discontinuation	Assessor	Co-assessor
Sasanlimab	Treatment of bladder cancer	ATMP	*13/02/2026* Withdrawal of marketing authorisation application by the health technology developer	The Netherlands	Denmark
Catequentinib	Treatment of synovial sarcoma or leiomyosarcoma	Chemicals	*22/06/2026* JCA dossier fails to meet the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282	Sweden	Norway
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded (Tacquell)	Treatment of melanoma	ATMP	*22/06/2026* JCA dossier fails to meet the requirements laid down in Article 9(2), (3) and (4) of Regulation (EU) 2021/2282	France	Poland