

The Committee for Advanced Therapies (CAT)

First Workshop on ATMPs

3 April 2009

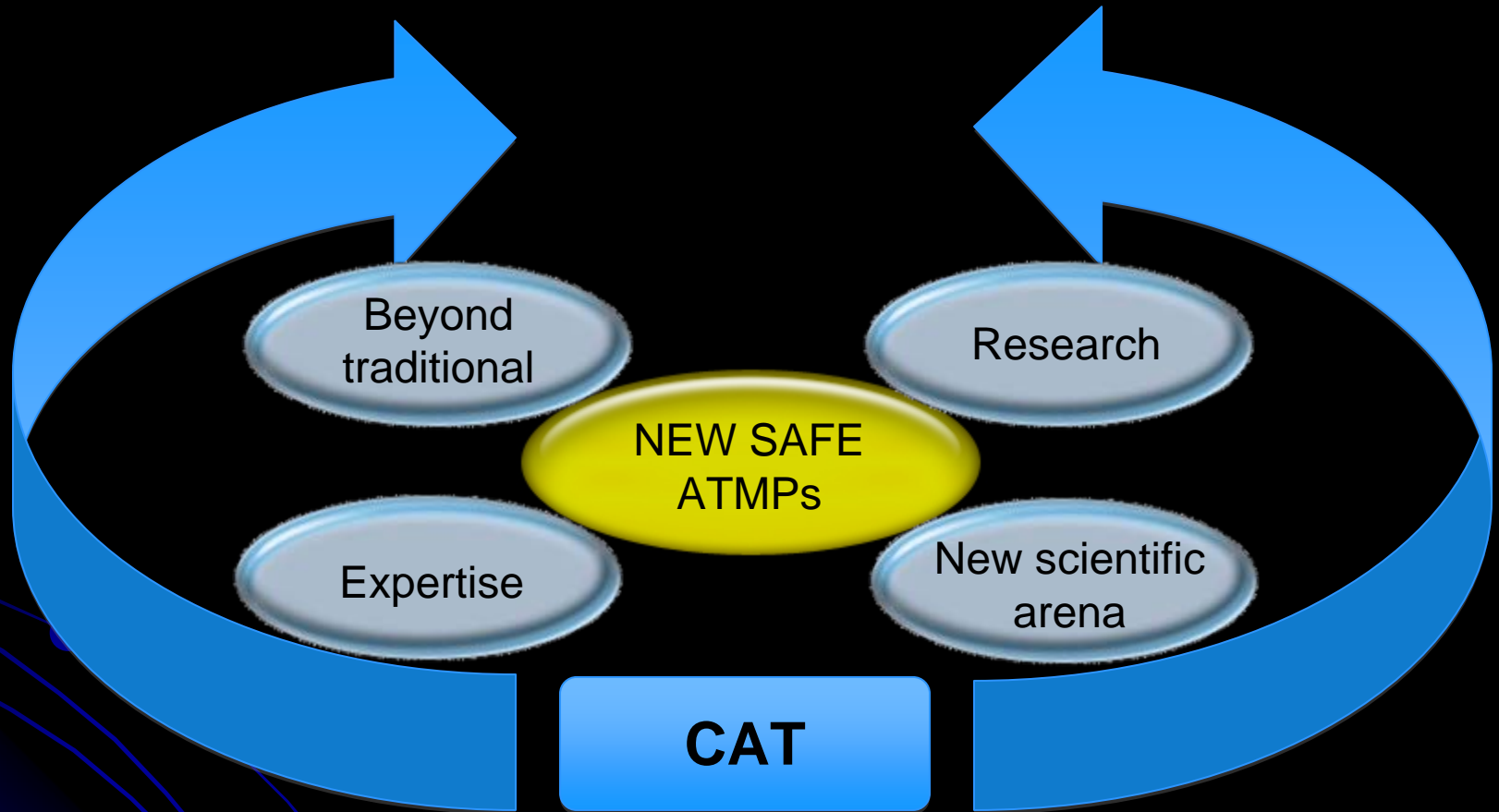


Lucia D'Apote



Committee for Advanced Therapies

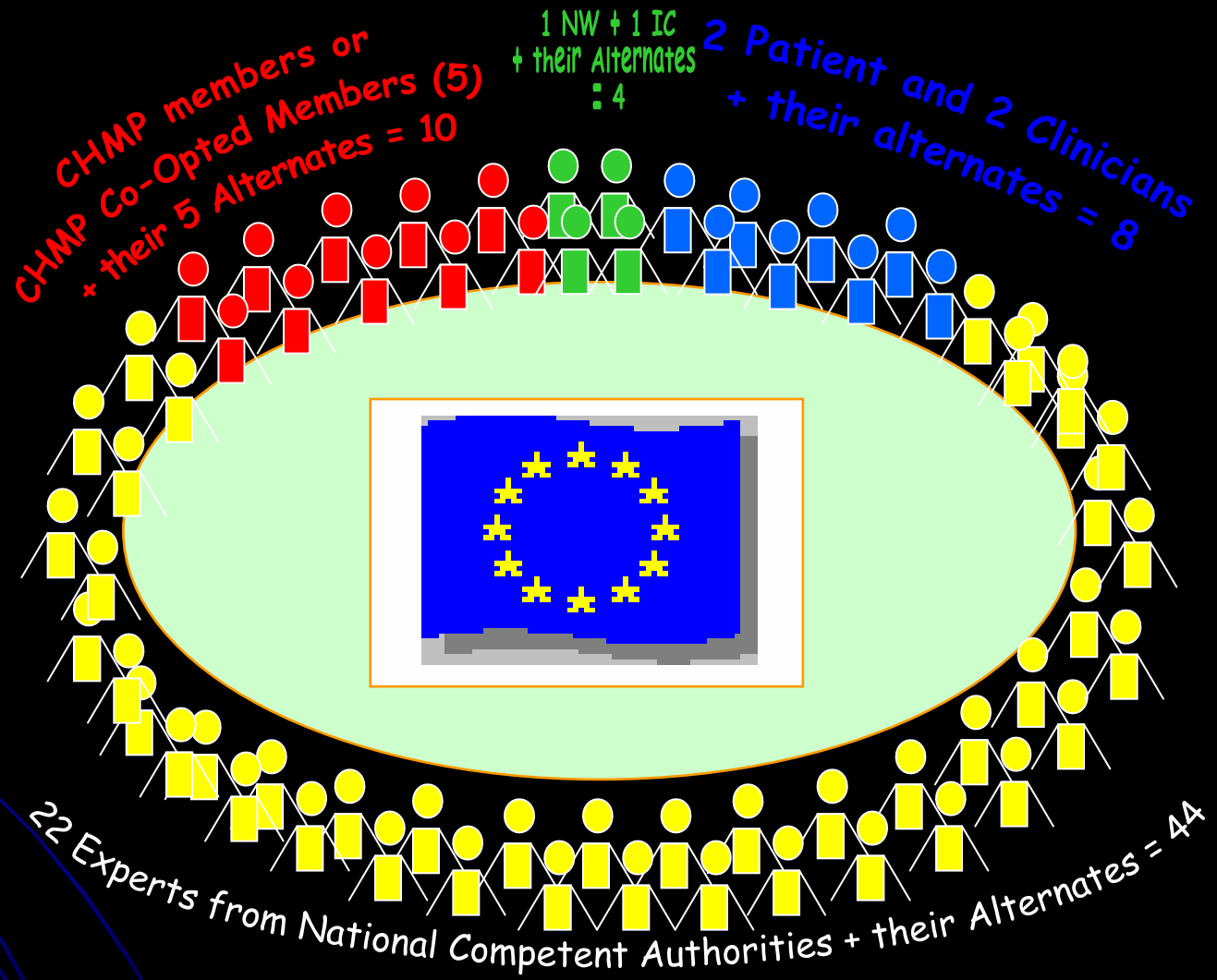




Composition

Expertise

Expertise overview

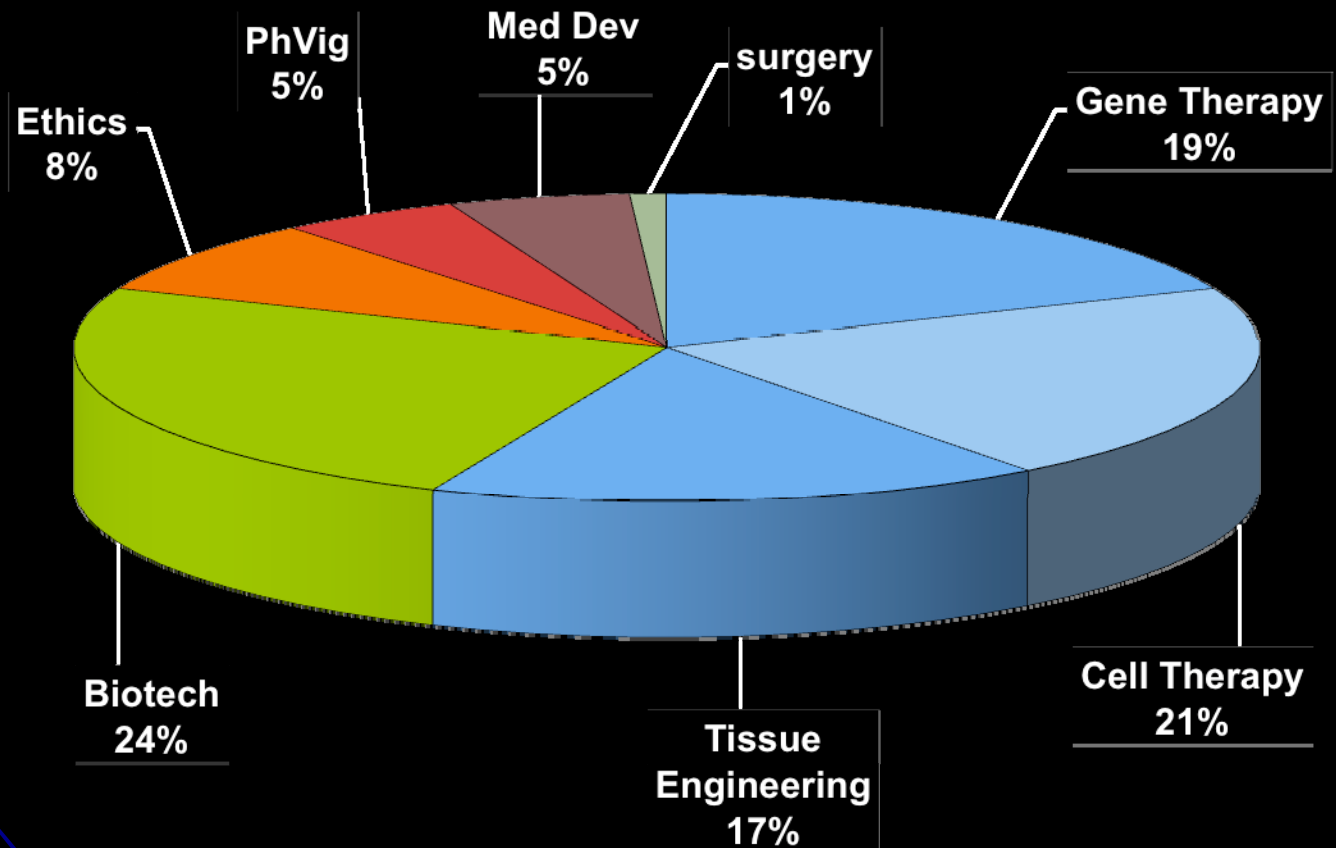


[Composition](#)[Expertise](#)[Expertise overview](#)

CAT covers the scientific areas relevant to advanced therapies, including:

- **medical devices**
- **tissue engineering,**
- **gene therapy,**
- **cell therapy,**
- **biotechnology,**
- **surgery,**
- **pharmacovigilance,**
- **risk management**
- **ethics.**

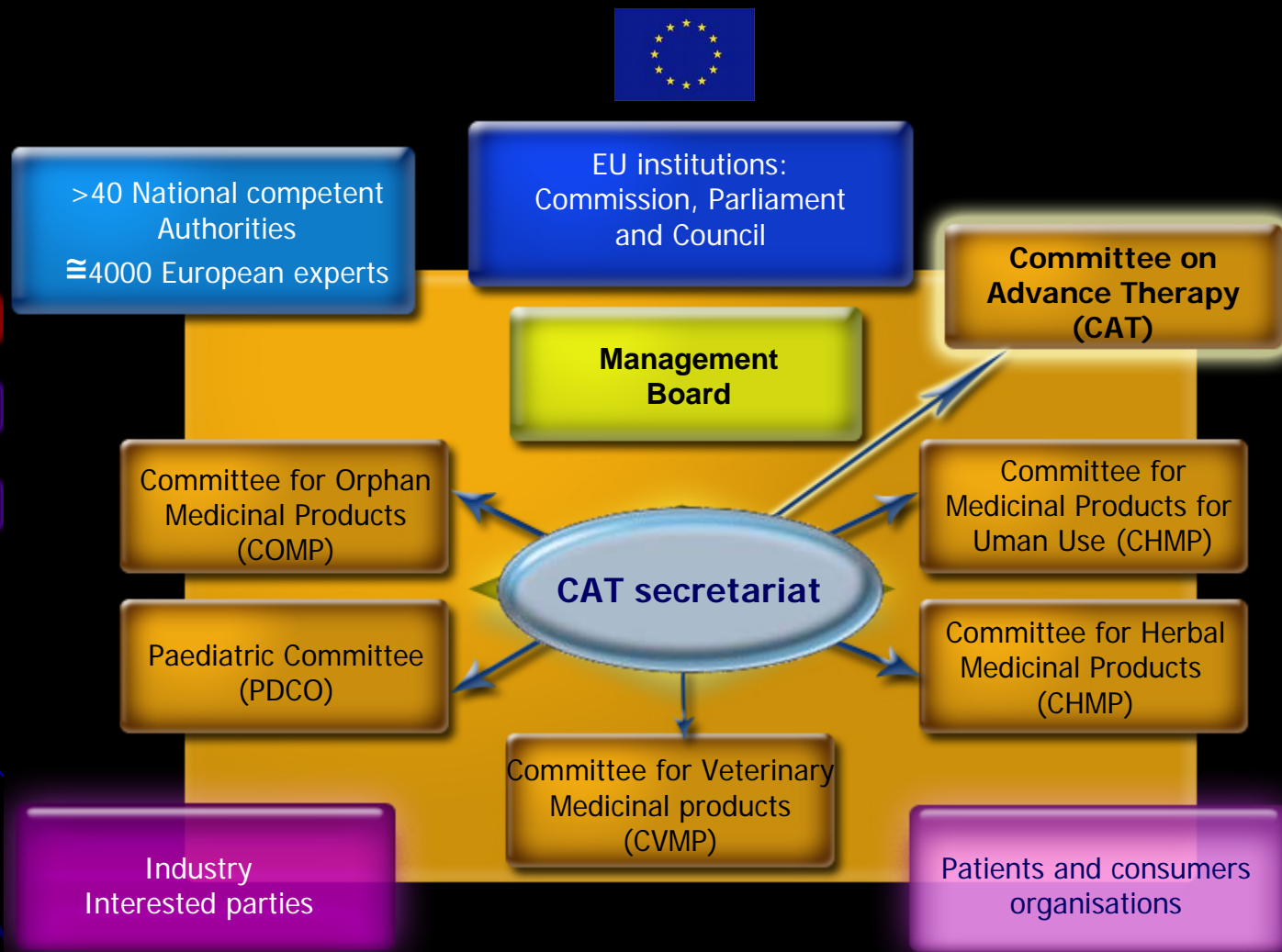
[Recital 9 & Art.21 of Regulation EC 1394/2007]

[Composition](#)
[Expertise](#)
[Expertise overview](#)


CAT within the EMEA

EMEA/CAT secretariat

CAT and EMEA



[CAT within the EMEA](#)[EMEA/CAT secretariat](#)[CAT and EMEA](#)

- Regulatory
- Legal
- Technical
- Scientific
- Administrative

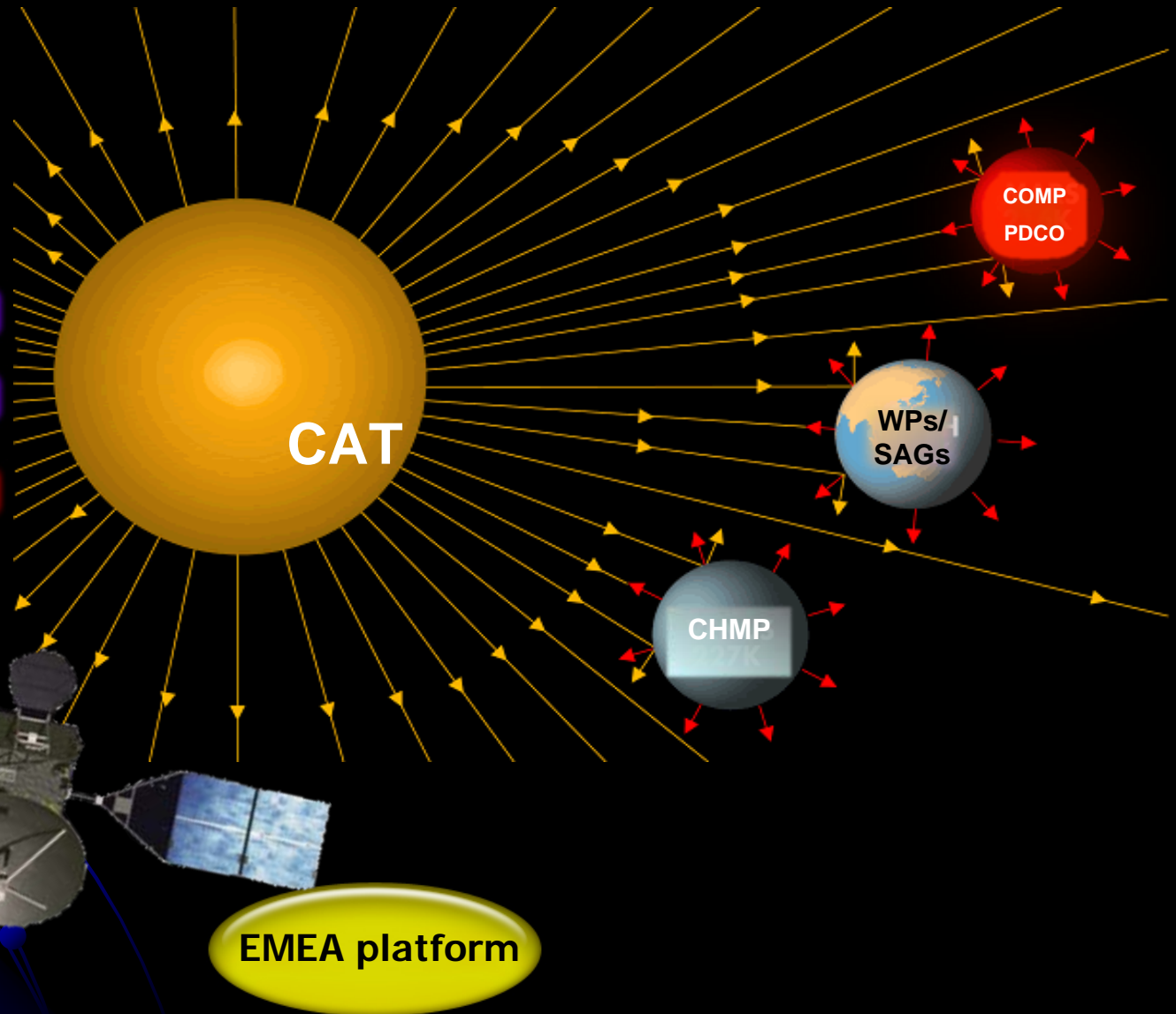
A yellow, three-dimensional oval shape with a gradient and a shadow.

Support

CAT within the EMEA

EMEA/CAT secretariat

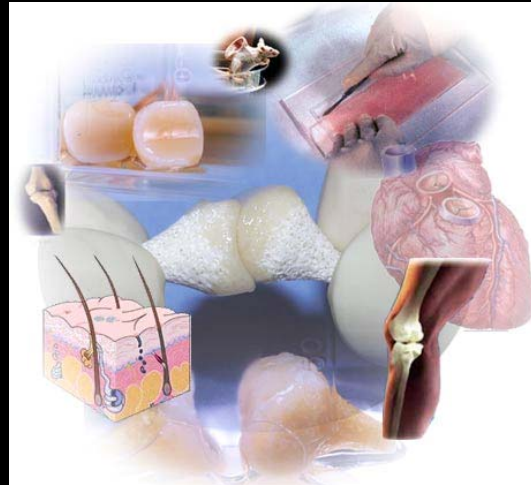
CAT and EMEA



MAIN TASKS

OTHER TASKS

WHERE WE ARE



EVALUATION

CERTIFICATION

CLASSIFICATION

MAIN TASKS

OTHER TASKS

WHERE WE ARE

- Scientific Advice

- Evaluation on non-ATMPs

- Implementation of the ATMP Regulation

- Advice for Community initiative

- Task identified in WPs' workplans

- Setting up of CAT

- CAT Rules of Procedure

- Procedural advice on evaluation of ATMPs

- Procedural advice on re-examination (Revision adopted by CHMP)

- Procedural advice on ATMPs classification

- Templates available

- Contribution to SA/PA

MAIN TASKS

OTHER TASKS

WHERE WE ARE



■ PRODUCTS

■ GENERAL SCIENTIFIC DISCUSSIONS

■ GUIDANCE DOCUMENTS

“The establishment of the CAT, the sixth scientific committee here at the EMEA, is a milestone in the history of pharmaceutical regulation in Europe. Some of the best experts in the field of advanced therapies will be working together so that patients suffering from serious diseases and injuries across the EU can safely benefit from revolutionary new treatments. Their work will help pharmaceutical companies, in particular small and medium-sized ones, to unleash their innovative potential and bring new medicines to the market.”

Thomas Lönngren

**THE CAT IS READY TO EVALUATE ATMPs: ARE YOU
READY TO TAKE THIS OPPORTUNITY?**



Thank you for your attention!



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