

**Priority question for written answer P-004173/2026
to the Commission**

Rule 144

Valentina Palmisano (The Left)

Subject: Urgent access to the drug ‘daraxonrasib’ for patients in the EU suffering from metastatic pancreatic cancer

On 26 August 2026, the US Food and Drug Administration (FDA) approved daraxonrasib for certain patients with metastatic pancreatic cancer. RASolute 302, a phase three trial, showed that patients lived for a median of 13.2 months, compared with 6.7 for those treated with chemotherapy.

The European Medicines Agency (EMA) started a phased review on 7 July without setting an end date. In the meantime, the Italian Association of Medical Oncology (AIOM) has asked the manufacturer, Revolution Medicines, to launch a free compassionate use programme.

Given the prognosis of patients and with due regard for the independence of scientific evaluation, can the Commission answer the following:

1. What is the state of play of Europe’s assessment, and has the full dossier been submitted? What other fast-track measures can be deployed, including an exchange of data with the FDA under Project Orbis?
2. In cooperation with the EMA and the national authorities, will it encourage the Committee for Medicinal Products for Human Use to adopt an opinion pursuant to Article 83 of Regulation (EC) No 726/2004 to pave the way for compassionate use programmes?
3. What specific initiatives could it promote alongside Member States and the company, in order to give eligible patients early access, free from discrimination on economic or geographic grounds?

Submitted: 14.10.2026