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EMA recommends authorisation of Rasonque for metastatic pancreatic cancer

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Phased review fast tracks assessment of medicine addressing unmet medical need

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EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation in the European Union for Rasonque (daraxonrasib), an oral treatment for adults with metastatic pancreatic adenocarcinoma (pancreatic cancer that has spread) who have received at least one previous treatment.

People with metastatic pancreatic adenocarcinoma whose disease has worsened after prior treatment have limited treatment options and a poor prognosis. Given the seriousness of the disease, the limited efficacy and substantial toxicity of standard-of-care chemotherapy, there is a need for better treatment options for these patients.

EMA's recommendation follows a phased review of data on Rasonque, which was identified under EMA's [Cancer Medicines Pathfinder](#) project as a high-priority medicine that could address this unmet medical need.

The phased review allowed CHMP to start the assessment several months before the anticipated submission of the complete application. During the review, which started in early July 2026, the CHMP evaluated the data (quality, non-clinical and clinical) in phases, as they were submitted by the company. This approach shortened the assessment time to less than 150 days, while maintaining the standards for quality, safety and effectiveness. By comparison, a standard evaluation can take up to 210 active days and usually takes around a year overall, including time for the company to respond to questions.

The lessons learnt from the phased review of Rasonque will help inform the implementation and strengthened use of phased reviews under the EU's [new pharmaceutical legislation](#). In this context, the phased review is foreseen as a tool to allow a more agile, streamlined evaluation of medicines, which would ultimately lead to earlier patient access to promising

treatments.

The active substance in Rasonque, daraxonrasib, is a RAS inhibitor. RAS proteins are involved in cell growth and survival. In pancreatic adenocarcinoma, mutations in the RAS gene cause these proteins to be permanently switched on, leading to uncontrolled growth of cancer cells. Daraxonrasib works by binding to a protein called cyclophilin A to form a complex that attaches to RAS proteins, blocking their activity. This kills cancer cells and slows cancer growth.

Rasonque was investigated in an open-label, phase 3, multinational study involving 500 patients with metastatic pancreatic adenocarcinoma whose disease had worsened after prior systemic (whole-body) treatment. Of these patients, 92% had a confirmed RAS G12 mutation, which includes the most common RAS mutations associated with this disease. Patients treated with Rasonque lived for a median of 12.4 months, compared with 6.7 months for those treated with chemotherapy. In addition, the median time patients lived without their disease worsening was 7.2 months with Rasonque, compared with 3.6 months with chemotherapy (see Note 3 for data cut-off dates). The most common side effects reported with Rasonque were diarrhoea, rash, stomatitis (inflammation of the lining of the mouth), nausea and vomiting.

The opinion adopted by the CHMP is an intermediary step on Rasonque's path to patient access. The opinion will now be sent to the European Commission, which will fast-track the decision on an EU wide marketing authorisation for Rasonque. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

Looking ahead, EMA, in agreement with the CHMP, will consider further medicines under development for phased review when this approach is feasible and expected to accelerate assessment. This will be decided on a case-by-case basis, based on whether the medicine is likely to address an unmet medical need and is expected to be of major interest from the point of view of public health, in particular as regards

therapeutic innovation.

Notes

1. The applicant for Rasonque (daraxonrasib) is Revolution Medicines.
2. Daraxonrasib was [designated an orphan medicinal product](#) for the treatment of pancreatic cancer on 20 April 2026.
3. Overall survival analysis based on data collected up to 15 June 2026; analysis of progression-free survival based on data collected up to 10 February 2026.
4. Daraxonrasib falls under the scope of the EU Health Technology Assessment Regulation. The [joint clinical assessment](#) is independent of EMA's review of the marketing authorisation application and is coordinated by the HTA Secretariat within the European Commission.

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