<date>

Pazenir® (paclitaxel formulated as albumin bound nanoparticles) 5 mg/ml powder for dispersion for infusion: temporary supply shortage

Dear Healthcare professional,

ratiopharm GmbH in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

Summary

- Increased demand in Europe for albumin-stabilised nanoparticle paclitaxel will lead to temporary supply shortage in some EU markets. This is expected at the beginning of January 2023. *[The duration of the supply shortage is market specific – each of the affected markets to include country specific information to reflect local situation]*
- Certain European countries will be impacted by this situation, including Austria, Bulgaria, Czech Republic, Denmark, France, Greece, Italy, Netherlands, Portugal, Romania and Spain.
- Production of albumin-stabilised nanoparticle paclitaxel at our manufacturing plant has been significantly ramped up. Furthermore, we are working with health authorities and our supply chain colleagues to assess how allocations can be made across countries.

Background on the temporary supply shortage

Albumin-stabilised nanoparticle paclitaxel is indicated:

- as monotherapy for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated;
- in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas;
- in combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.

The temporary supply shortage is due to significantly increased demand in Europe for albumin-stabilised nanoparticle paclitaxel.

ratiopharm GmbH is the marketing authorisation holder for Pazenir®, a generic version of albumin-stabilised nanoparticle paclitaxel, and is one of the suppliers of this medicine in the EU.
The supply shortage is not related to a quality defect of the product or a safety issue.

During this temporary supply shortage of albumin-stabilised nanoparticle paclitaxel please consider alternative treatment options for your patients based on your clinical judgement and as per market availability.

We will continue to provide updates on the current supply situation to your local health authority as new information becomes available. We are deeply committed to doing all we can to bring this important medicine to patients and to ensure future supplies meet increased market demand.

Company contact point
For access to further information, please contact [xxx]

Kind regards,

Signature*

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Pazenir® 5 mg/ml powder for dispersion for infusion / paclitaxel formulated as albumin bound nanoparticles
Marketing authorisation holder(s)	ratiopharm GmbH
Safety concern and purpose of the communication	Temporary supply shortage
DHPC recipients	Prescribing healthcare professionals that treat patients with the following therapeutic indications: - as monotherapy for the treatment of metastatic breast cancer in adult patients who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated; - in combination with gemcitabine for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas; - in combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.
Member States where the DHPC will be distributed	EU/EEA countries where the product is marketed and the temporary shortage is expected

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	12/01/2023
Submission of translated DHPCs to the national competent authorities for review	18/01/2023
Agreement of translations by national competent authorities	20/01/2023
Dissemination of DHPC	24/01/2023