Summary of risk management plan for Letrozol Orion 2.5 mg Film-coated tablet (Letrozole) Orion Corporation

Date: 25.05.2020, Version 2

This is a summary of the risk management plan (RMP) for Letrozol Orion. The RMP details important risks of Letrozol Orion, how these risks can be minimised, and how more information will be obtained about Letrozol Orion's risks and uncertainties (missing information).

Letrozol Orion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Letrozol Orion should be used.

Important new concerns or changes to the current ones will be included in updates of Letrozol Orion's RMP.

I. The medicine and what it is used for

Letrozol Orion is authorised for following indications:

Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer.

• Extended adjuvant treatment of hormone-dependent-invasive breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy for 5 years.

• First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer.

• Advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status, who have previously been treated with anti-oestrogens.

• Neo-adjuvant treatment of postmenopausal women with hormone receptor positive, HER-2 negative breast cancer where chemotherapy is not suitable and immediate surgery not indicated.

Efficacy has not been demonstrated in patients with hormone receptor negative breast cancer.

It contains letrozole as the active substance and it is given by mouth.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Letrozole Orion, together with measures to minimise such risks and the proposed studies for learning more about Letrozole Orion's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies required for Letrozol Orion.