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Orion's collaboration partner Bayer today announced the submission of a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for the oral androgen receptor inhibitor (ARI) darolutamide. Bayer is seeking approval for the use of darolutamide in combination with androgen deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC). The submission is based on positive results from the pivotal Phase III ARANOTE trial which showed that darolutamide plus androgen deprivation therapy (ADT) significantly reduced the risk of radiological progression or death by 46% compared to placebo plus ADT in patients with mHSPC.

The compound is already approved in mHSPC, under the brand name Nubeqa®, in combination with ADT and docetaxel in over 80 markets around the world. The compound is also approved in combination with ADT for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of

developing metastatic disease in more than 85 countries around the world. Darolutamide is developed jointly by Orion and Bayer.

Bayer also today announced that in September 2024, the in-market sales of Nubeqa® exceeded sales of one billion euros year-to-date making darolutamide the first ever Orion-originated product to gain blockbuster status.

“This is a historic achievement for Orion and yet another proof of the high-quality research and development work we have been doing for years. With the current track record the future of darolutamide looks bright. In addition, our clinical pipeline as well as our research pipeline have improved recently. With that we are increasing the probability to be able to commercialise new innovative medicines in the future to address the various unmet needs of patients”, says Liisa Hurme, the President and CEO of Orion Corporation.

Contact person:

Tuukka Hirvonen, Investor Relations, Orion Corporation

tel. +358 10 426 2721

Publisher:

Orion Corporation

Communications

Orionintie 1A, FI-02200 Espoo, Finland

<http://www.orion.fi/en>

<http://www.twitter.com/OrionCorplR>

Orion is a globally operating Finnish pharmaceutical company – a builder of well-being for over a hundred years. We develop, manufacture and market human and veterinary pharmaceuticals and active pharmaceutical ingredients. Orion has an extensive portfolio of proprietary and generic medicines and consumer health products. The core therapy areas of our pharmaceutical R&D are oncology and pain. Proprietary products developed by Orion are used to treat cancer, neurological diseases and respiratory diseases, among others. Orion's net sales in 2023 amounted to EUR 1,190 million and the company had about 3,600 employees at the end of the year. Orion's A and B shares are listed on Nasdaq Helsinki.

Source: Orion Oyj