



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

Bayer raises peak sales for Nubeqa to exceed three billion euro amid positive Phase III ARASENS trial data

- Raise in peak sales expectations follows presentation of positive Phase III trial ARASENS with darolutamide (Nubeqa) in metastatic hormone-sensitive prostate cancer at 2022 ASCO GU Cancers Symposium and publication in *The New England Journal of Medicine* on February 17, 2022
 - Broad development program underway with three additional ongoing or planned large clinical studies for darolutamide across a broad spectrum of prostate cancer
-

Berlin, February 17, 2022 – At the 2022 ASCO GU Cancers Symposium Bayer presented results from the Phase III ARASENS trial which demonstrated that the use of the oral androgen receptor inhibitor (ARi) darolutamide plus androgen deprivation therapy (ADT) and docetaxel significantly increased overall survival (OS) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) compared to ADT plus docetaxel. Darolutamide plus ADT and docetaxel significantly reduced the risk of death by 32.5% compared to ADT plus docetaxel (HR=0.68, 95% CI 0.57-0.80; P<0.001). At the data cutoff date for the primary analysis (October 25, 2021), the median treatment duration was longer for darolutamide plus ADT and docetaxel (41.0 months) versus ADT plus docetaxel (16.7 months).

Amid these positive results Bayer raised peak sales expectation for Nubeqa™ (darolutamide) to exceed €3 billion.

“Subject to regulatory approval, the team at Bayer is excited to be able to offer even more patients suffering from prostate cancer an additional treatment option backed by strong clinical data,” said Stefan Oelrich, Member of the Board of Management of Bayer and President of the Pharmaceuticals Division. “With the confirmation of darolutamide’s

clinical profile and expansion into the metastatic setting as well as the investments that we are making in clinical trials in other potential indications, we feel that Nubeqa has the potential to generate peak sales of more than 3 billion euros”.

Darolutamide is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company. Based on results from the pivotal Phase III ARAMIS trial, the compound is already approved for the treatment of patients with nmCRPC, who are at high risk of developing metastatic disease, in more than 60 markets worldwide. Results from the second Phase III ARASENS trial evaluating darolutamide plus androgen deprivation therapy (ADT) in combination with docetaxel in patients with metastatic hormone-sensitive prostate cancer (mHSPC) were presented yesterday as an oral presentation at the 2022 ASCO GU Cancer Symposium and simultaneously published in *The New England Journal of Medicine*. Bayer is already in discussions with health authorities worldwide regarding the submission for marketing authorization in this additional indication.

Darolutamide is being investigated in a broad development program with additional three ongoing or planned large clinical studies, to investigate its potential across prostate cancer patients from the early- to the late-stage of this disease. This includes another Phase III trial in mHSPC (ARANOTE) as well as an ANZUP-led international co-operative group Phase III trial, evaluating darolutamide as an adjuvant treatment for localized prostate cancer with very high risk of recurrence (DASL-HiCaP, ANZUP1801). Information about these trials can be found at www.clinicaltrials.gov. In addition, a study to explore the potential of darolutamide in the early setting for patients who have been treated with surgery or radiation and now see a rise in their prostate specific antigen (PSA) levels is also planned.

About Nubeqa™ (darolutamide)

Darolutamide is an oral androgen receptor inhibitor (ARi) with a distinct chemical structure that binds to the receptor with high affinity and exhibits strong antagonistic activity, thereby inhibiting the receptor function and the growth of prostate cancer cells. The low potential for blood-brain barrier penetration for darolutamide is supported by preclinical models and neuroimaging data in healthy humans. A low blood-brain barrier penetration would explain the overall low incidence of central nervous system (CNS)-related adverse events (AEs) compared to placebo as seen in the ARAMIS and ARASENS Phase III trials

and the improved verbal learning and memory observed in the darolutamide arm of the Phase II ODENZA trial.

The product is approved under the brand name Nubeqa™ in more than 60 markets around the world, including the U.S., EU, Japan, China, for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease. The compound is also currently being investigated in further studies across various stages of prostate cancer, including another Phase III trial in mHSPC (ARANOTE) as well as an ANZUP-led international co-operative group Phase III trial, evaluating darolutamide as an adjuvant treatment for localized prostate cancer with very high risk of recurrence (DASL-HiCaP, ANZUP1801). Information about these trials can be found at www.clinicaltrials.gov.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Anna Koch, phone +49 30 468-15942

Email: anna.koch@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

www.bayer.com/en/investors/ir-team

Find more information at <https://pharma.bayer.com/>

Follow us on Facebook: <http://www.facebook.com/bayer>

Follow us on Twitter: [@BayerPharma](https://twitter.com/BayerPharma)

ko (2022-0026E)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.