The Prostate Cancer Registry
Fact Sheet

OVERVIEW

- ***The Prostate Cancer Registry* is the first and largest prospective observational database of patients with metastatic castration-resistant prostate cancer (mCRPC)[1]**
- **The Registry has the capacity to address the key medical and scientific questions concerning the optimal care of mCRPC patients in routine practice**
- **To date, The Registry has enrolled over 3000 mCRPC patients from 199 centres in over 16 European countries**

RATIONALE & BACKGROUND

- When initiated in 2013, limited data regarding mCRPC treatment patterns and outcomes in routine practice in both urology and oncology settings existed[2]
- Real-world studies can offer insights into the experiences of a wider, less restricted group of mCRPC patients (i.e. those with co-existing health problems and taking other medications) to complement clinical trials[3]
- This Registry was set up to provide a large set of real-world data in order to address the key medical and scientific questions concerning the optimal care of mCRPC patients in routine practice, such as:
    - o Characteristics of patient populations outside interventional studies
    - o Treatment use and outcomes
    - o Patient quality of life
    - o Hospital resource use

SCOPE AND DESIGN

Scope:
- The Registry is the largest real-world study in mCRPC, following the highest number of patients in the most countries across Europe to date[1]

- The Registry is a prospective, non-interventional, multicentre registry of men with mCRPC, aged 18 or older and managed in a range of oncology and urology settings[1]
- To date, The Registry has enrolled over 3000 mCRPC patients from 199 centres in over 16 European countries.[1]

Design:

- The Registry was designed in consultation with specialists in mCRPC, aiming to reflect routine clinical practice by enrolling a broad range of patients with mCRPC[1]
- Patients are enrolled upon initiating a mCRPC treatment or a period of surveillance, defined as not currently receiving an active treatment for castration resistance[1]
- Information on disease history is collected at enrolment and this is followed by prospective data capture of patient characteristics, clinical status, disease management, quality of life, medical resource utilisation and outcomes, including survival[1]

FIRST ANALYSIS OF DATA

- The first analysis, presented at the European Cancer (ECC) 2015 Congress in Vienna, Austria, reported on data of 505 patients enrolled between June 2013 and January 2014 and followed for up to 9 months[1]
- Results indicated that:
  - *Demographics and disease characteristics:*
    - Real-life population has a mean age of 71.5 years and a high incidence of comorbidities (62.8%), the most common being cardiovascular disease (54.9%) and hypertension (44.6%)[1]
    - 79.2% were also receiving concomitant medications, 41.4 percent of patients had previously received chemotherapy and 58.6 percent were chemotherapy-naïve at enrolment[1]
    - Majority (59.8%) of patients at initial diagnosis had a Gleason score of 8 or higher and almost half (45.7%) had distant metastases[1]
  - *Treatment:*
    - 76% of patients initiated a new treatment for mCRPC during the first 9 months of follow-up[1]

INTERIM ANALYSIS OF DATA

- An interim analysis, presented at the American Society of Clinical Oncology (ASCO) 2016 Congress, Chicago, USA, described characteristics at study entry of 1323

mCRPC patients. 549 (41.5%) had distant metastases (M1) at initial diagnosis and 526 (39.8%) had prostate cancer that had not metastasised at initial diagnosis (M0). 248 were not evaluable (Mx, 18.7%) at initial diagnosis[4]

- The data reveal:
  - Men with mCRPC who had distant metastases at primary diagnosis (M1), as compared to those whose cancer had not metastasised at primary diagnosis (M0), had higher prostate-specific antigen (PSA) levels, increased incidence of bone lesions and slightly worse level of functioning, in terms of their ability to care for themselves, daily activity, and physical ability (measured by ECOG Scale of Performance Status)[4]
    - PSA levels were 34.4% higher (61.7 ng/mL vs 45.9 ng/mL) for M1 vs M0
    - Incidence of bone lesions (>5) were 24% higher (51% vs 41%) for M1 vs M0
    - ECOG Scale of Performance Status >2 were higher (17% vs 13%) for M1 vs M0

NEXT STEPS

- Further abstracts are being developed for ESMO and ISPOR 2016
- Final analysis is planned for 2019

- ENDS –

References

1 Chowdhury S et al. The Prostate Cancer Registry: First Results from an International, Prospective, Observational Study of Men with Metastatic Castration- Resistant Prostate Cancer (mCRPC). Poster presented at the European Cancer Congress 2015, September 25-29, Vienna, Austria. Poster Presentation. ECC abstract #2548. Available at: https://www.europeancancercongress.org/Scientific-Programme/Abstract-search?abstractid=21001. Last accessed September 2015.
2 European Association of Urology. Guidelines on Prostate Cancer, 2016.
3 Gandaglia G, et al. Eur Urol. 2015; epub June 6th.
4 Chowdhury S et al. The Prostate Cancer Registry: Do patients with metastatic castration-resistant prostate cancer (mCRPC) differ according to metastatic status at diagnosis? Poster presented at the American Society of Clinical Oncology 2016, June 3-7, Chicago, USA. Poster