Real-World Safety and Efficacy Outcomes with Abiraterone Acetate Plus Prednisone or Prednisolone as the First- or Second-Line Treatment for Metastatic Castration-Resistant Prostate Cancer: Data from the Prostate Cancer Registry

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Supplementary figure

Fig. S1 Study flow.

mCRPC, metastatic castration-resistant prostate cancer.
Table S1 Treatment-emergent adverse events of special interest

| Preferred term                                      | AAP     | AAP-PD   |
|-----------------------------------------------------|---------|----------|
|                                                    | All patients | All patients | Patients with CV | Patients with CV |
|                                                    | (N=754)  | (N=394)  | (n=504)          | (n=234)          |
| Number of patients with at least one TEAE, n (%)    | 487 (64.6) | 338 (67.1)| 222 (56.3)       | 132 (56.4)       |
| Vascular disorders                                 | 69 (9.2) | 42 (8.3) | 26 (6.6)         | 18 (7.7)         |
| Hypertension                                       | 24 (3.2) | 12 (2.4) | 5 (1.3)          | 3 (1.3)          |
| Hot flush                                          | 20 (2.7) | 14 (2.8) | 9 (2.3)          | 4 (1.7)          |
| Hypotension                                        | 6 (0.8)  | 3 (0.6)  | 2 (0.5)          | 1 (0.4)          |
| Intermittent claudication                          | -       | -       | 2 (0.5)          | 2 (0.9)          |
| Hematoma                                           | 5 (0.7)  | 3 (0.6)  | -               | -               |
| Lymphoedema                                        | 5 (0.7)  | 1 (0.2)  | 1 (0.3)          | 1 (0.4)          |
| Deep vein thrombosis                               | 2 (0.3)  | 2 (0.4)  | 1 (0.3)          | 1 (0.4)          |
| Hypertensive crisis                                | 2 (0.3)  | -       | -               | -               |
| Orthostatic hypotension                            | 2 (0.3)  | 2 (0.4)  | 1 (0.3)          | 1 (0.4)          |
| Peripheral arterial occlusive disease              | -       | -       | 1 (0.3)          | 1 (0.4)          |
| Peripheral artery stenosis                         | -       | -       | 1 (0.3)          | -               |
| Phlebitis                                          | 2 (0.3)  | 1 (0.2)  | 1 (0.3)          | -               |
| Thrombophlebitis                                   | -       | -       | 1 (0.3)          | -               |
| Aortic stenosis                                    | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Capillary fragility                                | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Circulatory collapse                               | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Flushing                                            | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Pallor                                             | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Peripheral coldness                                | 1 (0.1)  | 1 (0.2)  | -               | -               |
| Subclavian vein thrombosis                         | 1 (0.1)  | -       | -               | -               |
| Superior vena cava stenosis                        | 1 (0.1)  | -       | -               | -               |
| Thrombosis                                         | 1 (0.1)  | -       | 2 (0.5)          | 2 (0.9)          |
| Aortic aneurism                                     | -       | -       | 1 (0.3)          | 1 (0.4)          |
| Diagnosis                                      | Count   | Percentage | Count   | Percentage |
|-----------------------------------------------|---------|------------|---------|------------|
| Arterial disorder                             |         |            |         |            |
| Capillary leak syndrome                       |         |            |         |            |
| Varicose vein                                 | 1 (0.1) |            | 1 (0.3) |            |
| Vasculitis                                    | 1 (0.1) |            | -       |            |
| Venous thrombosis                             | 1 (0.1) |            | -       |            |
| Cardiac disorders                             | 55 (7.3)| 39 (7.7)   | 16 (4.1)| 9 (3.8)    |
| Cardiac failure                               | 12 (1.6)| 11 (2.2)   | 4 (1.0) | 3 (1.3)    |
| Atrial fibrillation                           | 11 (1.5)| 8 (1.6)    | 3 (0.8) | 3 (1.3)    |
| Myocardial infarction                         | 7 (0.9) | 6 (1.2)    | 2 (0.5) | 2 (0.9)    |
| Angina pectoris                               | 6 (0.8) | 5 (1.0)    | 1 (0.3) | -          |
| Myocardial ischemia                           | 3 (0.4) | 1 (0.2)    | -       |            |
| Cardiac failure congestive                    | 2 (0.3) | 2 (0.4)    | 1 (0.3) | -          |
| Palpitations                                  | 2 (0.3) |            | -       |            |
| Tachycardia                                   | 2 (0.3) |            | 1 (0.3) | -          |
| Acute coronary syndrome                       | 1 (0.1) |            | -       | -          |
| Acute myocardial infarction                   | 1 (0.1) | 1 (0.2)    | 1 (0.3) | 1 (0.4)    |
| Angina unstable                               | 1 (0.1) | 1 (0.2)    | 1 (0.3) | -          |
| Aortic valve sclerosis                        | -       | -          | 1 (0.3) | -          |
| Aortic valve stenosis                         | 1 (0.1) | 1 (0.2)    | 1 (0.3) | -          |
| Arrhythmia                                    | 1 (0.1) |            | 1 (0.3) | 1 (0.4)    |
| Atrioventricular block first degree           | -       | -          | 1 (0.3) | -          |
| Atrial flutter                                | 1 (0.1) |            | -       | -          |
| Bradycardia                                   | 1 (0.1) | 1 (0.2)    | -       | -          |
| Cardiac arrest                                | 1 (0.1) |            | -       | -          |
| Cardiac disorder                              | 1 (0.1) |            | -       | -          |
| Cardiac failure chronic                       | 1 (0.1) | 1 (0.2)    | -       | -          |
| Cardiopulmonary failure                       | 1 (0.1) | 1 (0.2)    | -       | -          |
| Cardiotoxicity                                | 1 (0.1) | 1 (0.2)    | -       | -          |
| Coronary artery disease                       | 1 (0.1) |            | -       | -          |
| Coronary artery stenosis                      | 1 (0.1) | 1 (0.2)    | -       | -          |
| Left ventricular failure                      | 1 (0.1) | 1 (0.2)    | -       | -          |
| Supraventricular tachycardia                  | 1 (0.1) | 1 (0.2)    | -       | -          |
| Metabolism and nutrition disorders            | 59 (7.8)| 42 (8.3)   | 19 (4.8)| 11 (4.7)   |
| Condition                        | Count 1 | Count 2 | Count 3 | Count 4 |
|---------------------------------|---------|---------|---------|---------|
| Decreased appetite              | 16 (2.1)| 10 (2.0)| 8 (2.0) | 7 (3.0) |
| Hypokalemia                     | 16 (2.1)| 12 (2.4)| 3 (0.8) | 2 (0.9) |
| Hyperglycemia                   | 11 (1.5)| 8 (1.6) | 1 (0.3) | -       |
| Hypocalcemia                    | 10 (1.3)| 6 (1.2) | -       | -       |
| Hyperkalemia                    | 5 (0.7) | 3 (0.6) | -       | -       |
| Diabetes mellitus               | 4 (0.5) | 3 (0.6) | -       | -       |
| Hypertriglyceridemia            | 3 (0.4) | 2 (0.4) | -       | -       |
| Hyponatremia                    | 3 (0.4) | 3 (0.6) | -       | -       |
| Dehydration                     | 2 (0.3) | 2 (0.4) | 1 (0.3) | 1 (0.4) |
| Folate deficiency               | -       | -       | 1 (0.3) | -       |
| Hypoalbuminemia                 | 2 (0.3) | -       | 1 (0.3) | 1 (0.4) |
| Hypomagnesemia                  | -       | -       | 2 (0.5) | 1 (0.4) |
| Cachexia                        | 1 (0.1) | -       | 1 (0.3) | 1 (0.4) |
| Diabetes mellitus inadequate control | 1 (0.1) | 2 (0.4) | 1 (0.3) | -       |
| Diabetic metabolic decompensation | 1 (0.1) | 1 (0.2) | 1 (0.3) | -       |
| Dyslipidemia                    | 1 (0.1) | 1 (0.2) | 1 (0.3) | -       |
| Hypercalcemia                   | 1 (0.1) | 1 (0.2) | 1 (0.3) | -       |
| Hypoproteinemia                 | 1 (0.1) | 1 (0.2) | -       | -       |
| Increased appetite              | 1 (0.1) | 1 (0.2) | -       | -       |
| Vitamin B12 deficiency          | 1 (0.1) | 1 (0.2) | -       | -       |
| Vitamin D deficiency            | 1 (0.1) | 1 (0.2) | 1 (0.3) | -       |

*AAP* abiraterone acetate plus prednisone/prednisolone; *AAP-PD* AAP after docetaxel; *CV* cardiovascular; *TEAE* treatment-emergent adverse event.
Table S2 Treatment-emergent serious adverse events with occurrence in > 1% of patients who received AAP

| System-organ class/preferred term, n (%) | AAP |
|----------------------------------------|-----|
| Number of patients exposed             | 1490|
| Number of patients with at least one TESAE, n (%) | 496 (33.3) |

- **General disorders and administration site conditions**: 177 (11.9)
  - Disease progression: 55 (3.7)
  - General physical health deterioration: 53 (3.6)
  - Death: 28 (1.9)
- **Vascular disorders**: 19 (1.3)
- **Infections and infestations**: 106 (7.1)
  - Urinary tract infection: 24 (1.6)
  - Pneumonia: 22 (1.5)
- **Renal and urinary disorders**: 63 (4.2)
  - Hematuria: 25 (1.7)
- **Cardiac disorders**: 58 (3.9)
  - Cardiac failure: 15 (1.0)
- **Musculoskeletal and connective tissue disorders**: 48 (3.2)
  - Back pain: 16 (1.1)
- **Gastrointestinal disorders**: 47 (3.2)
- **Injury, poisoning and procedural complications**: 37 (2.5)
- **Respiratory, thoracic and mediastinal disorders**: 37 (2.5)
- **Neoplasms benign, malignant and unspecified (including cysts and polyps)**: 36 (2.4)
- **Nervous system disorders**: 36 (2.4)
- **Blood and lymphatic system disorders**: 33 (2.2)
  - Anemia: 26 (1.7)

*AAP* abiraterone acetate plus prednisone/prednisolone, *TESAE* treatment-emergent serious adverse event.